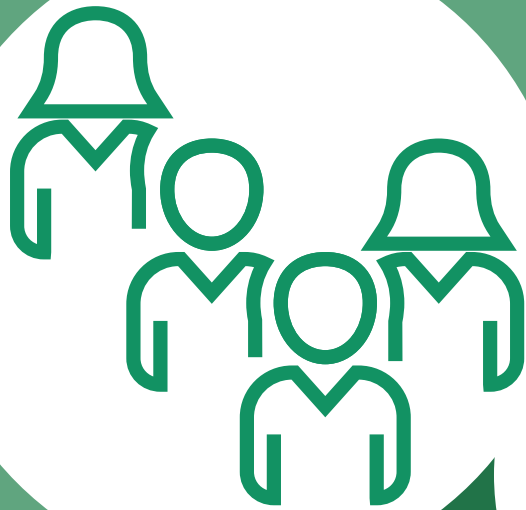




2020

# Incident Management Framework

Care | Compassion | Trust | Learning





# Foreword

The experience of most people with our health and social care organisations is positive. Safety is an important component of this experience; the last thing that people should expect is to be harmed when they need care. There are times, however, when things go wrong. When we analyse why things can go wrong, we find that it is usually due to a combination of factors including errors in the delivery of care, the particular set of circumstances in which care is delivered and the ever-increasing complex nature of the health care environment.

The HSE's Incident Management Framework 2018 (IMF) sought to put in place a person-centred response to the management of these occasions, termed 'safety incidents'. The approach in the Framework was to align the response with the HSE's values of Care, Compassion, Trust and Learning.

The process used to develop the IMF was one of collaboration with both service users and patients which ensured it was both relevant and practical. Implementation was supported throughout 2018 with many briefing sessions and a tailored training programme for Quality and Safety Advisors.

As the Framework represented a considerable change to the way the organisation responded to incidents a commitment was made to conduct an early review of the IMF to identify any areas which needed additional clarification or guidance.

Similar to the process used to develop the IMF, the review process sought to engage with key stakeholders and staff at all levels to obtain their views and input. The review of the IMF also took account of the commitments made in the HSE's Patient Safety Strategy 2019.

During the course of the review, it was identified that staff throughout the HSE have demonstrated significant commitment to making changes required by the IMF and that the IMF is supporting their practice. This is to be welcomed.

I would like to reaffirm the HSE's commitment to the creation of a culture which supports patient safety and particularly one which seeks to support service users, their relevant persons and staff in the aftermath of incidents. I understand that to further support this commitment that a specific piece of guidance is currently in development.

Central to the management of incidents is a commitment to learn from incidents so as to improve the safety and quality of services. Whilst there is evidence of mechanism to share learning throughout the organisation, this is currently fragmented and not systematised. The absence of an organisation wide system for sharing learning is acknowledged and work has commenced on the development of this. I see this project as a priority and have committed my support to ensuring that it is delivered within agreed timeframes.

I would like to take the opportunity to thank the large number of staff across the health service and outside of it who contributed to the revision of this IMF. In particular, I would like to extend my appreciation to the many service users and staff who have dedicated their time, energy and vision to its development.

**Paul Reid**

*Chief Executive Officer*



# Contents

Introduction	2
Key Definitions used in the Incident Management Framework	3
Acronyms used in this document	7
Policy Statement	9
Purpose	9
Scope	9
Roles and Responsibilities for Incident Management	10
When to use the Incident Management Framework	10
Principles upon which the Incident Management Framework is based	13
Governance arrangements for incident management	14
Process for managing an incident	15
Step 1. Prevention through supporting a culture where safety is a priority	17
Step 2. Incident Identification and immediate actions required	18
Step 3. Initial reporting and notification	20
Step 4. Categorisation and Initial Assessment	22
Step 5. Review and analysis	27
Step 6. Improvement planning and monitoring	35
Supporting the Incident Management Framework at a national level	36
 <b>Appendices</b>	
<b>Appendix 1</b> Roles and responsibilities for incident management	37
<b>Appendix 2</b> HSE Risk Impact Table	41
<b>References</b>	42

# Introduction

The HSE's Incident Management Framework (IMF), originally launched in 2018 was co-designed in collaboration with representatives from all levels in the service delivery system. Central to this process, was the level of consultation and collaboration with staff and patient groups that occurred throughout its development.

The development process used assisted greatly in ensuring that the IMF provided services with a practical approach to the management of incidents which was aligned to best international practice. The IMF set out detail of the key principles and elements of a responsive and proportionate approach to the management of an incident i.e. from the prevention of incidents to learning from incidents which have occurred.

The Office of the Chief Clinical Officer (CCO) carried out an early review of the IMF in 2019. The purpose of this review was, to learn from the experience of those who had used the IMF in operation since its launch, to ascertain the extent to which the IMF was supporting practice and to identify any areas where further guidance may be required. The review also took account of the need to align the IMF to the [HSE's Patient Safety Strategy \(2019-2024\)](#)

A number of definitions supporting the IMF have also been reviewed to ensure that they are aligned to changes in legislation and HSE Policy, most notably the [Coroner's Amendment Act 2019](#) and the [HSE Open Disclosure Policy](#).

The review of the IMF was conducted through online questionnaires to Quality Patient Safety Advisors, meetings with a range of internal and external stakeholders and the hosting of a number of workshops and focus groups. The IMF and supporting guidance have been reviewed based on the outcome of this consultation. The revised IMF continues to place emphasis on the need, in the aftermath of an incident, to adopt an empathetic, person centred and practical response to persons affected by an incident.

Whilst minor changes have been made throughout the documents, areas which received significant revision include supporting guidance on the following areas;

1. Comprehensive Approach to Review;
2. Development of Recommendations;
3. SIMT guidance;
4. Retention of Records.

An additional piece of guidance relating to supporting service users, relevant person(s) and staff has been commissioned along with a framework for sharing learning.

## **Note:**

1. The Incident Management Framework 2020 supersedes the Incident Management Framework 2018
2. The Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 is a draft piece of legislation which was approved by Government on 3 December 2019. The enactment of this bill is included in the Programme for Government 2020. When enacted, the Incident Management Framework 2020 will be reviewed to take account of the requirements of this legislation.

# Key Definitions used in the Incident Management Framework

A full list of **terms and definitions** used in this document is available ([IMF Guidance Section 1](#)), however key definitions include:

Term	Definition
<b>Adverse Event</b>	An incident which results in harm, which may or may not be the result of an error.
<b>Category 1 Incident</b>	Clinical and non-clinical incidents rated as Major or Extreme as per the HSE's Risk Impact Table.
<b>Category 2 Incident</b>	Clinical and non-clinical incidents rated as Moderate as per the HSE's Risk Impact Table.
<b>Category 3 Incident</b>	Clinical and non-clinical incidents rated as Minor or Negligible as per the HSE's Risk Impact Table.
<b>Harm</b>	<p><b>Harm to a person:</b> Impairment of structure or function of the body and or any detrimental effect arising from this, including disease, injury, suffering, disability, and death. Harm may be physical, social or psychological. The degree of harm relates to the severity and duration of harm and the treatment implications that result from an incident (see Terms and Definitions document for a more detailed definition relating to degrees or levels of harm).</p> <p>(As adapted from the World Health Organization's Conceptual Framework for the International Classification of Patient Safety, 2009 (World Health Organisation, 2010).)</p> <p><b>Harm to a thing:</b> Damage to a thing may include damage to facilities or systems, for example, environmental, financial, etc.</p>
<b>Incident</b>	<p>An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service user complaints which are associated with harm.</p> <p>Incidents can be clinical or non-clinical and include incidents associated with harm to:</p> <ul style="list-style-type: none"> <li>■ patients, service users, staff and visitors</li> <li>■ the attainment of HSE objectives</li> <li>■ ICT systems</li> <li>■ data security e.g. data protection breaches</li> <li>■ the environment</li> </ul> <p>See also definition of a Patient Safety Incident.</p>
<b>Incident Review</b>	Incident review involves a structured analysis and is conducted using best practice methods, to determine what happened, how it happened, why it happened, and whether there are learning points for the service, wider organisation, or nationally.

Term	Definition
<b>Local Accountable Officer</b>	This is the local manager who is responsible for the service in which the incident occurred e.g. ADON, Person in Charge, Business Manager, Clinical Lead
<b>Look Back Review</b>	Review where a number of people may have been exposed to a specific hazard in order to identify if any of those exposed have been harmed and how to take care of them.
<b>Open Disclosure</b>	Open disclosure is defined as an open, consistent, compassionate and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents. It includes expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to on-going care and treatment, learning and the steps being taken by the health services provider to try to prevent a recurrence of the incident. (HSE 2019)
<b>Patient Safety Incident</b>	<p>A patient safety incident, in relation to the provision of a health service to a patient by a health services provider, means “an incident which occurs during the course of the provision of a health service” which:</p> <ul style="list-style-type: none"> <li>(a) has caused an unintended or unanticipated injury, or harm, to the Patient</li> <li>(b) did not result in actual injury or harm to the patient but was one which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>(c) unanticipated or unintended injury or harm to the patient was prevented, either by “timely intervention or by chance”, but the incident was one which the health services provider has reasonable grounds for believing could have resulted in injury or harm, if not prevented.</li> </ul> <p>(Civil Liability Amendment Act, 2017)</p> <p>Therefore a patient safety incident includes harm events, no harm events and near miss events.</p>
<b>Person Affected</b>	This refers to individual people e.g. service users, patients, employees, carers, relevant persons and visitors that may be affected as a consequence of an incident occurring. Persons can be affected either directly or indirectly.
<b>QPS Advisor</b>	For consistency purposes this term is used throughout the document to refer to the person whose role it is to advise and support a service in relation to their Quality and Patient Safety processes and response. It is noted that the title given to this role can vary between services e.g. Quality & Safety Manager, Quality, Risk and Safety Manager etc



Term	Definition
<b>Relevant Person</b>	<p>“Relevant person”, in relation to a patient, means a person;</p> <p>(a) who is;</p> <p>(i) a parent, guardian, son or daughter,</p> <p>(ii) a spouse, or</p> <p>(iii) a civil partner of the patient,</p> <p>(b) who is cohabiting with the patient</p> <p>or</p> <p>(c) whom the patient has nominated in writing to the health services provider as a person to whom clinical information in relation to the patient may be disclosed</p> <p><i>(Civil Liability (Amendment) Act 2017)</i></p> <p><b>Note:</b> This definition must not be confused with the definition of “relevant person” in the Assisted Decision-Making (Capacity) Act 2015.</p>
<b>Review Commissioner</b>	The person who commissions an incident review. For Category 1 incidents it is the Senior Accountable Officer (SAO) or person who has a direct reporting relationship to the SAO. For Category 2 incidents it is the Local Accountable Officer.
<b>Serious Incident Management Team</b>	A Serious Incident Management Team is a group whose role it is to oversee the management of all serious incidents relating to the service. It is also convened following notification of a Category 1 incident. It is chaired by the Senior Accountable Officer (SAO) or a person nominated by the SAO who has a direct reporting relationship to the SAO. Decisions in relation to the review of Category 1 incidents must be made within one working week of notification of the incident to the SAO.
<b>Senior Accountable Officer</b>	In the context of the management of an incident, the Senior Accountable Officer is the person who has ultimate accountability and responsibility for the services within the area where the incident occurred. In a hospital group it would be a person with delegated responsibility for a service and reporting directly to the Hospital Group CEO, e.g. a hospital manager or the person delegated with overall responsibility for the management of a clinical directorate or service, in a CHO it could be the Head of Service and in the case of the NAS, it could be the NAS corporate area manager.
<b>Serious Reportable Event</b>	Serious Reportable Events (SREs) are a defined subset of incidents which are either serious or that should not occur if the available preventative measures have been effectively implemented by healthcare providers. Serious Reportable Events are mandatorily reportable by services to the Senior Accountable Officer.
<b>Service User</b>	The term “service user” in relation to a health services provider means a person to whom a health service is, or has been, provided.
<b>Service User Designated Support Person</b>	This person is a contact point for the service user/relevant person(s) impacted by an incident. (See <b>IMF Appendix 1 Roles and Responsibilities for Incident Management</b> )

Term	Definition
<b>Staff</b>	<p>(a) a person who</p> <ul style="list-style-type: none"> <li>(i) has entered into, or works under (or where the employment has ceased, had entered into or worked under), a contract of employment, with the health services provider, or</li> <li>(ii) is (or was) placed for the purpose of vocational training with the health services provider, and</li> </ul> <p>(b) a fixed-term employee of the health services provider, and a reference to an employee, in relation to a health services provider, shall be construed as a reference to an employee employed by that health services provider.</p> <p>In line with the definition of Employee as defined in the (Civil Liability Amendment Act, 2017)</p>
<b>Staff Liaison Person</b>	<p>This person is a contact point at service delivery level for the staff member involved in an incident. (See <b>IMF Appendix 1 Roles and Responsibilities for Incident Management</b>)</p>
<b>Systems Analysis</b>	<p>A methodical review of an incident which involves the collection of data from the literature, records (general records in the case of non-clinical incidents and healthcare records in the case of clinical incidents), individual interviews with those involved where the incident occurred and analysis of this data to establish the chronology of events that led up to the incident, identifying findings that the reviewers considered had an effect on the eventual harm, the contributory factors, and recommended control actions to address the contributory factors to prevent future harm arising as far as is reasonably practicable. The principles of systems analysis can be applied using a comprehensive, concise or aggregate approach.</p>
<b>The National Treasury Management Agency (NTMA)</b>	<p>The NTMA is a State body which operates with a commercial remit to provide asset and liability management services to Government and is designated as the State Claims Agency when it performs the claims and risk management functions delegated to it under the National Treasury Management Agency (Amendment) Act, 2000</p>

## Acronyms used in this document

<b>AAR</b>	After Action Review
<b>ADON</b>	Assistant Director of Nursing
<b>ASSIST</b>	Acknowledge, Sorry, Story, Inquire, Solutions, Travel
<b>CCO</b>	Chief Clinical Officer
<b>CHO</b>	Community Healthcare Organisation
<b>CLEAR</b>	CLEAR is an acronym used to describe the key elements/features that a recommendation should have to support successful implementation i.e. <b>C</b> ase for Change, <b>L</b> earning Orientated, <b>E</b> vidence, <b>A</b> ssign, <b>R</b> eview
<b>HSE</b>	Health Service Executive
<b>HG</b>	Hospital Group
<b>HIQA</b>	Health Information and Quality Authority
<b>HR</b>	Human Resources
<b>HSA</b>	Health and Safety Authority
<b>IMF</b>	Incident Management Framework
<b>LAO</b>	Local Accountable Officer
<b>MHC</b>	Mental Health Commission
<b>NAS</b>	National Ambulance Service
<b>NIMS</b>	National Incident Management System
<b>NIRF</b>	National Incident Reporting Form
<b>NWIHP</b>	National Women and Infants Health Programme
<b>OSH</b>	Occupational Safety and Health
<b>PPPGs</b>	Policies, Procedures, Protocols and Guidelines

<b>QPS</b>	Quality and Patient Safety
<b>QRS</b>	Quality Risk and Safety
<b>SAO</b>	Senior Accountable Officer
<b>SCA</b>	State Claims Agency
<b>SIMT</b>	Serious Incident Management Team
<b>SRE</b>	Serious Reportable Event
<b>TOR</b>	Terms of Reference
<b>YCFF</b>	Yorkshire Contributory Factors Framework

# Policy Statement

It is the policy of the Health Service Executive (HSE) that all incidents are identified, reported and reviewed so that learning from events can be shared to improve the quality and safety of services.

In addition to the requirements set out in this Framework, patient safety incidents require disclosure in accordance with the requirements of the [HSE Open Disclosure Policy](#).

To support services in complying with this policy statement and to promote a consistent approach to the management of all incidents, the HSE has developed the IMF and related Guidance documents.

The IMF sets out the principles, governance requirements, roles and responsibilities and processes to be applied for the management of incidents in all service areas. The IMF is consistent with legislative and regulatory requirements.

# Purpose

The purpose of the IMF is to provide an overarching practical approach, based on best practice, to assist providers of HSE and HSE funded services to manage all incidents (clinical and non-clinical) in a manner that is cognisant of the needs of those affected and supports services to learn and improve.

This document replaces the HSE's Incident Management Framework 2018 and requires services to manage incidents in a manner which is consistent with the elements and processes outlined in it.

To support services in the application of the IMF a number of practical tools and guidance documents have been developed and these are referenced throughout the IMF.

The development of further guidance and training is planned and will, similar to the IMF, be designed in collaboration with services.

# Scope

The IMF is intended to cover all publicly funded health and social care services provided in Ireland including but not limited to:

- HSE Corporate Services/Functions
- Hospital Groups\*
- Community Health Organisations\*
- National Ambulance Services
- National Services e.g. National Screening Services, National Transport Medicine Programme, Organ Donation Transplant Ireland, National Rehabilitation Hospitals
- HSE Funded Care e.g. Section 38/39 agencies

\* Following planned organisational restructuring these entities will transition to Regional Health Areas

# Roles and Responsibilities for Incident Management

Clarity in relation to the roles and responsibilities of staff at all organisational levels is a fundamental governance requirement for effective incident management.

It is the role and responsibility of the Senior Accountable Officer (SAO) to have overall accountability for the management of incidents within their area of responsibility. This includes ensuring that the management arrangements and the roles of all staff in incident management are clearly defined.

Detail of the roles and responsibilities of staff, managers, and SAO and related teams/committees in HSE and HSE funded agencies in relation to the IMF are set out in **Appendix 1** of this document.

## When to use the Incident Management Framework

In the vast majority of cases, the causes of incidents are due to failures or weaknesses in the systems of care or management rather than the actions of any individual. The key to improving safety lies therefore in identifying and addressing any inherent weakness in the system. The focus of the IMF is therefore on understanding why an incident occurred and using this knowledge to improve safety.

There are a number of specific instances where the appropriate management of an issue, though reported as an incident, is not by way of the IMF. This is particularly in the case where the content and subject matter of the incident relates to the conduct or performance of individuals or where a specific management process is required to respond to an issue e.g. a Look Back Review, complaints which fall under Part 9 of the Health Act (Health Act, 2004), complaints which fall under the Protected Disclosures Act (2004), Protected Disclosures of Information, etc.

If it is identified, in the course of, or consequent to the conduct of one of these processes, that there is a system issue that increases the risk of harm, this may need to be reviewed to assist in improving safety and preventing future harm.

An unexpected outcome, though undesirable, may not be an incident if it is a recognised risk (albeit rare) of a procedure. Known risks relating to treatments and procedures should be discussed with service users in advance, as part of the consenting process.

In the interests of persons affected and the integrity of the incident review process, it is important that the IMF is only used when it is indicated.

**Figure 1** overleaf illustrates that although an issue can be raised through a number of routes the primary management pathway chosen should be that which best addresses the dominant concern raised. It may, therefore, be more appropriate to use an alternate pathway to review/investigate.

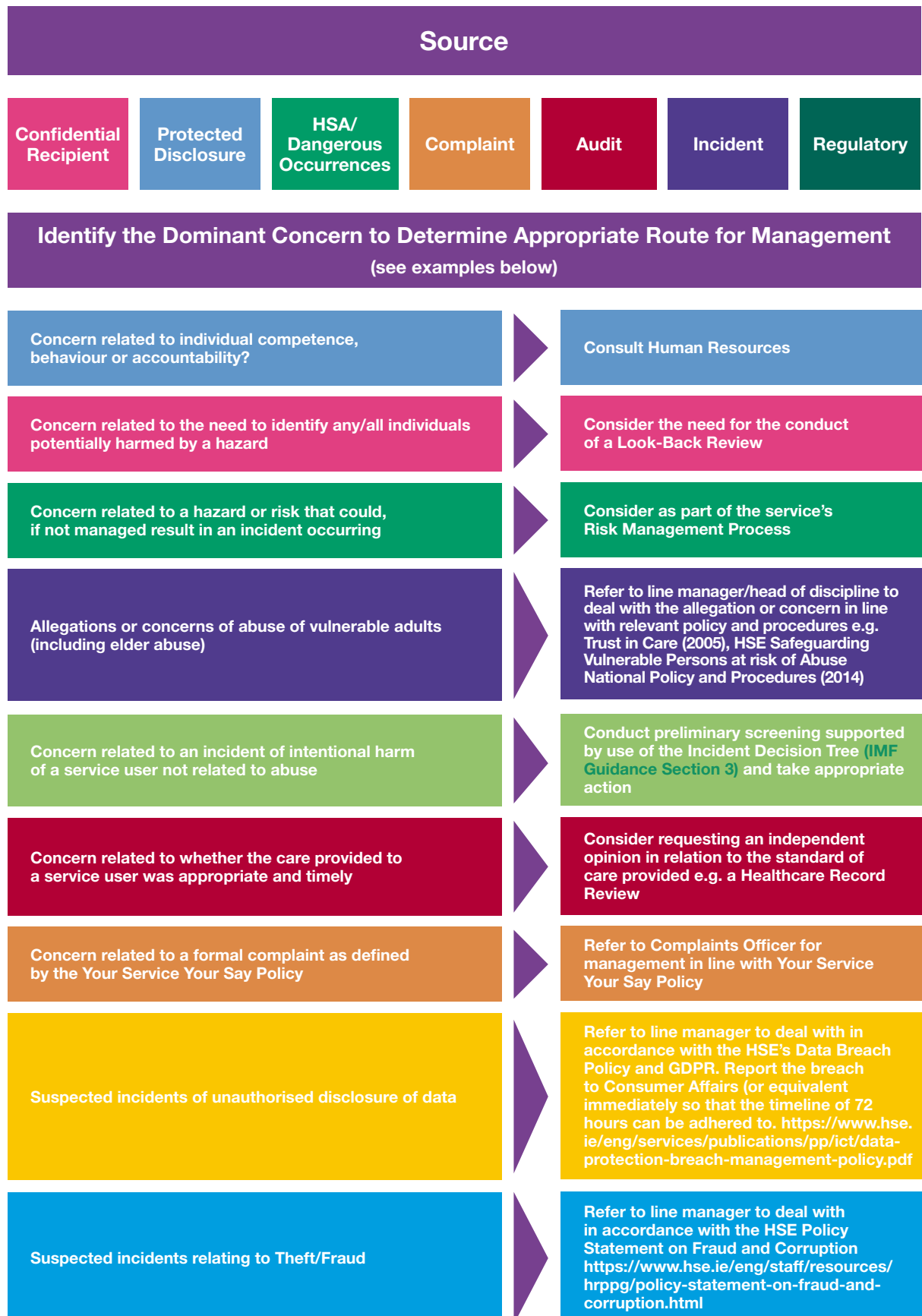
A ‘no wrong door’<sup>1</sup> approach should be operated irrespective of the entry point or mechanism of identification. There must be clear handover of the issue to the appropriate management process and the person affected must be advised of the route for on-going management and feedback.

For more detailed guidance, services should refer to **Guidance on making decisions about appropriate pathways for investigation/review. (IMF Guidance Section 3)**

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<sup>1</sup> ‘Wrong door’ refers to the occasion where an issue is raised through one route which may be more appropriately dealt with by another e.g. where a service user identifies an error occurring in relation to care received this may be more appropriately dealt with as a service user reported incident rather than as a complaint.

**Figure 1: Example of how the source by which an issue is identified may not indicate the appropriate route for the management of the issue.**



With respect to alternative pathways and processes, it should be noted that concurrent processes and/or pathways may be required in the service's overall response to an incident.

In circumstances where disciplinary or other administrative action has been taken, it is still possible to run a parallel system-based incident analysis.

The role of the Review Commissioner is critical to providing oversight to processes that may be running concurrently. When concurrent or related reviews/investigations are complete the learning generated from each process can be valuable for informing improvement.



# Principles upon which the Incident Management Framework is based

Principle	Description	Features of application
<b>Person Centred</b>	The needs of persons affected (service users and staff) are considered of primary importance and required supports are put in place from the outset and throughout any review process.	<p>All immediate care needs have been met in a manner that is caring, compassionate and respectful.</p> <p>Where harm has occurred that a designated service user/relevant person(s) person has been assigned.</p> <p>Where harm has occurred that a designated staff liaison person has been assigned.</p>
<b>Fair and Just</b>	<p>That all persons affected (service users, and staff) are treated in a manner which is fair and just.</p> <p>Where issues of individual accountability are identified that the service responds to these in a manner which is proportionate and safety focused.</p>	<p>Staff are confident that in reporting an incident that the process will not seek to assign blame but rather to understand any weaknesses in the systems of care/ work that contributed to the incident occurring.</p> <p>Persons affected are listened to, have an opportunity to contribute to the review process and are advised of the outcome.</p> <p>That proportionate responses are taken by the line manager to address any issues relating to individual staff culpability or performance issues. This may include seeking advice from clinical or human resources leads.</p>
<b>Openness and Transparency</b>	That all persons affected by an incident are aware of the incident and the steps to be taken to learn from it.	<p>Open and honest communication (Open Disclosure) is initiated as soon as practicable after the incident has been identified.</p> <p>That the planned review process has been described and communicated to all persons affected.</p>
<b>Responsive</b>	That the actions taken following the identification of an incident are taken in a timely and proportionate manner.	<p>That persons affected are aware of the actions to be undertaken and the timeframe for these has been communicated to them.</p> <p>In the event that there are unavoidable delays that the reasons for these are communicated immediately to persons affected.</p>
<b>Improvement Focused</b>	That incidents occurring are viewed by the service as an opportunity to improve.	That there is evidence that the service's Quality Improvement Plan has been informed by lessons learnt from incidents occurring. Where the incident has identified a risk that this risk is assessed and if required included on the relevant risk register to ensure it is appropriately mitigated.
<b>Learning</b>	That the incident management system is focused on learning both locally and within the wider service.	<p>That there are a range of tools and methods used to share learning from incidents at local, directorate/ service and organisational levels.</p> <p>Where feasible, that learning from incidents is considered alongside other sources of quality and safety information to inform improvement strategies</p>

# Governance arrangements for incident management

Primary responsibility and accountability for the effective management of incidents remains with the organisational level at which the incident occurs.

Effective governance arrangements are required to support the timely and effective management of incidents. Central to this is an explicit management commitment to safety that promotes a culture of openness, trust, and learning between persons who may be affected by incidents and those delivering and managing the services within which the incident occurs.

Governance arrangements must support the effective management of incidents at all stages; from incident prevention to immediate management, reporting, review, and learning. The accountability arrangements for incident reporting, notification of **Category 1** incidents to the SAO, notification to external agencies and arrangements for the management of cross-service or interagency incidents must be clearly defined.

As one of the key aims of incident management is learning and improvement, as part of their overall governance arrangements, services must have in place systems to monitor the implementation and evaluate the effectiveness of actions identified as a consequence of the review of the incident. Services should also identify the mechanisms they have in place to share learning from incident reviews internal and external to the service.

Governance arrangements for incident management should clearly set out the roles, accountabilities, and responsibilities for incident management at all levels of the service (**Appendix 1**). This should include details of delegated accountability, responsibility or authority. Services are required to set out their governance arrangements for incident management in a manner which is consistent and in compliance with the HSE's Accountability Framework. An organisational chart should be available setting out these arrangements.

An **IMF audit tool** has been developed in order to enable services to conduct a self-assessment against the IMF. This tool should be used periodically for the purposes of gaining assurance and/or to identify any compliance gaps to identify any compliance gaps that might exist. Compliance with the IMF may also be subject to verification audits of self-assessments undertaken.

Governance arrangements for incident management must be integrated with the service's overall governance and performance (KPIs) arrangements for quality and safety. This will enable information from incident management to be considered along with other sources of quality and safety information e.g. audit, surveys, complaints, claims, risk management, performance data, improvement data and internal and external review/inspection reports. This will provide services with a level of safety intelligence which can be used to inform and target programmes for quality and safety improvement.

To underpin the effectiveness of these arrangements, explicit management commitment to the development of capacity and capability and the consistent use of the National Incident Management System (NIMS) for management of data and information relating to incident management is required.

## Key Messages

From a governance perspective, the SAO is responsible for having in place systems and processes for the

1. governance of information arising from incident management processes.
2. notification of Category 1 incidents to them within 24 hours of occurrence in order for them to gain assurance on immediate actions taken and to convene a meeting of the SIMT
3. verification of compliance with the requirements of the IMF for managing incidents within services in their area of responsibility
4. monitoring implementation of recommendations made as a consequence of incident reviews;
5. integration of information relating to incident management within the service's overall governance arrangements for quality and safety to enable learning from the review of incidents to inform quality and safety improvement programmes;
6. monitoring key performance indicators relating to incident management;

# Process for managing an incident

Incidents, regardless of their impact, require management in line with the following steps:

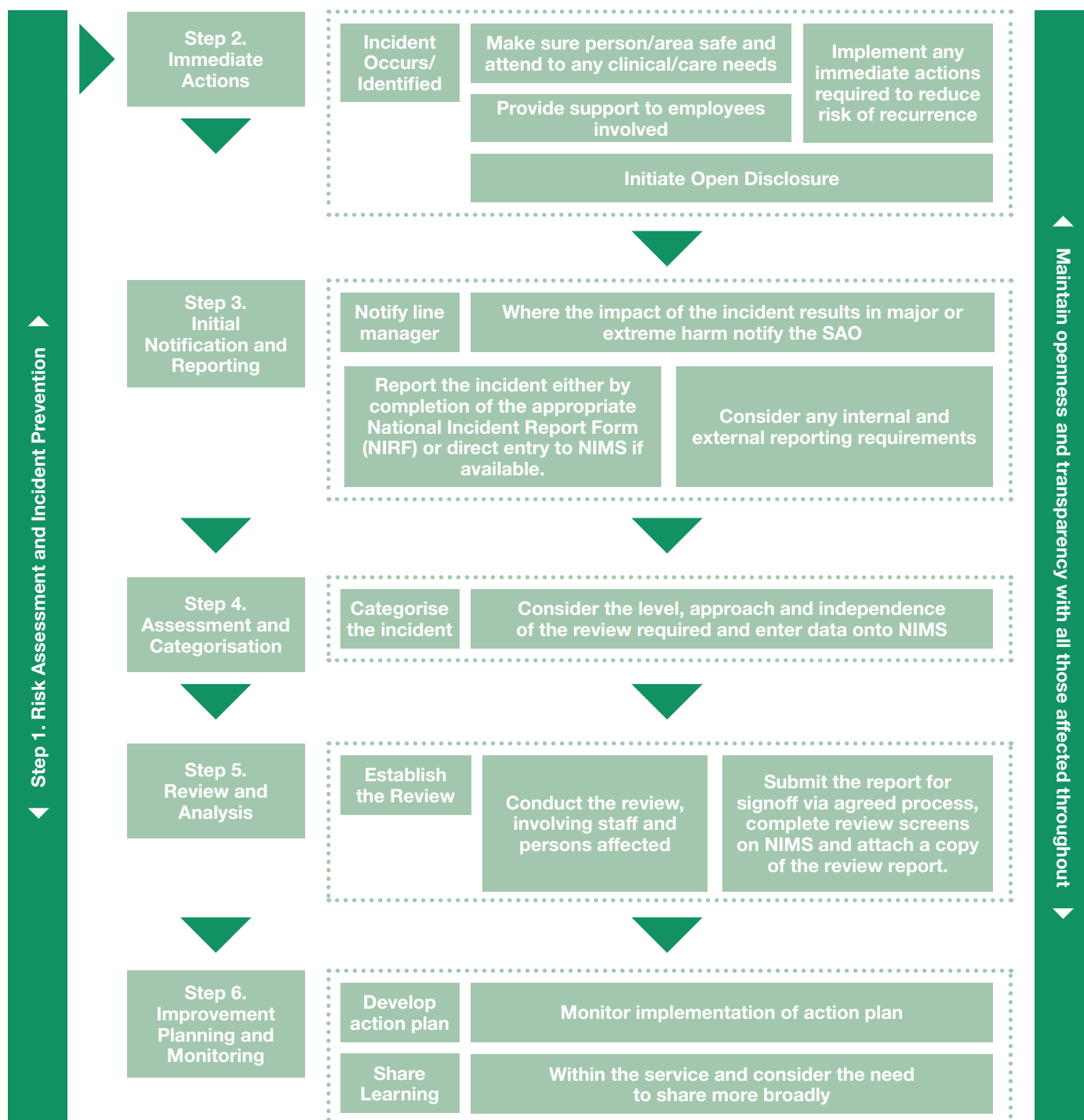
1. Prevention through supporting a culture where safety is considered a priority.
2. Identification and immediate actions required (for persons directly affected and to minimise risk of further harm to others).
3. Initial reporting and notification.
4. Assessment and categorisation.
5. Review and analysis.
6. Improvement planning and monitoring.

Though the process for managing incidents outlined in **Figure 2** below should be applied to all incidents, the level and depth of application will depend on a number of factors:

- The impact of the incident e.g. the level of harm caused.
- The number of persons harmed.
- The potential for learning from the incident.
- The degree to which service user or public confidence is an issue.
- The need to involve other services.

Therefore whilst every incident requires a response, this should be proportionate to the impact, scale, complexity, and potential for improving the safety of the service.

**Figure 2: Overview of the Incident Management Process**



## Step 1. Prevention through supporting a culture where safety is a priority

Support for incident reporting and review is significantly enhanced where staff feel safe in reporting incidents and believe that in so doing they will be personally supported and that reporting will lead to improvement. It is therefore vital that staff understand what constitutes an incident, how to report them and that they are provided with feedback on incidents reported and how these are used to identify opportunities to improve the quality and safety of services.

In healthcare, high reliability organisations commit to building a culture of safety. The key features of a safety culture are;

- Shared perceptions of the importance of safety at all levels in the organisation
- Open and constructive communication
- Mutual trust
- An engaged workforce that is always aware that things can go wrong
- Acknowledgment at all levels that incidents occur
- Ability to recognise, respond to, give feedback about, and learn from, incidents.

The development of a safety culture requires strong and consistent leadership support for safety at all levels of the service. The reality of this will be assessed by all those affected in the way the service responds to them in the aftermath of an incident. Consistency and proportionality in the response to incidents which occur is, therefore, key to this.

Services should also place emphasis on the importance of anticipating from experience and knowledge, the types of incidents that are likely to occur in their service area. In line with the **HSE's Integrated Risk Management Policy and Guidance** effort should be directed towards identifying areas where incidents are likely to occur and putting in place systems to prevent or reduce the likelihood of the risk of their occurrence.

The adoption of an integrated approach to the management of quality, safety, and risk, supports the implementation of a more proactive approach to quality and safety management. This is demonstrated where a service's risk management and quality improvement processes are informed by information from a variety of sources such as but not limited to incidents, complaints, claims management, coroner's reports, and regulatory inspection. The adoption of such an approach will support the development of quality and safety monitoring and contribute to quality assurance. The Quality and Safety Committee or equivalent has a key role in promoting, monitoring and sharing learning from the services' quality and safety processes.

### Key messages

1. Clear leadership and governance arrangements at all service levels is important to support a culture of quality and safety.
2. Anticipate and manage risk which may lead to incidents by ensuring that any controls required to mitigate it are in place.
3. Clearly define your structures and processes for incident management to ensure effective governance and operational efficiency.
4. Integrate your quality and safety information to enhance its effectiveness.

## Step 2. Incident identification and immediate actions required

The immediate actions taken by services following the identification of an incident significantly influence the degree to which the service is viewed as supportive and trustworthy by those affected. The importance of this cannot be over emphasised. Where a service is not perceived as being person focused and concerned with the well-being of those affected by the incident, the greater the risk of all those affected losing trust in the capability of the service to respond to the incident. Trust when lost is difficult to regain and considerably influences the subsequent management actions required. The Institute for Healthcare Improvement (IHI) in their publication *Respectful Management of Serious Clinical Adverse Events* (Conway, Federico, & Campbell, 2011) proposes that an adverse event does not necessarily break down trust between people involved in an incident and the service, rather it is the way that a service responds to an incident which does.

When an incident occurs/is identified it should trigger a cascade of immediate responses to those:

- (i) Person(s) harmed or directly affected by the incident, i.e. the service user and staff
- (ii) to those who are not directly affected but who may be indirectly affected by what has happened, i.e. relevant person(s) and other staff of the healthcare team/organisation
- (iii) to those who could be affected going forward if risks are not identified and mitigated.

### (i) Immediate Responses to the person directly affected and their relevant person(s)

When an incident occurs/is identified, the first response must be to the person directly affected. This can be either a service user or a staff member who suffers a workplace incident. It is important to focus first and foremost on the affected person's clinical and care needs through the provision of appropriate medical treatment or other care to manage the harm that has occurred, relieve suffering and minimise the potential for further harm to occur.

**Open Disclosure:** Where the incident relates to a service user attention and effort must also be given at this time to initiating Open Disclosure as prompt, open and transparent communication with the person affected and their relevant person (as appropriate) is required. This can provide an opportunity for the service to engage with the person affected and/or their relevant person about what has happened and providing reassurance in relation to the management of the affected person's on-going care, the immediate steps being taken by the organisation to mitigate further harm and the organisation's commitment to review the incident and to share the review findings with the person affected.

Communicating effectively with persons affected and their relevant person in a compassionate, empathetic and thoughtful manner, especially when disclosing information about an incident, is a crucial part of the therapeutic relationship and if done well can mitigate anxiety and enhance the person affected, carers and relevant person(s)'s trust in the staff, the institution, and the health care system. It also offers services with the opportunity to enquire about any supports required, physical or psychological.

The [HSE's Open Disclosure Policy and Guidelines](#) are important resources in this regard and provide detailed information on how to manage the open disclosure process, including guidance on apologising to service users.

**Designated Support Person:** A person directly affected or their relevant person(s) who have been impacted by the incident will likely need emotional and psychological support and this should arrive seamlessly. For this purpose a person directly affected or their relevant person(s) should be advised of a named person to act as a single point of contact for them.

The role of this person is to ensure that a person directly affected or their relevant person(s) do not feel isolated and that their support and communication needs are met both in the immediate aftermath of the incident, in planning for the review of the incident and throughout the conduct of the review. The person identified should have the necessary skills and experience required to fulfill their role.

## (ii) Immediate Responses to Staff

Similar to persons directly affected and their relevant person(s), staff may be significantly impacted, emotionally and functionally, following an incident which causes harm.

In the immediate aftermath of an incident it is important to identify the staff involved and to initiate appropriate support mechanisms. It is also important to consider the impact of the event on other staff who are not directly involved but who may be affected by the event such as other members of the health care team/the organisation as a whole. The HSE's **Supporting Staff following an adverse event: The "ASSIST ME" Model** and the **HSE Policy for Preventing and Managing Critical Incident Stress** are important resources in this regard. Detail of supports offered and availed of should be documented.

**Staff Liaison Person:** A named staff member should be identified to act as a single point of contact for staff directly impacted by the incident. The role of this person is to ensure that staff affected do not feel isolated and that their support and communication needs are met throughout the incident management process including any review of the incident that may be required. The person identified should have the necessary skills and experience required to fulfill their role.

## (iii) Mitigating risk to others

There is also a need to consider whether the incident has highlighted any immediate safety concerns that may affect others and if so that immediate steps are taken to assess and mitigate any associated risk. This includes securing/removing any equipment/drugs/records etc. that may have been associated in the incident and ensuring continuity of services for other service users.

### Documentation

All incidents involving service users should be factually documented in the service user's clinical/care record including details of the care provided and the salient points of the open disclosure discussion.

#### Key Messages

1. The first response must be to any person harmed to ensure that the impact of the incident is minimised and any remedial actions are taken.
2. An assessment must take place to ensure that any immediate actions required to prevent the risk of recurrence are identified and actioned.
3. The needs of persons affected i.e. service users, relevant person(s) and staff, should be identified and supported.
4. The open disclosure process must be initiated as soon as is reasonably practicable and ideally within 24-48 hours after the incident occurs or becomes known to the service provider or as soon as the service user or relevant person(s) is available physically and emotionally to take part in the discussion.
5. For incidents involving service users, the event should be factually documented in the service users clinical/care record along with details of the information and care provided to the service user.
6. Named service user/relevant person(s) designated support person and staff liaison persons are to be identified.

## Step 3. Initial reporting and notification

When any immediate action required has been taken, the staff member identifying the incident should, if they have not already done so, notify the incident to the manager on duty within the area where the incident occurred. On occasion an incident may be identified in one service that may have occurred in another e.g. on attendance at an ED or following discharge from an acute hospital. In such cases the identifying service is required to notify the service in which the incident occurred so that they can instigate an incident management plan. It is essential that services have a defined pathway of communication for such incidents.

It is the responsibility of the staff member identifying the incident to report the incident either by completion of the appropriate National Incident Report Form (NIRF) or direct entry to NIMS if available. This should be done as soon as is practicable after the incident<sup>2</sup> occurs and within one working day of its occurrence. In a small percentage of cases, the incident may not be identified at the time of occurrence; it could be identified through receipt of a complaint, the outcome of an audit or consequent to a Look Back Review. In these cases, the incident is reported at the time of identification.

In reporting the incident staff must ensure that they provide all information and complete all mandatory fields required. They must ensure that any information provided is factual and not subjective. This is important as it assists in supporting a just and fair culture. Where a NIRF is used services must clearly identify the route for submission of this for input onto the National Incident Management System (NIMS). The timely entering of incidents onto NIMS assists service performance in relation to the relevant HSE KPI for incident reporting and fulfills the service's obligation to inform the State Claims Agency.

Service polices must identify the route and process for notification of **Category 1**<sup>3</sup> incidents to the SAO within 24 hours of occurrence. Timely reporting of such incidents to the SAO enables assurance to be gained in relation to any immediate actions required and the activation of the SIMT (**IMF Guidance Section 7**) to make an assessment of further actions that may be required. All maternal deaths must also be reported to the NWIHP within 48 hours of occurrence. The process should distinguish both the arrangements for notifying incidents within and outside normal working hours. As these incidents, in particular, may be subject to further review, staff involved should be advised by their line manager at this time to prepare a **written personal recollection of events**<sup>4</sup> (**IMF Guidance Section 5**).

Services also have an obligation **to notify specific incidents external to the service where the incident occurred, (IMF Guidance Section 7)** including but not limited to the following:

- Health Information Quality Authority
- Mental Health Commission
- Health and Safety Authority
- State Claims Agency
- Health Products Regulatory Authority
- TUSLA
- Coroner
- Medical Exposure Radiation Unit
- Gardai
- Commercial Insurers (this may be applicable where the incident relates to an area not covered by the State Claims Agency)

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2 In cases where the incident, though identified in one service occurred in another, the responsibility for completion of the NIRF lies with the service where the incident occurred when notified of it.

3 See Definition on page 3.

4 The main purpose of writing a personal recollection of events is for staff to have a contemporaneous record of the event, for them to use in relation to an incident review or other process. The availability of written Personal Recollection of Events to a Review Team, are extremely helpful in building a picture of events and may allow them to limit the number of staff interviews that are required.



**The SAO should be aware of their external reporting obligations and have in place systems to ensure that these notifications are consistently made in a timely manner.**

#### **Key messages**

1. Incidents must be reported by the identifying staff member by completion of the appropriate National Incident Report Form (NIRF) or direct entry to NIMS if available. This must be done in a timely manner having regard for the immediate needs of persons affected i.e. within 24 hours of their occurrence.
2. NIMS is the primary reporting system across HSE and HSE funded agencies.
3. Notification of Category 1 Incidents to the SAO must occur within 24 hours of occurrence.
4. Services must be aware of their external reporting requirements and have in place systems to ensure that, where required, reporting occurs within designated timeframes.

## Step 4. Categorisation and Initial Assessment

The purpose of categorising and assessing incidents is to assist with determining the level of review required. The level and approach to review must also be proportionate to the impact of the incident and the opportunity provided by the incident to identify learning that can be used to minimise the risk of a similar incident occurring in the future.

The line manager in whose service the incident occurred will in reviewing the NIRF submitted to them, have identified the level of harm relating to the outcome of the incident. The level of harm experienced informs the categorisation of the incident.

Incidents are categorised as follows:

1. **Category 1 Major/Extreme** – Clinical and non-clinical Incidents rated as major or extreme as per the HSE's Risk Impact Table.
2. **Category 2 Moderate** – Clinical and non-clinical incidents rated as moderate as per the HSE's Risk Impact Table.
3. **Category 3 Minor/Negligible** – Clinical and non-clinical incidents rated as Minor or Negligible as per the HSE's Risk Impact Table.

A copy of the HSE's Risk Impact Table is included at **Appendix 2**.

Due to the level of harm incurred, **Category 1** and **Category 2** incidents require preliminary assessment to support a formal decision being taken in relation to review. Detail of the assessment and decision making process must be recorded using the **Preliminary Assessment Form (IMF Guidance Section 8)**.

In relation to **Category 2** incidents, the completion of Part A of this form is the responsibility of the Local Accountable Officer in whose service the incident occurred. Part B is also completed by them in consultation with the QPS Manager.

**Category 1 incidents** must be referred to the **Serious Incident Management Team (SIMT) (IMF Guidance Section 7)** for decision making in relation to their management. Ideally, decisions relating to the review of **Category 1** incidents **should be** made within 72 hours of occurrence of the incident and at latest **must be** made within one working week.

In order to assist decision making at the SIMT the SAO, on notification of the incident, should assign an appropriate person, for example, the QPS Manager, to gather the information required for the completion of Part A of the **Preliminary Assessment Form**. This will be presented at the SIMT meeting in order to assist in framing the discussion relating to the need for further review of the incident.

### Deciding on the Level of Review

Whilst all incidents must be subject to review, the level of review should be guided by the categorisation outlined above i.e.

**Level 1 Review** – Comprehensive Review (**Category 1 incidents**)

**Level 2 Review** – Concise Review (**Category 2** and some **Category 1 incidents**)

**Level 3 Review** – Aggregate Review (**Category 3 incidents**)

**Note:** *While the categorisation of an incident according to its severity is one of the primary mechanisms for deciding on the level of review, the opportunity for an incident to identify learning to improve safety is another such mechanism e.g. where a **Category 3** incident was a near miss but its impact could have resulted in a severe outcome a Level 1 or 2 review may assist in identifying learning, which when implemented, would reduce the risk of a more serious impact occurring in the future.*

Where a decision is taken to conduct a Level 1 or Level 2 Review, staff who were involved in the care of the service user/workplace where the incident occurred should be advised, if they have not done so already, to write and retain their **written personal recollection of events (IMF Guidance Section 5)**.

It should be noted that in relation to clinical care, whilst a case may have resulted in a poor outcome it does not always follow that this was as a result of an incident occurring in the course of the delivery of that care. In cases where it is not clear whether the outcome was as a result of an incident occurring, it may be prudent to request a **Healthcare Record Review (IMF Guidance Section 9)** of the case. Such a review will clarify whether the care provided was appropriate and timely or whether there was an incident requiring review. In conducting a Healthcare Record Review, the Reviewer must be impartial and be aware of the issue of outcome bias in the conduct of the review. This is necessary in order to seek to avoid the tendency to judge a decision by its eventual outcome instead of judging it based on the quality of the decision at the time it was made, taking account of the situation that pertained.

In addition to supporting decision making relating to an incident, a Healthcare Record Review may also be requested to provide an expert report to support the conduct of a review of an incident. Expertise to conduct a Healthcare Record Review can be sourced within the Hospital Group/CHO/NAS Corporate Area/other service or by way of an external request e.g. to the [Forum of Post Graduate Training Bodies](#). Requests for a Healthcare Records Review should be approved by the SAO or Clinical Director.

## Making decisions in relation to the approach to review

Within each level, a number of approaches to review have been endorsed for use within the HSE and HSE Funded Services. Regardless of the level of review selected the basic process should be consistent with the objective of finding out, what happened, why it happened and what actions are required to minimise the risk of recurrence. Some incidents, however, require the approach to review adopted to take a deeper and more detailed examination of the incident to comprehensively understand the causes of the incident and the factors that contributed to these.

The table below summarises these approaches and **Approaches to Incident Review Guidance (IMF Guidance Section 10)** has been developed to provide a more detailed description of each. To assist decision making the guidance also provides staff with advice regarding the strengths and weaknesses of each approach.

Level of Review	Approaches to Review	Methodology underpinning approach
Comprehensive	1. Review Team	Systems Analysis
Concise	1. Facilitated Multidisciplinary Team approach	Systems Analysis or After Action Review (AAR)
	2. Desktop approach	Systems Analysis
	3. Incident Specific Review Tool e.g. Falls and Pressure Ulcers	Systems Analysis
Aggregate	1. Aggregate approach	Systems Analysis

**Systems Analysis:** A structured process that aims to identify what happened, how and why it happened, what can be done to reduce the risk of recurrence and make services safer. The process applied considers how all parts of the healthcare system may have interacted and contributed to the outcome. In considering an incident in this manner it is more likely that the findings identified will lead to actions required to address any system issues which may have existed. The principles of **Systems Analysis (IMF Guidance Section 13)** can be applied using a Comprehensive, Concise or Aggregate Approach.

**After Action Review (AAR):** This is a structured facilitated discussion of an event, the outcome of which enables the individuals involved in the event to understand why the outcome differed from that which was expected and what learning can be identified to assist improvement. Apart from its use as a concise review approach, AAR can also be used to debrief with staff following a **Category 1** incident for which a comprehensive review is planned.

Note: In circumstances where AAR is used as a mechanism to debrief staff in the aftermath of a Category 1 incident, the outcome of this does not require the development of a formal report and is kept separate from any subsequent incident review which may be commissioned.

## Independence attaching to the Review Process

The review of incidents should not be led or facilitated by a person who was directly involved in the incident as this may introduce bias and represent either a real or perceived conflict of interest. A degree of independence is therefore always required when reviewing incidents.

Whilst it is preferable that the incident is reviewed as closely to the service as practicable there will be occasions when a greater level of independence is required. One such occasion relates to the review of a 'direct maternal death'. The review though commissioned by the Hospital Group where the death occurred must be undertaken by a Review Team external to the Hospital Group. The conduct of this review and selection of appropriate Review Team members will be supported by guidance from the NWIHP.' Levels of independence, therefore, range from a review being carried out by a team within a service up to the review being carried out by an external review team. For example options for independence as they would apply to Hospital Groups, Community Healthcare Organisations, and the National Ambulance Service (NAS) are illustrated below.

Option	Organisational level at which the membership of a review team is drawn.	Degree of Independence
1.	Membership of team internal to the team/department/NAS Operational Region.	Low
2.	Membership of team internal to the service/hospital/NAS Operational Area.	Moderate
3.	Membership of team external to the service/hospital but internal to the CHO/ Hospital Group/NAS Corporate Area.	High
4.	Membership of team involve persons external to the CHO/Hospital Group/ NAS Directorate.	Very High

The choice of Option will depend on:

- the nature of the incident
- the prevalent culture within the team to engage positively in relation to safety issues
- the level of trust that has been established and maintained with the service user/relevant person(s) at Step 2 of the process i.e. the immediate actions taken following the identification of the incident.

The level of independence required is often a factor of perceived confidence in the service to carry out an impartial review. The aim should always be to have the review carried out at the lowest level appropriate to the categorisation of the incident.

**The importance of initial and continued attention to supporting and communicating with persons affected by the incident (Step 2) therefore cannot be over-emphasised.**

**Category 3 incidents** are generally reviewed internal to the team/department (Option 1). The review of **Category 3 incidents** should occur both at the time of occurrence/identification to identify any immediate actions required and further discussed as part of the business of the service's multidisciplinary team meeting.

**Category 2 incidents** are generally reviewed internal to the team/department with some being commissioned internal to the service/hospital by the Local Accountable Officer (LAO) i.e. Option 1 or 2.

**Category 1 incidents** are the most serious incidents and require formal commissioning by the SAO. The choice of Option can be dependent on the nature of the incident and the effectiveness of the incidents immediate management such as the process of Open Disclosure and the rapport established with the service users and other persons affected.

**Category 1 incidents** require notification to the SAO within 24 hours of occurrence. In the event that a **Category 1 incident** is notified to the SAO there is an immediate requirement for the SAO to gain assurance that all immediate actions have been taken to ensure the safety of persons affected and to address any immediate risk to others (see actions required at Step 2).

*"Insensitive responses to families actually create new incidents – the trauma arising from how we are received following adverse events can often be more damaging than the event itself."*

Mother of a service user

## Timeframes for completion of reviews

To assist with a responsive and timely approach to review and with building a culture of safety, reviews should be completed within the shortest possible timeframe. For Concise and Comprehensive Reviews this should not exceed 125 days from the time of occurrence of the incident. It is however accepted that in some circumstances this timeframe will not be achievable, for example when a Review Team is commissioned external to the HG/CHO where the incident occurred.

*"Following the incident, I was kept in the loop in relation to the review. I met with the review team and was asked if I had any particular questions that I wanted the process to address. The staff member who liaised with me was great and provided me with support. I felt that I was a partner in the process."*

A service users relevant person

## Commissioning a review

All reviews are required to be carried out in keeping with **the principles of fair procedures and natural justice (IMF Guidance Section 12)**. A **terms of reference (TOR) (IMF Guidance Section 11)** must be developed. The TOR must set out the following detail; background to the incident, Review Commissioner, purpose, scope, membership of the Review Team, timeframe, the delivery of a report setting out findings and recommendations and detail of service user/relevant person(s) and staff designated support person(s)

The availability of terms of reference is required for **all** comprehensive reviews and is recommended as best practice for concise reviews, as it clearly sets out the scope and governance of the process.

The level at which a review is commissioned will depend on the category of the individual incident. **Category 1** incident reviews, however, require commissioning by the SAO or a person who has a direct reporting relationship to the SAO. The SAO also has a coordination and oversight responsibility where concurrent reviews are being undertaken in relation to a multi-incident event.

The Review Team should not include any person directly involved in the incident or any person with a conflict of interest, perceived or actual. The Review Commissioner or a person delegated by them must meet with the Review Team prior to commencement of the review to discuss the TOR and ensure that relevant supports are in place.

Services are responsible for ensuring that appropriate governance arrangements are in place for the duration of the review process to include monitoring to ensure that timeframes are complied with. In the case of **Category 1** incidents monitoring of commissioned reviews is a function of the SIMT. This is of particular importance to ensure that reviews are completed within the 125-day timeframe. Reviews at risk of breach of this timeframe should be the subject of active management by the SIMT.

Where the SIMT have decided not to review a **Category 1** incident, the decision supported by a reason or basis for the decision must be signed off by the SAO and reviewed at the relevant committee e.g. the Quality and Safety Committee.

Decisions not to review a **Category 2** incident should also be supported by a reason or basis for the decision and must be signed off by the Local Accountable Officer in whose area/service the incident occurred.

Persons affected i.e. service users, relevant person(s) and staff, must be advised of the decision to proceed or not to proceed with a review. This applies to both **Category 1** and **Category 2** incidents.

When decisions have been taken in relation to review, relevant data fields on NIMS must be completed.

#### Key Messages

1. The level of review assigned to incidents will be informed by their categorisation. The review of Category 1 incidents must be commissioned by the SAO or a person who has a direct reporting relationship to the SAO.
2. The level of independence applied to a review is often directly proportionate to the level of openness and rapport established and maintained with persons affected.
3. Where it is decided not to review a Category 1 incident that decision, supported by the reason or basis for the decision must be signed off by the SAO and reviewed at the relevant committee e.g. the Quality and Safety Committee.
4. Persons affected i.e. service users, relevant person(s) and staff, must be advised of the decisions to proceed to review or not to proceed to review.
5. Governance arrangements must be in place to ensure that reviews are carried out in line with the principles of fair procedures and natural justice and within required timeframes.
6. Enter details of decisions relating to review onto the NIMS.

## Step 5. Review and analysis

The purpose of review is to find out what happened, why it happened and what learning can be gained in order to minimise the risk of a similar incident occurring in the future. The review and analysis of incidents should, therefore, be viewed as a key tool for improvement. Individual performance issues identified in the course of or as a consequence of an incident review should be managed under the relevant HSE Human Resource Policy.

Incident review is not just about what happened at the point of occurrence of the incident e.g. at the point of care delivery, but to develop an understanding of the factors that contributed or influenced the occurrence so that these can be addressed. It is, therefore, important that the approach to review seeks to examine the systems in place and how weaknesses in these may have contributed to the incident. Failure to correct systems issues identified will result in them failing again in the future. If used effectively, this process should assist in moving the focus from responding to incidents to preventing them i.e. safety management underpinned by learning and improvement. The approach to review, therefore, needs to be a systematic and structured.

The actions of staff are examined within the context of the overall system. If, however, during the course of a review or consequent to the completion of a review, issues relating to the performance or conduct of staff are identified these must be brought to the attention of the Review Commissioner by the Chair of the Review Team. Such issues should be managed with an appropriate and proportionate Human Resources response in line with the relevant HSE Human Resource Policy.

*"I was present at Kevin's birth and know every detail of that birth. I was also present when he died. As his mother, I needed and deserved to also know everything relating to how that came about."*

Mother of a service user

It is essential that the review process is supportive to those affected by the incident i.e. service users, relevant person(s) and staff. They must also be confident that the process applied is open and fair and follows the **principles of fair procedures and natural justice (IMF Guidance Section 12)**. These principles must be seen to work in practice at all stages in the process i.e. from the establishment of the review to the point at which the report is finalised. The **HSE's Open Disclosure Policy** and associated tools and guidance are an important resource that can support services achieve openness and transparency with persons affected.

*"I was so nervous during the review, it was so formal, took so long and I sometimes wondered was it more focused on blame than learning. Maybe if I was supported better it would have been easier."*

Staff Member

The review of any incident must be balanced and be capable of identifying both the things that could be improved along with highlighting any areas of good performance. It should, therefore, be conducted in a manner that focuses on learning and improvement.

Whereas the following places focus on reviews commissioned by the SAO it is important that all incidents are considered for review in a manner that is proportionate and focused on learning to improve safety. The IMF guidance provides a range of **approaches to review** to support this. **(IMF Guidance Section 10).**

## Requirements for reviews commissioned by the SAO

All reviews commissioned by the SAO, irrespective of the approach chosen require the following features:

1. That the review is managed within the context of the service's governance arrangements for quality and safety (clinical and non-clinical).
2. A **terms of reference (TOR)** has been developed<sup>5</sup>. **(IMF Guidance Section 11)**
3. In line with the designated **approaches to incident review**, a multidisciplinary Review Team with clearly defined roles is appointed i.e. a technical lead who is trained in the chosen approach to review and a person(s) with subject matter knowledge in the area under review. **(IMF Guidance Section 10)**
4. That members of the Review Team are sufficiently removed from the incident to ensure that it can provide an objective assessment of the incident and avoid any conflict of interest (real or perceived).
5. Membership of the Review Team should be kept to a manageable number and facilitated to access additional expertise relevant to the area under review if required.
6. A service user/relevant person(s) designated support person and a staff liaison person should be identified and contact details of these persons communicated to these parties. The role of these persons in the context of the review process is to advise those directly impacted by the incident of the plan for review and to provide for effective and on-going communication and support during the review process.
7. The service user/relevant person(s) designated support person should be in a position to advise the service user/relevant person(s) in relation to supports available to them, for example, independent advocacy services such as the [Patient Advocacy Service](#).
8. In the case of patient safety incidents that the service user/relevant person is provided with an opportunity to meet the Review Team in order to provide their perspective on the incident (their story) and outline any issues/questions that they would like considered.
9. Staff liaison persons should also ensure that relevant staff are aware of available supports and the importance of completing their **written personal recollection of events** **(IMF Guidance Section 5)**.
10. The Review Team should be facilitated with access to all information relevant to the issue under review e.g. healthcare records, relevant PPPG's, staff training records, staff rosters, etc.
11. To ensure appropriate record retention requirements are met, systems for the **management of documentation and information** relevant to or created as part of the review is established and maintained. **(IMF Guidance Section 17)**.
12. Systems for monitoring the progression of reviews should be established to ensure that it is completed within timeframes. This will assist in the identification of potential delays that may need to be escalated to the Review Commissioner for management. In the case of **Category 1** incidents, it is recommended that such monitoring be a function of a scheduled **SIMT**. **(IMF Guidance Section 7)**
13. Reports are finalised in line with the **governance approval process** **(IMF Guidance Section 16)**

## Analysis

It is important when reviewing an incident to understand both what happened, and why it happened in order to determine what actions if any are required to prevent a recurrence.

Any review being undertaken must, therefore, go beyond simply setting out a chronology (what happened) but seek to identify key findings (causes) and factors that contributed to these. Use of the tools to assist the analysis such as those set out in the **Systems Analysis Guidance** will assist services to look beyond issues at the point of occurrence. **(IMF Guidance Section 13)**

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5 Incident specific review tools for Pressure Ulcers and Service User Falls are the exception to this as they include standardised terms of reference within the tool.



The tools set out in the Systems Analysis Guidance are used to optimise learning and address the causes of patient safety incidents through the identification of those factors that contribute to incidents occurring in clinical and care settings. Though designed primarily for use in relation to service user safety incidents, these tools are in the main also relevant to non-clinical incidents.

The underlying aim of these tools is to develop a more sophisticated understanding of the factors that contribute to the occurrence of incidents. These factors can then be addressed through changes in systems, structures, and local working conditions. Finding the true causes of incidents offers an opportunity to address systemic flaws effectively, for the benefit of service users and staff.

## Making recommendations

Recommendations form the basis for services to develop action plans to improve safety and prevent recurrence. It is critical that in **developing recommendations (IMF Guidance Section 14)** that these are:

1. clearly linked to the findings and factors that contributed to the incident
2. applied to the context or service in which the incident occurred.
3. framed in a manner that conforms with CLEAR<sup>6</sup> principles
4. capable of supporting any changes in practice required and
5. where possible aimed at changing systems in a manner that supports people to behave in a safe and consistent manner rather than relying on people to behave in a specific manner.

## Identifying Learning for Sharing

Learning from a review can form a valuable source of information for other services where there may be a risk of a similar incident occurring.

If it is identified that the learning from a review could be of assistance to other services a short description of that learning should be included in review reports.

*"As a Commissioner of reviews sometimes when I receive the final report I find that the analysis is poor and I cannot see how the recommendations link to the findings. I am then in a position that I have a report which I would not be confident has adequately reviewed the issue and a set of recommendations that I am not confident will serve to reduce the risk of the incident recurring."*

A Senior Accountable Officer

## Writing the Review Report

The quality of the report is critical both from the perspective of those affected by the incident and also the service within which it occurred. It provides an opportunity to reflect on what happened and why it happened and to set out the recommendations for change to reduce the risk of recurrence. High quality **report writing** is therefore essential as a well written report can assist in gaining closure on the incident; conversely, a poorly written report can leave questions unanswered in relation to the incident or a lack of clarity for services in relation to the need and basis for change. **(IMF Guidance Section 15).**

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<sup>6</sup> CLEAR is an acronym used to describe the key elements/features that a recommendation should have to support successful implementation i.e. **C**ase for Change, **L**earning Orientated, **E**vidence, **A**ssign, **R**evue.

## Acceptance of the final report by the Review Commissioner

Prior to accepting the final report, the Review Commissioner needs to have in place a **governance approval process for the final draft report (IMF Guidance Section 16)**. From the perspective of the Review Commissioner, the purpose of this is to assure themselves of completeness and robustness of the process applied and not to question the findings of the process.

The governance approval process should, therefore, focus on ensuring that:

- The review has been pseudo-anonymised as per requirements
- The scope of the review was in keeping with that set out in the terms of reference
- The process applied conforms to the approach identified in the terms of reference
- There is evidence that the process conformed to the principles of fair procedures and natural justice
- There is clear linkage between the findings and any recommendations made
- Recommendations made are consistent with CLEAR principles are consistent with the policy framework within which the service operates and when implemented (either in the short or long term) will seek to address any systems weaknesses identified
- The report conforms with relevant legislative requirements e.g. Data Protection.

If the report conforms to the requirements of the governance approval process it is accepted by the Commissioner.

In circumstances where the report does not conform to the requirements of the governance approval process, the Review Commissioner should outline to the Review Team the reason for this decision, request that they address any issues and following this resubmit the report. Where the Review Team indicates an unwillingness to address the issues identified the Review Commissioner can decide to step down the Review Team, (and their draft report) advise those affected by the decision (staff, service user/relevant persons) and move to appoint a new team. The reason for this should be documented and available for audit purposes.

When the report is accepted by the Review Commissioner, NIMS data fields relating to the outcome of the review process must be completed and a copy of the review report uploaded to NIMS. All review reports relating to maternal deaths (direct, indirect or coincidental) must also be submitted to the NWIHP for inclusion in aggregate analysis to support learning with other maternity units nationally.

## Provision of the report to persons affected (a service user/relevant person(s) and staff)

Providing a report to persons affected should be carried out in a supportive manner. It is one of the final tasks prior to completion of the incident management cycle and it is important that appropriate attention is given to this. See **Point 7. Page 63 IMF Guidance** for a more detailed description of this process.

*"I had participated in the review process and knew that the report was complete. The report was presented to staff at a team meeting. This was helpful in understanding how the incident occurred and what we as staff could do to prevent a similar incident occurring in the future."*

A staff member

The Review Commissioner should agree the process for providing the report to persons affected.

*"I knew the review was in progress and that a report would issue to me. One day, out of the blue it arrived by post. The language was technical and I was not sure I understood it or its implications."*

Mother of a service user

## Sharing Learning from the Review Report

At a minimum, services must arrange to have final reports discussed at the relevant Committee, for example, the Quality and Safety Committee. This is to ensure that any learning identified can be shared internal to the service for the purpose of patient safety and quality improvement.

Consideration should also be given to the completion of a learning summary which sets out a brief description of the background to the incident and the learning adduced. Such summaries can then be shared with services beyond the particular service/organisation within which the incident occurred so as to act as a prompt for them to ask the question; 'What controls (systems and processes) do we have in place to reduce the risk of a similar incident occurring here and how assured are we that these are effective?'

## Publication of the Review Report

Publication in this regard means putting the report in the public domain. Reports relating to service user incidents are personal to the service user and their relevant person(s) and as such are not generally published. If there is a request for such a report to be published, this request should be discussed with the Hospital Group CEO, CHO CO or equivalent senior manager.

## Communication with the public or other agencies (e.g. Department of Health)

To avoid any loss of public confidence or the risk of misinformation there is a need to ensure that there is consistent communication with parties outside of those responsible for the management of the incident. Following the identification of the incident and for the duration of the review until the report is finalised, all formal communications with the public or other agencies should come through the Review Commissioner in consultation with the Review Team. In circumstances where the Review Commissioner is a direct report of the SAO; it is the responsibility of the Review Commissioner to brief the SAO on communication requests and responses. Finalised approved reports will be shared first and foremost with the person affected/relevant person(s) and staff/service involved. In the event the report is released to other agencies the person affected/service should be notified. Communication with the Department of Health should be in line with the HSE and the Department of Health's Protocol for Communications in relation to major/significant patient safety issues and incidents.

### Key Messages

1. The purpose of review is to find out what happened, why it happened and what learning can be gained in order to minimise the risk of a similar incident occurring in the future.
2. Reviews should be overseen by the service's governance arrangements for quality and safety.
3. Review teams should be multidisciplinary and have the technical and subject matter knowledge required for the conduct of the review.
4. The approach to the review should be proportionate to the incident and consider the WHY as well as the WHAT of what happened.
5. Reviews must be conducted in keeping with the principles of fair procedures and natural justice.
6. The support requirements for persons affected and staff must be actively managed through a designated support person(s). This includes providing service users/relevant person(s) with information about advocacy services that may be of assistance in providing support to them.
7. Recommendations made must be in line with the principles of CLEAR and focused on avoiding recurrence.
8. A formal process for acceptance of the final report by the Review Commissioner must be in place and applied to all reviews.
9. Complete the required NIMS Incident Management fields relating to the review and its outcome and upload a copy of the report.
10. Issues relating to other internal, external or cross service reviews must be considered and addressed.
11. During the conduct of a review, communication with parties outside of those directly involved in the review process should be managed through the Review Commissioner of the review or their nominated person.
12. Systems for the management of documentation and information relevant to or created as part of the review are established and maintained in accordance with best practice.
13. Sharing learning from reviews and publication of reports or findings are separate processes and require consideration when reports are finalised.
14. Communication with the Department of Health should be in line with the HSE and the Department of Health's Protocol for Communications in relation to major/significant patient safety issues and incidents

## Other internal reviews or investigations

In the interest of safety, reviews relating to incidents should always proceed where possible and in a timely manner. However, the Review Commissioner may, where necessary, refer to other investigation/review processes e.g. HR, Look Back Review, etc, in the course of, or after the completion of the incident review. In those circumstances, the Review Commissioner must ensure there is separation between the processes to ensure that each process remains robust and retains the integrity required to achieve the intended outcome in a timely manner.

## Look Back Reviews

A Look Back Review is a process that is initiated where it has been determined that a number of people have been exposed to a specific hazard. The process seeks to identify if any of those exposed to the hazard have been harmed and what needs to be done to ameliorate the harm. This process consists of three key stages: Preliminary Risk Assessment, Audit, and Recall.

Look Back Reviews should be carried out in line with the [HSE Guideline for the Implementation a Look-back Review Process in the HSE](#).

## Cross service reviews

Due to the manner in which care is delivered, incidents may cross organisational/care boundaries, for example, pre-hospital/hospital care, hospital/community care, inter-hospital transfers, mental health/acute care, etc. In circumstances where it is established that an incident is identified in one location and the review requires the participation of another service/location, the SAO in the identifying location/service must contact the SAO in the corresponding location/service to advise them of the incident and the requirement to conduct a review.

The TOR, membership of the Review Team and the service taking the lead in carrying out the review should be jointly agreed. In circumstances where the incident has occurred in one service/location but has been identified by another service/location, the primary responsibility for the management of the incident lies with the service/location where the incident occurred. Procedures should be put in place to ensure the seamless conduct of the review including an agreement in relation to data protection, confidentiality, the sign-off of the final report and development of the implementation plan. The implementation and monitoring of recommendations particular to a service/location are the responsibility of that service/location regardless of which service led on the review.

## Reviews/Investigations being carried out by agencies external to the HSE/HSE funded services

An incident review may also be carried out while external reviews/investigations relating to the incident are on-going or anticipated. Examples of external reviews/investigations include civil litigation and risk reviews managed by the State Claims Agency (SCA), Inquests by Coroners and investigations by the Health and Safety Authority (HSA), Health Information and Quality Authority (HIQA), the Mental Health Commission (MHC), the Medical Council, the Nursing and Midwifery Board, CORU and/or An Garda Síochána.

**In general, with the exception of some investigations conducted by An Garda Síochána, there is no impediment to the review of incidents proceeding. In fact, a service has an obligation to service users/relevant person(s) and staff to ensure that the review takes place in a timely and responsive manner.**

In the cases of a HSE review coinciding with an investigation by An Garda Síochána, the Commissioners of HSE reviews must link with the relevant An Garda Síochána superintendent prior to commencing the review to inform them of the intention to undertake a review and to ensure that the commencement of the review will not compromise/adversely affect the investigation being undertaken by An Garda Síochána. This communication should be followed up formally and in writing.

## Reviews relating to Multi-Incident Events

Multi-incident events may arise where a cluster of similar incidents are identified by the service or concerns are received by a service from members of the public relating to an aspect of service provision. Clusters of concerns may in particular arise in the aftermath of the public reporting of an incident(s).

Considered and effective management of such events is essential as such events, if not effectively managed, can lead to significant issues of public confidence which can have long term effects for service users, their relevant person(s) and staff. The SAO and SIMT have an important role in ensuring that there are effective oversight and coordination of such events.

Incidents identified by a service require a **preliminary assessment (IMF Guidance Section 8)** in line with the IMF. This allows the service make decisions in relation to the need for and the type of further review that may be required.

Concerns raised by members of the public that may be indicative of a Multi Incident Event may not be as straightforward as they may contain elements other than incident that also require attention. For example, the concern may include elements that relate more to a complaint which may be appropriately managed in line with Your Service Your Say Policy and not the Incident Management Framework. It is therefore important that, from the outset, concerns raised by a service users/relevant person(s) are assessed and triaged for management through the appropriate pathway(s) (**IMF Pages 10-12 – When to use the Incident Management Framework**). Triage allows for the recognition that a differentiated approach may be required to manage the concerns received and, there may also be an opportunity to resolve some of these issues at an early stage.

The service user/relevant person(s) and relevant staff should be advised of the pathway(s) allocated to best manage their concerns. To ensure that service users/relevant persons are kept informed at this point and throughout the duration of any further action required a formal line of communication should be established with each service user/relevant person(s) from the outset. Such an arrangement provides an opportunity to; establish personal contact and express empathy, to ascertain a clear understanding of their issues and to advise them of progress in relation to their case.

Where cases relate to clinical care, identified either by the preliminary assessment of incidents or as a consequence of the assessment of concerns raised by a service user/relevant person(s), a starting point may be to request an independent **Healthcare Record Review (IMF Guidance Section 9)**. This combined with the preliminary assessment undertaken can be reviewed with relevant staff in the service where the incident occurred and used to develop a report to the individual service user/relevant person(s) to explain what happened in their case i.e. the findings.

The findings from each of the individual reports can then be aggregated as a starting point for a systems analysis review. In circumstances where a systems analysis review had previously been completed for any of the cases, the findings from these can also be aggregated with the findings from the individual reports provided to service users.

The Review Team appointed should review the aggregated findings and analyse the factors that contributed to each. It is from this analysis that recommendations can be developed to ensure that any deficits in the system of care or care delivery can be addressed.

It is recommended, that as part of the analysis process that the Review Team engages with members of the multidisciplinary team in the service to which the incidents relate. This provides an opportunity for the Review Team to obtain a more detailed view of the systems and environment of care. This will result in the Review Team gaining a better understanding of areas which may require improvement.

The outcome of the above will feed into the report of the Review Team which when accepted by the Review Commissioner can be shared with the service to inform service improvements required. It should also be shared with the service users/relevant persons(s) to provide them with assurance that the learning from their cases has been identified and that the service has committed to making any changes required to reduce the risk of recurrence of an incident from similar causes.

The management of the totality of cases as outlined above should be co-ordinated by a member of the SIMT via a formal management plan, the delivery of which is actively monitored by the SIMT.

In circumstances where the event is in the public domain the primary duty of care of the service must remain with those affected (service users/relevant persons and staff). Pressure placed on a service by external demands for an immediate response must be balanced with the need for a considered and effective review process from the perspective of affected persons. It is important therefore that the pace of the process is informed primarily by the needs of the persons affected as opposed to the needs of other stakeholders.

## Step 6. Improvement planning and monitoring

It is the responsibility of the SAO to ensure that an action plan to support the implementation of recommendations made as a consequence of the review is developed.

It is recommended that rather than monitor action plans for individual reviews, that action plans developed are interfaced with the relevant service improvement plan with implementation monitored via these. This is of particular importance where a number of reviews have made similar recommendations.

In cases where monitoring of implementation is being done through the service improvement plan, a record should be kept of the actions in the service improvement plan which relate to the implementation of recommendations in a particular review report. This will assist in the services ability to report on the implementation of recommendations relating to an individual report when required.

To facilitate monitoring, actions developed must be assigned to named individuals with a due date for completion. A monitoring process must be in place to track the completion of actions and where there is evidence that actions are behind schedule, appropriate corrective action must be taken to address this. Improvement plans must, therefore, be owned by the service and reviewed and updated regularly. If an action is identified which is outside the control of the service, a formal system of escalation should be applied so that the action can be appropriately located for implementation. At a minimum, progress on implementation of actions from **Category 1** incidents must be reported to the relevant committee e.g. Quality and Safety Committee on a quarterly basis.

Reports relating to aggregate analysis of data from NIMS and thematic learning should be collated over specific timeframes to assist and inform the wider service improvement programmes. This includes sharing this learning with national divisions and other relevant internal stakeholders.

Whilst the IMF focuses on the issue of Incident Management when it comes to identifying areas for improvement, it is important to also consider other relevant sources of information, for example, complaints, closed claims, inspection reports, etc. Information from all sources should be used to both inform the services improvement plan and to monitor the impact of improvement actions taken. An example of this might be the effect that adopting a more responsive and person centred approach to the management of incidents has on a service's complaints management process.

Services should have in place systems to verify implementation and monitor the effectiveness of improvement strategies which aim to improve the safety and quality of services. The use of audit and monitoring should be central to this and should occur both at the unit level and organisational level through the relevant committee e.g. Quality and Safety Committee. Services are required to publish an annual overview report in relation to incident reporting and management. This should include detail of incidents reported by type, speciality, and severity, compliance with key performance indicators relating to incident management and detail on how the actions and recommendations from reviews are being implemented in the service to improve safety.

### Key messages

1. An improvement plan should be developed to take account of the actions required to implement recommendations arising from a review.
2. To enable the effective monitoring of actions identified from sources such as incident and complaints reviews and inspections, an overall or overarching service improvement plan should be in place. This reduces duplication of effort and provides a service with an overall view of improvements required and assists in a more rational approach to monitoring.
3. Reports relating to thematic learning should be collated over specific timeframes to assist and inform the wider service improvement programmes.

## Supporting the Incident Management Framework at a national level

The Office of the Chief Clinical Officer (CCO) commits to continuing to work with relevant National Teams and services to both revise the IMF and to design and develop the guidance, tools and training required by services to operate in line with the requirements of the IMF. National Human Resources (National Health and Safety Function) also work to support services in relation to meeting their obligations for incidents that relate to Occupational Health and Safety.

This revision of the IMF has enabled the opportunity for the Office of the CCO to re-engage with services to identify areas which would benefit from additional clarification or indeed supplementary guidance. This has resulted in the revision of the guidance relating to both the role of the SIMT and the development of recommendations. Guidance on Supporting Service Users and Relevant person(s) and Staff in the aftermath of Patient Safety Incidents was commissioned as a piece of new guidance.

The Office of the CCO has committed to the development of a national system for sharing learning in a systematic and integrated manner. This system builds on work already undertaken and will identify new opportunities for the development of learning to inform safety improvement. Key to this is ensuring the most appropriate information is accessible to all, in a format and of a quality that is trusted and supports improvement and change.



# Appendix 1 Roles and responsibilities for incident management

Clarity in relation to the roles and responsibilities of staff are fundamental to the governance and accountability arrangements for incident management.

The roles and responsibilities of staff, managers, and SAO in HSE and HSE funded agencies in relation to the IMF are as follows.

## Senior Accountable Officer (SAO)

In the context of the IMF, the SAO is the person has ultimate accountability and responsibility for the services within the area where the incident occurred.

It is the role of the SAO (or his/her senior nominee) to:

- Reduce the risk of incidents occurring by ensuring that robust structures and processes are in place to both proactively and retrospectively enhance quality and safety systems throughout their organisation or service.
- Have overall accountability for the management of incidents occurring within their area of responsibility.
- Set out the governance and management arrangements for incident management in a manner that is consistent with the approach outlined in the HSE's IMF
- Ensure there are systems and processes in place to enable staff to report incidents.
- Have in place resources required to ensure incidents reported are logged on the National Incident Management System within required timeframes.
- Be aware of any external reporting obligations relevant to the service and have in place systems to ensure that these notifications are consistently made in a timely manner.
- Ensure that throughout the incident management process, there are systems and structures in place to address the support needs of persons affected (service users, relevant person(s) and staff) as a consequence of the incident.
- Have clear systems of governance in place to implement actions required as a consequence of recommendations made following the review of incidents.
- Receive an annual report in relation to incident reporting and management within their area of responsibility.

In relation to **Category 1** incidents specifically to:

- Have in place formal procedures to ensure that **Category 1** incidents are notified to them, or where off duty their deputy, within 24 hours of occurrence.
- Assure themselves that all care has been provided to any person affected/harmed as a result of the incident.
- Notify the relevant National Director (or equivalent) of the occurrence of these incidents in accordance with agreed pathways.
- Ensure that a Serious Incident Management Team (SIMT) is convened within 5 days of the notification of the incident to them.
- Receive and consider recommendations of the SIMT in relation to the commissioning of reviews
- Directly commission reviews of incidents or nominate one of their direct reports as the Review Commissioner
- Receive monitoring reports in relation to the progress of reviews and to take necessary corrective action where a review is experiencing delays.
- Have in place a governance approval process for the acceptance of final review reports they have commissioned.

- When a multi-incident event occurs, to assign a member of the SIMT to manage and coordinate all aspects of the process and to report progress and raise any issues requiring the attention of the SAO.
- Have in place a system to monitor the implementation of recommendations arising from the review.
- To maintain oversight and coordination where concurrent reviews are being undertaken in relation to a multi-incident event.

## Local Accountable Officer (LAO)

Reporting to the SAO, it is the role and responsibility of all Local Accountable Officers (LAO) to promote compliance with this IMF by ensuring that within their area of responsibility:

- They and staff reporting to them are aware of their obligations in respect of the IMF.
- Incidents occurring are reported and managed in line with the requirements of the IMF including recording of required information onto the NIMS.
- Staff are facilitated to participate in incident management training relevant to their role.
- Staff are supported and enabled to participate in the review of incidents.
- Have in place formal procedures to ensure that **Category 1** and 2 incidents are notified to them. **Category 1** incidents require notification within 24 hours of occurrence.
- Assure themselves that all care has been provided to any person directly affected as a result of the incident.
- Notify the relevant SAO within 24 hours of the occurrence of **Category 1** incidents in accordance with agreed pathways.
- Following consultation with the QPS/H&S Advisor commission reviews of **Category 2** incidents where applicable.
- Receive monitoring reports in relation to the progress of reviews commissioned by them and to take necessary corrective action where a review is experiencing delays.
- Have in place a governance approval process for the acceptance of final review reports they have commissioned.
- Have in place a system to monitor the implementation of recommendations arising from any reviews relating to their area of responsibility.

## Line Manager

It is the role and responsibility of all line managers to promote compliance with this IMF by ensuring that within their area of responsibility:

- They and staff reporting to them, are aware of their obligations in respect of the IMF.
- Incidents occurring are reported and managed in line with the requirements of the IMF including recording of required information onto the NIMS.
- Staff are facilitated to participate in incident management training relevant to their role.
- Staff are supported and enabled to participate in the review of incidents.
- Actions required as a consequence of recommendations made in reviews are included in their services Quality Improvement Plan.
- The service's Quality Improvement Plan is subject to monitoring and that corrective action is taken, where required.

## Staff (including temporary and contracted staff)

It is the role and responsibility of all staff to:

- Comply with local services procedures established in compliance with the IMF.
- Ensure that incidents are reported in a timely manner.
- Participate in and co-operate with reviews conducted in accordance with local service procedures.
- Participate in the introduction of change identified as a consequence of a review.
- Comply with their professional codes of conduct as they relate to incident management.

## Quality Patient Safety Advisor/Manager<sup>7</sup>

Within their area of responsibility, the Quality Patient Safety Advisor/Manager is responsible for;

- Supporting the SAO, LAO, line managers and staff, to enhance their capacity and capability to meet their responsibilities for the management of incidents in line with the IMF.
- To provide support and guidance to staff so as to facilitate the reporting and logging of incidents on the National Incident Management System.
- Providing feedback on incidents reported, to include aggregate reports to LAO line managers and relevant committees/teams.
- Providing expertise to SIMT to assist decision making in relation to incident review.
- Supporting services and staff to utilise learning from reviews to improve safety.

## Serious Incident Management Team

The chairing of the SIMT is a function the SAO or a person nominated by the SAO who has a direct reporting relationship to the SAO. The SIMT has the following key responsibilities:

- As a standing group to provide oversight for the effective management of all **Category 1** incidents within the service.
- To convene on an unscheduled basis and within 5 working days of the notification of a **Category 1** incident to the SAO in order to gain assurance in relation to immediate actions required and to advise the SAO on the need for further review.

Detailed guidance in relation to the role and responsibilities of the SIMT is set out in **IMF Guidance Section 7**.

## Review Team Chairperson

The Chair of Review Team reports to the commissioner of the review (SAO/LAO) and is responsible for ensuring that:

- The review of the incident is conducted in a manner that is impartial and in keeping with the scope of their terms of reference.
- Any immediate risk issues identified in the course of the review are brought to the attention of the Review Commissioner.
- There is effective liaison with designated support persons in the context of issues relating to the conduct of review.
- Updating the Review Commissioner on the progress of the review and any issues which may impact on the completion of the review within agreed timeframes.

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<sup>7</sup> Where incidents relate to OSH and where there is a Local Health and Safety Officer, Coordinator/Manager or Specialist in place, these responsibilities may, in line with local arrangements, be fulfilled by them.

## QPS Committee or Equivalent Committee

In the context of incident management, it is the responsibility of the QPS Committee or Equivalent Committee to:

- Obtain assurance that the processes for incident reporting and management are being adhered to.
- Receive, review and ratify decisions taken 'not to review' **Category 1** incidents.
- Make clear recommendations to the SAO where they do not agree to ratify the decision 'not to review' a **Category 1** incident.
- Receive and review completed incident review reports so as to identify learning and ensure this is appropriately disseminated to relevant services.
- Oversee the implementation of recommendations and actions from **Category 1** incidents.
- Monitor how the learning from reviews is shared and used to prioritise areas for safety and quality improvement.
- Receive from and report to the management team data relating to service performance relevant to incident management.
- Report to the SAO in relation to the capacity and capability required for the effective management of incidents within their area of responsibility.

## Staff Liaison Person\*

This person is a contact point at service delivery level for the staff member involved in an incident. As support is needed from the outset, the line manager typically takes on this role in the immediate aftermath of the incident and until the designated support person is confirmed (this might continue to be the line manager or maybe another person).

The staff liaison may facilitate communication with regard to the progress of the review. They may also facilitate access to support services.

## Service User Designated Support Person\*

This person is a contact point for the service user/relevant person(s) impacted by an incident. The service-user designated support person may facilitate feedback between the service user and the Review Team, as appropriate during the review process. They may also facilitate access to support services. To avoid any conflict of interest, the service-user designated support person should be impartial and sufficiently removed from the incident or its management.

\* In some services the staff liaison person and service user designated support person may be the same individual.

# Appendix 2 HSE Risk Impact Table

## 1. IMPACT TABLE

	Negligible		Minor	Moderate	Major	Extreme
Harm to a Person	Adverse event leading to minor injury not requiring first aid. No impaired Psychosocial functioning.	Minor injury or illness, first aid treatment required.  <3 days absence. Impaired psychosocial functioning greater than 3 days less than one month.	Significant injury requiring medical treatment e.g. Fracture and/or counselling. Agency reportable, e.g. HSA, Gardaí (violent and aggressive acts). >3 Days absence. 3-8 Days extended hospital Stay. Impaired psychosocial functioning greater than one month less than six months.	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling. Impaired psychosocial functioning greater than six months.	Incident leading to death or major permanent incapacity.  Event which impacts on large number of service users or member of the public. Permanent psychosocial functioning incapacity.	
Service User Experience	Reduced quality of service user experience related to inadequate provision of information.	Unsatisfactory service user experience related to less than optimal treatment and/or inadequate information, not being talked to & treated as an equal; or not being treated with honesty, dignity/ & respect – readily resolvable.	Unsatisfactory service user experience related to less than optimal treatment resulting in short term effects (less than 1 week).	Totally unsatisfactory service user outcome resulting in long term effects, or extremely poor experience of care provision.		
Compliance (Statutory, Clinical, Professional & Management)	Minor non compliance with internal PPPGs. Small number of minor issues requiring improvement.	Single failure to meet internal PPPGs. Minor recommendations which can be easily addressed by local management.	Repeated failure to meet external standards. Failure to meet national norms and standards/ Regulations (e.g. Mental Health, Child Care Act etc). Critical report or substantial number of significant findings and/or lack of adherence to regulations.	Gross failure to meet external standards. Repeated failure to meet national norms and standards/regulations. Severely critical report with possible major reputational or financial implications.		
Objectives/Projects	Barely noticeable reduction in scope, quality or schedule.	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Inability to meet project objectives. Reputation of the organisation seriously damaged.		
Business Continuity	Interruption in a service which does not impact on the delivery of service user care or the ability to continue to provide service.	Short term disruption to service with minor impact on service user care.	Some disruption in service with unacceptable impact on service user care. Temporary loss of ability to provide service.	Permanent loss of core service or facility. Disruption to facility leading to significant 'knock on' effect.		
Adverse Publicity/ Reputation	Rumours, no media coverage. No public concerns voiced. Little effect on staff morale. No review/ investigation necessary.	Local media coverage – short term. Some public concern. Minor effect on staff morale/public attitudes. Internal review necessary.	Local media – adverse publicity. Significant effect on staff morale & public perception of the organisation. Public calls (at local level) for specific remedial actions. Comprehensive review/investigation necessary.	National media/adverse publicity, less than 3 days. News stories & features in national papers. Local media – long term adverse publicity. Public confidence in the organisation undermined. HSE use of resources questioned. Minister may make comment. Possible questions in the Dail. Public calls (at national level) for specific remedial actions to be taken possible HSE review/investigation.	National/International media/adverse publicity, > than 3 days. Editorial follows days of news stories & features in National papers. Public confidence in the organisation undermined. HSE use of resources questioned. CEO's performance questioned. Calls for individual HSE officials to be sanctioned. Taoiseach/ Minister forced to comment or intervene. Questions in the Dail. Public calls (at national level) for specific remedial actions to be taken. Court action. Public (independent) Inquiry.	
Finance	0.33% budget deficit. Nuisance Release.	0.33-0.5% budget deficit. On site release contained by organisation.	0.5-1.0% budget deficit. On site release contained by organisation.	1.0-2.0% budget deficit. Release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service, etc.).	>2.0% budget deficit. Toxic release affecting off-site with detrimental effect requiring outside assistance.	

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2020

# Incident Management Framework – Guidance

Care | Compassion | Trust | Learning





# Contents

Introduction	2
<b>Section 1</b> Terms and Definitions	3
<b>Section 2</b> Acronyms used in this document	14
<b>Section 3</b> Making decisions about appropriate pathways for review/investigation	16
<b>Section 4</b> Creating a Just Culture	21
<b>Section 5</b> Writing a Personal Recollection of Events	26
<b>Section 6</b> Reporting requirements external to the service where the incident occurred	29
<b>Section 7</b> Serious Incident Management Team (SIMT)	41
<b>Section 8</b> Preliminary Assessment Form	44
<b>Section 9</b> Healthcare Record Review	49
<b>Section 10</b> Approaches to Incident Review	51
<b>Section 11</b> Development of Terms of Reference (TOR) for incident reviews	67
<b>Section 12</b> Fair Procedures and Natural Justice	70
<b>Section 13</b> Systems Analysis Guidance	72
<b>Section 14</b> Developing Recommendations	86
<b>Section 15</b> Writing Review Reports	92
<b>Section 16</b> Governance approval process for finalising a review report	101
<b>Section 17</b> Retention of Records relating to an incident review	110

# Introduction

The following guidance has been developed to support services in applying the **Incident Management Framework 2020** (IMF) in a consistent manner.

The guidance contained in this document has been developed in accordance with best available practice and is set out in the sequence in which it is referenced in the IMF 2020.

Further guidance will be developed in response to service need.

This guidance, along with any revisions of the guidance contained in this document is available on the HSE website [here](#).

The version on the HSE's internet site is therefore the most up to date version of the IMF and Guidance and therefore supersedes the Incident Management Framework and Guidance 2018.

## Section 1 Terms and Definitions

Term	Definition
<b>Accountability</b>	Being answerable to another person or organisation for decisions, behaviour and any consequences.
<b>Adverse Event</b>	An incident which results in harm, which may or may not be the result of an error.
<b>After Action Review</b>	An After Action Review (AAR) is a structured facilitated discussion of an event, the outcome of which enables the individuals involved in the event to understand why the outcome differed from that which was expected and what learning can be identified to assist improvement.
<b>Apology</b>	<p>“Apology”, in relation to an open disclosure of a patient safety incident, means an expression of sympathy or regret.</p> <p>(Civil Liability (Amendment) Act 2017)</p> <p>It is a genuine expression of being sorry for what has happened.</p>
<b>Audit</b>	The assessment of performance against any standards and criteria (clinical and non-clinical) in a health, mental health or social care service.
<b>Best Practices</b>	Clinical, scientific or professional practices that are recognised by a majority of professionals in a particular field. These practices are typically evidence based and consensus-driven.
<b>Category 1 Incident</b>	Clinical and non-clinical incidents rated as Major or Extreme as per the HSE’s Risk Impact Table.
<b>Category 2 Incident</b>	Clinical and non-clinical incidents rated as Moderate as per the HSE’s Risk Impact Table.
<b>Category 3 Incident</b>	Clinical and non-clinical incidents rated as Minor or Negligible as per the HSE’s Risk Impact Table.
<b>Clinical audit</b>	A quality improvement process that seeks to improve care and outcomes through systematic review of care against explicit criteria and the implementation of change.
<b>Clinical Governance</b>	A system through which service providers are accountable for continuously improving the quality of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. This includes mechanisms for monitoring clinical quality and safety through structured programmes, for example, clinical audit.
<b>Competence</b>	The knowledge, skills, abilities, behaviours, experience and expertise to be able to perform a particular task and activity.

Term	Definition
<b>Complaint</b>	<p>The Health Act 2004 defines a complaint as:</p> <p>A complaint means a complaint made about any action of the Executive, or a Service Provider (see definition below) that, is claimed does not accord with fair or sound administration practice, adversely affects the person by whom, or on whose behalf, the complaint is made.</p>
<b>Complaint Manager</b>	A person delegated by their organisation for the purpose of championing the feedback management process, including the routine monitoring and review of same.
<b>Complaints Officer</b>	A person designated by the HSE for the purpose of dealing with complaints made to it in accordance with procedures established under section 49 (1) of the Health Act 2004 or a person designated by a service provider with whom the HSE has an arrangement under section 38 of the Health Act 2004 or given assistance under section 39 of the Health Act 2004.
<b>Concerns and Enquiries</b>	A concern or enquiry is a problem raised that can be resolved/responded to straight away, (by the end of the next working day). These are not reported as complaints and fall outside the complaints management arrangements.
<b>Confidential Recipient</b>	The Confidential Recipient is an independent person appointed by the HSE to receive concerns and allegations of abuse, negligence, mistreatment or poor care practices in HSE or HSE funded residential care facilities from patients, service users, relevant person(s), other concerned individuals and staff members.
<b>Contributory Factor</b>	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.
<b>Culture</b>	The shared attitudes, beliefs and values that define a group or groups of people and shape and influence perceptions and behaviours.
<b>Dangerous Occurrences</b>	Dangerous occurrences may result from a sequence of events and circumstances involving a combination of unsafe acts, unsafe conditions, system failures, human factors and/or omissions. It most directly relates to the term 'reportable circumstance' as defined by the WHO (2009).
<b>Data</b>	Data are numbers, symbols, words, images, graphics that have yet to be organised or analysed.
<b>Effective</b>	A measure of the extent to which a specific intervention, procedure, treatment or service, when delivered, does what is intended for a specific population.
<b>Error</b>	The failure of a planned action to be completed as intended or use of a wrong inappropriate or incorrect plan to achieve an aim.

Term	Definition
<b>Evaluation</b>	A formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved.
<b>Evidence</b>	The consistent and systematic identification, analysis and selection of data and information to evaluate options and make decisions in relation to a specific question.
<b>Fair Procedures and Natural Justice</b>	<p>Natural justice is legal language for two ancient rules from the Romans who believed that some legal principles were self-evident and did not require a statutory basis.</p> <p>The first is a rule against bias and is known as “<i>nemo iudex in causa sua</i>”. It means that no person can judge a case in which they have an interest.</p> <p>The second rule “<i>Audi alteram partem</i>” means “hear the other side too”. It is most often used to refer to the principle that no person should be judged without a fair hearing in which each party is given the opportunity to respond to the evidence against them.</p>
<b>Findings</b>	<ol style="list-style-type: none"> <li>1) Factors that, if corrected, would likely have prevented the incident or mitigated the harm;</li> <li>2) Factors that if corrected, would not have prevented the incident or mitigated the harm, but are important for patient/staff safety or safe patient care in general (incidental findings); and</li> <li>3) Mitigating factors – factors that did not allow the incident to have more serious consequences and represent solid safeguards that should be kept in place.</li> </ol> <p>(Ref: Canadian Incident Analysis Framework – Canadian Patient Safety Institute 2012)</p>
<b>Harm</b>	<p><b>Harm to a person:</b> Impairment of structure or function of the body and or any detrimental effect arising from this, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological. The degree of harm relates to the severity and duration of harm and the treatment implications that result from an incident.</p> <p>Degrees or levels of harm include:</p> <ul style="list-style-type: none"> <li>■ None – outcome for affected person is not symptomatic or no symptoms have been detected and no treatment is required.</li> <li>■ Mild – outcome for affected person is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (for example, extra observation, investigation, review or minor treatment) is required.</li> <li>■ Moderate – outcome for affected person is symptomatic, requiring intervention (for example, additional operative procedure or additional therapeutic treatment), an increased length of stay, or causing permanent or long-term harm or loss of function.</li> </ul>

Term	Definition
	<ul style="list-style-type: none"> <li>■ Severe – outcome for affected person is symptomatic, requiring life-saving intervention or major surgical or medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function.</li> <li>■ Death – on balance of probabilities, death was caused or brought forward in the short-term by the incident.</li> </ul> <p><i>(As adapted from the World Health Organisation's Conceptual Framework for the International Classification of Patient Safety, 2009.)</i></p> <p><b>Harm to a thing:</b> Damage to a thing may include damage to facilities or systems, for example environmental, financial etc.</p>
<b>Hazard</b>	A circumstance, agent or action with the potential to cause harm.
<b>Health Information</b>	Information, recorded in any form, which is created or communicated by an organisation or individual relating to the past, present or future, physical or mental health or social care of an individual (also referred to as a cohort). Health information also includes information relating to the management of the health care system.
<b>Health Service Provider</b>	<ul style="list-style-type: none"> <li>(a) a person, other than a health practitioner, who provides one or more health services and for that purpose: <ul style="list-style-type: none"> <li>(i) employs a health practitioner for the provision (whether for, or on behalf of, that person) by that practitioner, of a health service,</li> <li>(ii) enters into a contract for services with a health practitioner for the provision (whether for, or on behalf of, that person) by that health practitioner of a health service,</li> <li>(iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, that person,</li> <li>(iv) enters into an arrangement with a health practitioner: <ul style="list-style-type: none"> <li>(I) for the provision by that health practitioner of a health service (whether for, or on behalf of, that person, or through or in connection with that person),</li> <li>(II) for the provision by that health practitioner of a health service on his or her own behalf (whether through or in connection with, or by or on behalf of, that person or otherwise), or</li> <li>(III) without prejudice to the generality of clause (II), to provide that health practitioner with privileges commonly known as practising privileges (whether such privileges are to operate through or in connection with, or by or on behalf of, the person or otherwise), or</li> </ul> </li> </ul> </li> </ul>



Term	Definition
	<p>(v) insofar as it relates to the carrying on of the business of providing a health service:</p> <ul style="list-style-type: none"> <li>(I) employs one or more persons,</li> <li>(II) enters into a contract for services with one or more persons,</li> <li>(III) enters into an agency contract for the assignment of an agency worker, or</li> <li>(IV) enters into an arrangement with one or more persons, in respect of the carrying on of that business, or</li> </ul> <p>(b) a health practitioner who, or a partnership which, provides a health service and does not provide that health service for, or on behalf of, or through or in connection with (whether by reason of employment or otherwise), a person referred to in paragraph (a) and includes a health practitioner who, or a partnership which;</p> <ul style="list-style-type: none"> <li>(i) employs another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner or the partnership) by that other health practitioner of a health service,</li> <li>(ii) enters into a contract for services with another health practitioner for the provision (whether for, or on behalf of, the first-mentioned health practitioner or the partnership) by that other health practitioner, of a health service,</li> <li>(iii) enters into an agency contract for the assignment, by an employment agency, of an agency health practitioner to provide a health service for, or on behalf of, the first-mentioned health practitioner or the partnership, or</li> <li>(iv) insofar as it relates to the carrying on of the business of providing a health service; <ul style="list-style-type: none"> <li>(I) employs one or more persons,</li> <li>(II) enters into a contract for services with one or more persons,</li> <li>(III) enters into an agency contract for the assignment of an agency worker, or</li> <li>(IV) enters into an arrangement with one or more persons, in respect of the carrying on of that business;</li> </ul> </li> </ul> <p><i>(Civil Liability Amendment Act 2017 p.19)</i></p>
<b>Human Factors</b>	An understanding of human limitations, designing the workplace and the equipment healthcare providers use to allow for variability in humans and human performance.
<b>Incident</b>	<p>An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service user complaints which are associated with harm.</p> <p>Incidents can be clinical or non-clinical and include incidents associated with harm to:</p> <ul style="list-style-type: none"> <li>■ patients, service users, staff and visitors</li> <li>■ the attainment of HSE objectives</li> <li>■ ICT systems</li> <li>■ data security e.g. data protection breaches</li> <li>■ the environment</li> </ul> <p>See also definition of a Patient Safety Incident.</p>

Term	Definition
<b>Incident Review</b>	Incident review involves a structured analysis and is conducted using best practice methods, to determine what happened, how it happened, why it happened, and whether there are learning points for the service, wider organisation, or nationally.
<b>Incident type</b>	A descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features.
<b>Incidental Findings</b>	Issue(s) that arose in the process of delivering and managing health services identified during the course of a review which the reviewers consider did not impact on the outcomes but which serve to identify issues for system improvement e.g. issues relating to documentation, communications etc.
<b>Integrated Risk Management</b>	A continuous proactive and systematic process to understand, manage and communicate risk from an organisation-wide perspective.
<b>Just Culture</b>	Just culture refers to a values based supportive model of shared accountability.
<b>Local Accountable Officer</b>	This is the local manager who is responsible for the service in which the incident occurred e.g. ADON, Person In Charge, Business Manager, Clinical Lead.
<b>Look Back Review</b>	Review where a number of people may have been exposed to a specific hazard in order to identify if any of those exposed have been harmed and how to take care of them.
<b>Monitoring</b>	Systematic process of gathering information and tracking change over time. Monitoring provides a verification of progress towards achievement of objectives and goals.
<b>National Incident Management System (NIMS)</b>	The National Incident Management System, hosted by the State Claims Agency, is a highly secure web-based database which facilitates direct reporting of adverse events by State authorities and healthcare enterprises; it is the single designated system for reporting of all incidents in the public healthcare system i.e. for HSE and HSE funded services.
<b>National Incident Reporting Form</b>	The <a href="#">National Incident Report Form (NIRF)</a> was developed by the State Claims Agency in conjunction with all stakeholders including the HSE and voluntary hospitals. Use of a NIRF assures the accuracy of data and clarity of information being reported. There are four forms in total; Person, Property, Crash/Collision and Dangerous Occurrences/Reportable Circumstance i.e. Dangerous Occurrences/Reportable Circumstances.
<b>Near Miss</b>	An incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user.  <i>(National Standards for the Conduct of Reviews of Patient Safety Incidents)</i>

Term	Definition
<b>No Harm Incident</b>	An incident occurs which reaches the service user but results in no injury to the service user. Harm is avoided by chance or because of mitigating circumstances.
<b>Open Disclosure</b>	Open disclosure is defined as an open, consistent, compassionate and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents. It includes expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to on-going care and treatment, learning and the steps being taken by the health services provider to try to prevent a recurrence of the incident. (HSE 2019)
<b>Patient Safety</b>	The term used nationally and internationally to describe the freedom from unnecessary harm or potential harm associated with healthcare services and the reduction of risk of unnecessary harm to an acceptable minimum (World Health Organisation, 2009). Where the term patient is used to describe 'patient safety incident', 'quality and patient safety committees' or 'patient safety data', it is intended to encompass all definitions of people who use health (including mental health) care services e.g. service users in both acute and community health care settings.
<b>Patient safety incident</b>	<p>A patient safety incident, in relation to the provision of a health service to a patient by a health services provider, means "an incident which occurs during the course of the provision of a health service" which:</p> <ul style="list-style-type: none"> <li>(a) has caused an unintended or unanticipated injury, or harm, to the Patient</li> <li>(b) did not result in actual injury or harm to the patient but was one which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm or</li> <li>(c) unanticipated or unintended injury or harm to the patient was prevented, either by "timely intervention or by chance", but the incident was one which the health services provider has reasonable grounds for believing could have resulted in injury or harm, if not prevented.</li> </ul> <p>(Civil Liability Amendment Act 2017)</p> <p>Therefore a patient safety incident includes harm events, no harm events and near miss events.</p>
<b>Patient safety data</b>	The broad and heterogeneous information that includes, but is not limited to, the description of incidents with medical errors or near misses, their causes, the follow-up corrective actions, interventions that reduce future risk, and patient safety hazards.
<b>Person</b>	This refers to individual people e.g. service users, patients, members of staff, carers, relevant person(s) and visitors.
<b>Person Affected</b>	This refers to individual people e.g. service users, patients, employees, carers, relevant persons and visitors that may be affected as a consequence of an incident occurring. Persons can be affected either directly or indirectly.

Term	Definition
<b>Protected Disclosure</b>	Protected Disclosure describes a procedure where staff members have reasonable grounds for believing that the health or welfare of patients/clients or the public may be put at risk, or where there is waste of public funds or legal obligations are not being met, can report these so that the matter can be investigated. The Protected Disclosures of Information as provided for in the Health Act 2004 (as amended by the Health Act 2007) legislation also provides statutory protection for health service staff from penalisation as a result of making a protected disclosure in accordance with this procedure.
<b>Pseudonymisation</b>	Replacing any identifying characteristics of data with a pseudonym, or, in other words, a value which does not allow the data subject to be directly identified.  <i>Ref. Guidance Note: Guidance on Anonymisation and Pseudonymisation. Data Protection Commission. June 2019.</i>
<b>QPS Advisor</b>	For consistency purposes this term is used throughout the document to refer to the person whose role it is to advise and support a service in relation to their Quality and Patient Safety processes and response. It is noted that the title given to this role can vary between services e.g. Quality & Safety Manager, Quality, Risk and Safety Manager etc.
<b>Relevant Person (previously referred to as Family)</b>	<p>“Relevant person”, in relation to a patient, means a person;</p> <ul style="list-style-type: none"> <li>(a) who is; <ul style="list-style-type: none"> <li>(i) a parent, guardian, son or daughter,</li> <li>(ii) a spouse, or</li> <li>(iii) a civil partner of the patient,</li> </ul> </li> <li>(b) who is cohabiting with the patient</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>(c) whom the patient has nominated in writing to the health services provider as a person to whom clinical information in relation to the patient may be disclosed</li> </ul> <p><i>(Civil Liability (Amendment) Act 2017)</i></p> <p><b>Note:</b> This definition must not be confused with the definition of “relevant person” in the Assisted Decision-Making (Capacity) Act 2015.</p>
<b>Reportable Circumstance</b>	A situation in which there was significant potential for harm, but no incident occurred. <i>(WHO Conceptual Framework for the International Classification for Patient Safety 2009).</i>
<b>Review Commissioner</b>	The person who commissions an incident review. For Category 1 incidents it is the Senior Accountable Officer (SAO) or a person who has a direct reporting relationship to the SAO. For Category 2 incidents it is the Local Accountable Officer.

Term	Definition
<b>Risk</b>	<p>Risk is the effect of uncertainty on objectives. It is measured in terms of consequence and likelihood. In the context of the HSE and its services, it is any condition or circumstance which may impact on the day to day operations. This includes failing to maximise any opportunity that would help the HSE or service meet its objectives.</p> <p><i>(HSE Integrated Risk Management Policy 2017)</i></p> <p><b>Note:</b> in the context of incident management the objective is often service user and staff safety from harm.</p>
<b>Risk Management</b>	Coordinated activities to direct and control an organisation with regard to risk. In the context of patient safety it is primarily concerned with creating and maintaining safe systems of care.
<b>Risk Management Process</b>	The systematic application of management policies, policies and practices to the activities of communicating, consulting, establishing the context, and identifying, analysing, evaluating, treating, monitoring and reviewing risk.
<b>Safety culture</b>	An integrated pattern of individual and organisational behaviour, based upon shared beliefs and values, which continuously seeks to minimise service user harm which may result from the processes of care delivery.
<b>Serious Incident Management Team</b>	A Serious Incident Management Team is a standing group whose role it is to oversee the management of all serious incidents relating to the service. It is also convened following notification of a Category 1 incident. It is chaired by the Senior Accountable Officer (SAO) or a person nominated by the SAO who has a direct reporting relationship to the SAO. Decisions in relation to the review of Category 1 incidents must be made within one working week of notification of the incident to the SAO.
<b>Senior Accountable Officer</b>	In the context of the management of an incident, the Senior Accountable Officer is the person who has ultimate accountability and responsibility for the services within the area where the incident occurred. In a hospital group it would be a person with delegated responsibility for a service and reporting directly to the Hospital Group CEO, e.g. a hospital manager or the person delegated with overall responsibility for the management of a clinical directorate or service, in a CHO it could be the Head of Service and in the case of the NAS, it could be the NAS corporate area manager.
<b>Serious Reportable Event</b>	Serious Reportable Events (SREs) are a defined subset of incidents which are either serious or that should not occur if the available preventative measures have been effectively implemented by healthcare providers. Serious reportable events are mandatorily reportable by services to the Senior Accountable Officer (SAO).

Term	Definition
<b>Service</b>	Please note that the term “service” as used throughout these guidelines refers to services provided by a Health Services Provider (as defined in the CLA 2017).
<b>Service Provider</b>	<p>(External to HSE) Part 7, Section 38 of the Health Act 2004 defines a Service Provider as a person with whom the Executive enters into an arrangement for the provision of a health or personal social service on behalf of the Executive, e.g. Nursing Homes, non-statutory Residential/Respite Homes/Centres etc.</p> <p>38.(1) The Executive may, subject to its available resources and any directions issued by the Minister under section 10, enter, on such terms and conditions as it considers appropriate, into an arrangement with a person for the provision of a health or personal social service by that person on behalf of the Executive.</p> <p>Part 7, Section 39 of the Health Act 2004 refers to any person or anybody that provides or proposes to provide a service similar or ancillary to a service that the Executive may provide, and to whom the Executive has given, or proposes to give, assistance. Assistance is defined in Section 39 as including;</p> <ul style="list-style-type: none"> <li>■ contributing to the expenses incurred by the person or the body.</li> <li>■ permitting the use by the person or the body of premises maintained by the Executive, and where requisite, executing alterations and repairs and supplying furniture and fittings for such premises.</li> <li>■ providing premises (with all requisite furniture and fittings) for use by the body or the person</li> </ul>
<b>Service User</b>	The term “service user” in relation to a health services provider means a person to whom a health service is, or has been, provided.
<b>Service User Designated Support Person</b>	This person is a contact point for the service user/relevant person(s) impacted by an incident. (See <a href="#">IMF Appendix 1 Roles and Responsibilities for Incident Management</a> ).
<b>Staff</b>	<p>(a) a person who:</p> <ul style="list-style-type: none"> <li>(i) has entered into, or works under (or where the employment has ceased, had entered into or worked under), a contract of employment, with the health services provider, or</li> <li>(ii) is (or was) placed for the purpose of vocational training with the health services provider, and</li> </ul> <p>(b) a fixed-term employee of the health services provider, and a reference to an employee, in relation to a health services provider, shall be construed as a reference to an employee employed by that health services provider.</p> <p>In line with the definition of Employee as defined in the <i>(Civil Liability Amendment) Act 2017</i></p>
<b>Staff Liaison Person</b>	This person is a contact point at service delivery level for the staff member involved in an incident. (See <a href="#">IMF Appendix 1 Roles and Responsibilities for Incident Management</a> ).
<b>Statement of Findings</b>	Statements which describe the relationships between the contributing factors and the incident and/or outcome. (See definition of Findings above).

Term	Definition
<b>Suspected Harm Event</b>	A suspected harm event is an incident which is an event or circumstance which could have or did lead to unintended and/or unnecessary harm (WHO).
<b>Systems Analysis</b>	A methodical review of an incident which involves collection of data from the literature, records (general records in the case of non-clinical incidents and healthcare records in the case of clinical incidents), individual interviews with those involved where the incident occurred and analysis of this data to establish the chronology of events that led up to the incident, identifying findings that the reviewers considered had an effect on the eventual harm, the contributory factors, and recommended control actions to address the contributory factors to prevent future harm arising as far as is reasonably practicable. The principles of systems analysis can be applied using a comprehensive, concise or aggregate approach.
<b>The National Treasury Management Agency (NTMA)</b>	The NTMA is a State body which operates with a commercial remit to provide asset and liability management services to Government and is designated as the State Claims Agency when performing the claims and risk management functions delegated to it under the National Treasury Management Agency (Amendment) Act 2000.

## Section 2 Acronyms used in this document

<b>AAR</b>	After Action Review
<b>ADON</b>	Assistant Director of Nursing
<b>CCO</b>	Chief Clinical Officer
<b>CHO</b>	Community Healthcare Organisation
<b>CLEAR</b>	CLEAR is an acronym used to describe the key elements/features that a recommendation should have to support successful implementation i.e. <b>C</b> ase for Change, <b>L</b> earning Orientated, <b>E</b> vidence, <b>A</b> ssign, <b>R</b> eview
<b>HSE</b>	Health Service Executive
<b>HG</b>	Hospital Group
<b>HIQA</b>	Health Information and Quality Authority
<b>HR</b>	Human Resources
<b>HSA</b>	Health and Safety Authority
<b>IMF</b>	Incident Management Framework
<b>LAO</b>	Local Accountable Officer
<b>MHC</b>	Mental Health Commission
<b>NAS</b>	National Ambulance Service
<b>NIMS</b>	National Incident Management System
<b>NIRF</b>	National Incident Reporting Form
<b>PPPGs</b>	Policies, Procedures, Protocols and Guidelines
<b>QPS</b>	Quality and Patient Safety
<b>QRS</b>	Quality Risk and Safety
<b>SAO</b>	Senior Accountable Officer



SCA	State Claims Agency
SIMT	Serious Incident Management Team
SMART	SMART is an acronym used to describe the key elements/features that a recommendation should have to support successful implementation i.e. <b>S</b> pecific, <b>M</b> easurable, <b>A</b> chievable, <b>R</b> easonable/ <b>R</b> ealistic, <b>T</b> ime-bound.
SRE	Serious Reportable Event
TOR	Terms of Reference
YCFF	Yorkshire Contributory Factors Framework

## Section 3 Making decisions about appropriate pathways for review/investigation

The HSE has a number of policies and procedures dealing with issues requiring review/investigation. In order to deal effectively and efficiently with issues requiring review/investigation it is critical that the correct review/investigation process is applied from the outset. A primary consideration for managers is that whilst an issue may be reported to them through one route, the issue outlined may in fact require application of a different process. Examples of this are provided in Box 1 below.

### Box 1.

- An issue raised by a service user through the complaints process relates to clinical judgement and is therefore excluded for examination under Part 9 of the Health Act (2004). Such an issue, if it fits the definition of an incident, may following discussion with the Clinical Director (or equivalent), be appropriately dealt with under the Incident Management Framework.
- An isolated patient safety incident involving a staff member referred into HR that on examination and in discussion with the Clinical Director or QPS Advisor, fits the definition of an incident should be more appropriately dealt with under the Incident Management Framework.
- An allegation of service user abuse may be reported as an incident but should be investigated in the first instance under the relevant legislation and HSE policy e.g. Children First Act 2015 and Trust in Care and where deficiencies have been identified in the systems in place to prevent abuse a systems review as outlined in the IMF should also be considered. The scheduling of this should be decided on a case by case basis taking account of any immediate safety concerns.
- An issue which relates to a risk of harm occurring (but where no incident has occurred) reported via the incident management route as a near miss. These are more appropriately considered as part of the services risk management process.

It is therefore essential for managers to consider, on receipt of an issue requiring review/investigation, what is the most appropriate route for the review/investigation of that issue i.e. in some instances the management route may be different from the reporting route.

A further issue arises in a number of cases in that it may be difficult to assign the issue into one review/investigation route as it might contain elements requiring differing review/investigation approaches to run either concurrently or sequentially. In such cases, decision making should be shared between the respective parties and result in an agreed approach which is consistent with organisational policy and due process. The role of the Review Commissioner(s) of such reviews/investigations is important in providing overall co-ordination and governance to any process being undertaken. Examples of this are provided in Box 2.

### Box 2.

- A complaint is received which has elements that come under Part 9 of the Health Act 2004 but also has elements relating to clinical judgement. In this case the complaints officer should, in line with governance arrangements, consult with the QPS Advisor and Clinical Director and/or relevant service manager to propose an overall approach to the management of the issue. The complaints officer collates all information (including the response/report in relation to the clinical element) and responds to the complainant.

**Note:** Where the management of the complaint involves a commissioned review/investigation it is the responsibility of the Review Commissioner to issue the response to the complainant.

- An isolated patient safety incident involving a staff member is referred to HR, the incident is not obviously a HR issue and therefore the HR manager is reluctant to commence an investigation. The HR manager consults with the QPS Advisor and service manager and based on the known facts and supported by use of the Just Culture Guide, it appears that this event is most likely by definition an incident. It is decided, in the first instance, to review it in line with the Incident Management Framework. It is also agreed that if individual staff issues are identified in the course of the review that require a formal HR response that these will be referred back to HR for management in line with the appropriate HR Procedure.
- An incident form is received by the line manager which outlines an allegation of elder abuse against a staff member. The line manager in line with governance arrangements liaises with the QPS and HR Manager and it is decided that an investigation under Trust in Care will be initiated. It is also agreed that if this investigation identifies issues of a systemic nature e.g. service delivery systems weaknesses with the potential to result in elder abuse opportunities. In such instances a systems review may be also required to ensure these and any other weaknesses are identified and addressed. The scheduling of these processes should be decided on a case by case basis i.e. it is possible to run a systems analysis and a Trust in Care investigation concurrently.
- An incident form is received which identifies a risk relating to over-crowding in ED but does not identify that an incident or near miss occurred to a patient, a member of staff or a member of the public. Though reported on an incident form this event is not an incident. It should therefore be considered as a risk and managed through the risk management process.

## Tips for Managers

1. Screen all issues reported – Just because an issue is reported via a particular process does not mean that it has been considered in the context of the appropriate policy/procedure.
2. Operate a ‘no wrong door’ approach i.e. irrespective of the entry point for the issue ensure that its review/investigation is conducted under the appropriate policy by discussing it with relevant personnel.
3. In cases where there is uncertainty in relation to individual culpability versus systems error, managers are often uncertain whether to deal with the issue of concern by way of a Human Resources or Incident Management response. In such instances, it is often useful to consider use of the Incident Decision Tree to guide discussions and assist decision making.
4. Communicate any change in review/investigation route to the person making the report and the person(s) affected, so that they know who is leading on the management of the issue.
5. Be prepared to co-manage issues which do not clearly fall into one process or another and that may need concurrent reviews/investigations. In such situations, it is the responsibility of the Review Commissioner to ensure that there are clear governance arrangements in place. Agree who is taking the lead role and communicate this to the person reporting the issue and the person affected.
6. Document decisions made – i.e. decision to take the chosen review/investigation pathway

## Summary table setting out the types of incidents/Complaints and Allegations and the primary Policy/Procedure/Guideline/Legislation which governs the management of these<sup>1</sup>

Details of Incident/ Complaint/Allegation	Policy/Procedure, Guideline or legislation to be followed
Complaints which fall under Part 9 of the Health Act 2004	Your Service Your Say Policy and Guidance. (YSYS)
Complaints containing both clinical and non-clinical issues	Manage the non-clinical issues under YSYS. Refer clinical issues back to SAO and Clinical Lead for review. Compile one response to the complainant reflecting the outcome of the review of both the clinical and non-clinical issues.
Incidents (clinical or non-clinical)	Manage in line with the requirements of the HSE Incident Management Framework.
Concerns that a number of people have been exposed to a specific hazard	Look back Review Guideline (2015) – to identify if any of those exposed have been harmed and what needs to be done to take care of them.
Allegations of abuse of a child	Refer to designated liaison person to deal with the complaint in line with the: Children First, National Guidelines for the Protection and Welfare of Children, 2017 and Children First Act 2015.
Allegations of abuse of vulnerable adults including elder abuse	<p>Where the allegation pertains to staff refer to line manager/head of discipline to deal with the complaint in line with some or all of the following:</p> <ul style="list-style-type: none"> <li>■ Trust in Care, Policy for Health Service Employers on upholding the Dignity and Welfare of Patients/Clients and the procedure for managing allegations of abuse against staff members (2005)</li> <li>■ Safeguarding Vulnerable Persons at Risk Policy (2014)</li> </ul> <p>Where the allegation relates to a person who is not a staff member line manager/head of discipline to refer to their CHO Safeguarding and Protection Team.</p>
Concerns made to the Confidential Recipient (CR)	<p>Concerns received by the Confidential Recipient are sent to the relevant CHO Chief Officer for management. Detail of the process can be accessed via the following web-link.</p> <p><a href="https://www2.hse.ie/services/hse-complaints-and-feedback/report-a-concern-about-a-vulnerable-adult-in-care-to-the-confidential-recipient.html">https://www2.hse.ie/services/hse-complaints-and-feedback/report-a-concern-about-a-vulnerable-adult-in-care-to-the-confidential-recipient.html</a></p>

<sup>1</sup> In some instances it may be required to conduct additional reviews/investigations under other legislation or Policies, Procedures, Protocols and Guidelines. Where this is required decisions are required in relation to the primacy and sequencing of these i.e. whether they are carried out concurrently or sequentially.

Details of Incident/ Complaint/Allegation	Policy/Procedure, Guideline or legislation to be followed
Protected Disclosures	The nature of the examination/investigation to be carried out into a Protected Disclosure will generally be determined by the Commissioning Manager and will depend on the content of the disclosure. In some cases more than one form of investigation may be required.
Allegations of Professional Misconduct, Fitness to Practice Issues	Referral to the appropriate Professional Regulatory Body for consideration under the relevant Act e.g. Irish Medical Council, Nursing Midwifery Board of Ireland, Health and Social Care Professionals Council (CORU), Pharmaceutical Society of Ireland etc.
Complaints by staff of inappropriate behaviour of other staff at work	<ul style="list-style-type: none"> <li>■ Safety Health and Welfare at Work Act 2005</li> <li>■ Grievance and Disciplinary Procedures for the Health Service (2004)</li> <li>■ Dignity at Work Policy for Health Services (2009)</li> </ul>
Complaints about bullying and harassment made against staff	<p>Head of Discipline/HR to deal with complaint in line with some or all of the following:</p> <ul style="list-style-type: none"> <li>■ Dignity at Work Policy for Health Services (2009)</li> <li>■ Grievance and Disciplinary Procedures for the Health Services (2004)</li> </ul>
Complaints against the HR/ Recruitment process	Utilise the appeal processes contained in the Recruitment Licenses and Codes of Practice specifically in line with Section 7 and Section 8 of the Codes of Practice.
Complaints in relation to decisions of Freedom of Information internal reviewers	Refer to Consumer Affairs Area Office for further advice on the management of the complaint in line with the Freedom of Information Act 2014.
Complaints in relation to breaches of Data Protection Rights	Notify the Data Protection Commissioner in line with the requirements of the Data Protection Acts 1988-2018 and the General Data Protection Regulation GDPR (2016). Consumer Affairs Area office can be contacted as they can assist services to ensure that proper procedures are put in place immediately to mitigate any harm that might arise as a result of the breach.
Complaints in relation to Environmental Issues	<p>Refer to local Environmental Health Office to deal with the complaint in line with some or all of the following:</p> <ul style="list-style-type: none"> <li>■ Food Safety Authority of Ireland Act 1998</li> <li>■ European Communities (Hygiene of Foodstuffs) Regulations 2006</li> <li>■ Food Hygiene Regulations 1950-1989</li> <li>■ Public Health (Tobacco) Acts 2002 and 2004</li> </ul>
Complaints in relation to Nursing Homes (private)	Refer to the Head of Service, Social Care in the relevant Community Healthcare Organisation to deal with the complaint in line with the Health (Nursing Homes) Act 1990.

Details of Incident/ Complaint/Allegation	Policy/Procedure, Guideline or legislation to be followed
Complaints relating to Pre-School Services	Refer to the relevant Tusla Childcare Manager to deal with the complaint in line with the Childcare (Pre-school Services) Regulations 1996.
Disability Act (Part 2, Assessment of Need and Service Statements)	Refer to the HSE Disability Complaints Officer (Part 2) in line with the Disability Act 2005.
Disability Act (Part 3, Access to Buildings and Services and Sectoral Plans)	Manage in line with Your Service Your Say Policy and Guidance.

## Section 4 Creating a Just Culture

Just culture refers to a values based supportive model of shared accountability. It together with a reporting culture and a learning culture contribute to an organisation's safety culture. The degree to which a safety culture exists significantly impacts on an organisations ability to prevent, report and manage incidents in a way which promotes learning and improvement. Critical to both the reporting and learning culture and ultimately to the existence of a safety culture is the degree to which staff perceive that a just culture exists.



A just culture proposes that individual practitioners should not be held accountable for system failings over which they have no control. In a just culture, staff feel psychologically safe both to report errors and to ask for assistance when faced with an issue beyond their competence. They see these as contributing to both their individual learning and to the development of safer systems for service users.

Whilst a just culture recognises that individual practitioners should not be held accountable for system failings over which they have no control staff also recognise that it does not absolve them of the need to behave responsibly and with professionalism. In contrast to a culture that touts no blame as its governing principle, a just culture does not tolerate conscious disregard of clear risks to service users or professional misconduct, such as falsifying a record, performing professional duties while intoxicated, etc.

Dr. Lucian Leape, a member of the Quality of Health Care in America Committee at the Institute of Medicine and adjunct professor of the Harvard School of Public Health, stated that the single greatest impediment to error prevention in the medical industry is “that we punish people for making mistakes.” Leape (2009) indicated that in the healthcare organisational environment in most hospitals, at least six major changes are required to begin the journey to a culture of safety:

- We need to move from looking at errors as individual failures to realising they are caused by system failures
- We must move from a punitive environment to a just culture
- We must move from secrecy to transparency
- Care must change from being clinician-centered to being patient-centered
- We must move our models of care from reliance on independent, individual performance to interdependent, collaborative, inter-professional teamwork
- Accountability must be universal and reciprocal, not top-down

There is therefore a need to create an environment that encourages staff to speak up whether this involves the reporting of incidents and raising issues that pose a risk to the safety of service users, without fear of reprisal.

A service with a just culture assesses the daily risk inherent in its service and works toward maximum reliability to prevent incidents, relentlessly improving both system design and making it easy for staff to deliver care safely.

Though many services espouse that they have a just culture it is when incidents occur that this is tested at all levels, from the SAO to staff at the front line of care and service delivery. It is therefore critical that the first response of services when an incident occurs is one of 'leaning in' to support those affected with what is called psychological first aid. There should not be an early rush to judgment rather the response should be one of inquiry to better understand, what happened, why it happened and what needs to change to reduce the risk of it happening again.

The 'Just Culture Guide' outlined overleaf aims to support a consistent, constructive evaluation of the actions of staff involved in patient safety incidents.

Its use is not required as a routine part of the incident management process, rather should be used only where the nature of an incident suggests that there may be concern in relation to the actions of an individual staff member. The guide allows for those actions to be examined in a structured way to ensure there is a proportionate response to these.

## A just culture guide

The purpose of the Just Culture Guide is to support a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely.

The actions of staff involved in an incident should not be routinely examined using the Just Culture Guide, but it can be useful if in the course of managing or reviewing an incident there is suggestion of a concern about the actions of an individual. The Just Culture Guide highlights important principles that need to be considered before formal management action is directed towards an individual staff member.

The approach does not seek to diminish the individual accountability of a health care professional, but encourages key decision makers to consider systems and organisational issues in the context of the management of error. Action singling out an individual is rarely appropriate – most patient safety issues have deeper causes and require wider action

The Just Culture Guide can be used by all parties to;

- explain how they will respond to incidents,
- as a reference point for organisational HR and incident reporting policies, and
- as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made.

The Just Culture Guide can be used at any stage in the incident management process. This may be at the time that a patient safety incident is first reported and where it is identified that a staff member involved in the incident may require specific individual support or intervention to work safely. In these circumstances use of the Just Culture Guide may help support decision making around the most appropriate management route for an incident (including review methodology).

It may also be used during the course of the review of a patient safety incident. An example of this might be where it is unclear if the actions of an individual involved in the incident suggest consideration of the need for a formal management action (e.g. training and supervision) or rather if this is an issue that is broader than the individual and should be considered and addressed in the context of the wider systems review being undertaken.



### Summary:

- **A just culture guide** is not a replacement for a review of a patient safety incident. Only a review carried out in line with the IMF can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point in a review, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

The guide comprises an algorithm with accompanying guidelines and poses a series of structured questions about an individual's actions, motives, and behaviour at the time of the incident. These may need to be answered on the balance of probability—i.e., determining the most likely explanation—taking into account the information available at the time, although the importance of pausing to gather data is emphasised.

The questions move through four sequential “tests”. These are:

- Deliberate harm
- Health Test
- Foresight
- Substitution

The Just Culture Guide concludes with a question about significant mitigating circumstances that might indicate consideration of broader issues that may explain what influenced the actions of the individual staff member.

The Just Culture Guide emphasises that the outcome of a particular incident needs to be based on a consideration of individual circumstances. The importance of the manager applying judgment rather than slavishly following the tool is emphasised.

The tool can be used for any employee involved in a patient safety incident, whatever his or her professional group. If new information comes to light during the course of a review, it can be worked through again and may or may not indicate a different outcome.

Start here – Q1. deliberate harm test

1a. Was there any intention to cause harm?

Yes

**Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory body, suspension of staff, and referral to Gardaí and disciplinary processes. Wider review is still needed to understand how and why service users were not protected from the actions of individuals.

END HERE

No, go to the next question – Q2. health test

2a. Are there indications of substance abuse?

Yes

**Recommendation:** Follow **HSE Policy and Procedure on the Management of Intoxicant Misuse**. Wider review is still needed to understand if intoxicant abuse could have been recognised and addressed earlier.

END HERE

2b. Are there indications of physical ill-health?

2c. Are there indications of mental ill-health?

Yes

**Recommendation:** Follow HSE policy for health issues affecting work e.g. [Managing Attendance Policy](#) and [Rehabilitation of employees back to work after injury or illness policy](#), and the need to make a referral to occupational health. Wider review is still needed to understand if health issues could have been recognised and addressed earlier.

END HERE

If No to all go to the next question – Q3. foresight test

3a. Are there agreed protocols/accepted practice in place that applies to the action/omission in question?

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

Yes

**Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident review should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual

END HERE

If Yes to all go to next question – Q4. substitution test

<p>4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?</p> <p>4b. Was the individual missed out when relevant training was provided to their peer group?</p> <p>4c. Did more senior members of the team fail to provide supervision that normally should be provided?</p>	Yes	<p><b>Recommendation:</b> Action singling out the individual is unlikely to be appropriate; the patient safety incident review should indicate the wider actions needed to improve safety for further patients. These actions may include, but not be limited to, the individual.</p>	END HERE
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If No to all go to next question – Q5. Mitigating circumstances

<p>5a. Were there any significant mitigating circumstances?</p>	Yes	<p><b>Recommendation:</b> Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident review should indicate the wider actions needed to improve safety for future service users.</p>	END HERE
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If No

<p><b>Recommendation:</b> Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident review should indicate the wider actions needed to improve safety for future patients.</p>	END HERE
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Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree replicated from Improvement NHS UK

# Section 5 Writing a Personal Recollection of Events – Guidance for Staff

## Introduction

In the context of incident management the main purpose of writing a Personal Recollection of Events is for you to have a contemporaneous record of the events in play at a time of the incident when your recall of these are fresh in your mind. Whilst this is not required for every incident, where an incident results in harm and is likely to be reviewed, the availability of a contemporaneously written recollection of events can be useful to you later.

It is important to ensure that information recorded about the event should be recorded at the time, or as soon afterwards, to produce a chronological and accurate record of events. This is vitally important as it captures the reality of the events within which the event occurred. They represent your best recollection of what happened.

Ideally staff on duty at the time of an incident that causes harm should not await a request to write a recollection of events as it is likely this will be required. It is good practice and advisable to do this even if it is not ultimately required as it provides you with an opportunity to personally reflect on the incident.

From the perspective of a Review Team, the availability of written Personal Recollection of Events from staff is extremely helpful in assisting them to build a picture of the circumstances which pertained at the time of the incident. The availability of Personal Recollection of Events for the incident review may allow the Review Team to limit the number of staff meetings that may be required.

Personal recollections are records relating to what you did and how you felt at the time and should not include subjective information in relation to other persons as you are accountable for the information within. If you wish, you may consult with your staff representative in the preparation of your written recollection.

## Storage and Sharing of Your Personal Recollection of Events

In circumstances where it is advanced or requested, you write a Personal Recollection of Events, it is your responsibility to ensure it is stored appropriately and securely. This is of particular importance if the recollection contains any information relating to individual service users where details of care may be included.

In the event that your Personal Recollection of Events is required to support the conduct of a review you will receive notification from your manager which sets out the reason for the request. If you are at all unclear as to why you are being asked to submit a Personal Recollection of Events, clarify this with your line manager or the person nominated as the Staff Liaison person for the incident.

In such circumstances, your recollection will be kept as part of the incident review file which will be retained by the organisation for 7 years in line with the records retention and FOI requirements.

You should be aware that the Personal Recollection of Events written by you as part of an incident review is not legally protected and may be requested to support further processes e.g. a complaint, an investigation under a HR procedure, or if a legal claim is initiated.

The position in relation to release of written Personal Recollection of events under Freedom of Information and Data Protection legislation is constantly evolving in line with decisions made by the Information Commissioner and all such requests for release will be reviewed and considered on an individual basis. Requests made under this legislation will therefore be assessed balancing what is required to support the public interest versus the right to privacy of the individual.

## Presentation of a written recollection of events

A recollection of events should be written clearly in black ink, if possible typed, on A4 paper.

At the opening of the recollection clear reference must be made to indicate whom or which incident the statement relates to e.g. MRN (if applicable) etc.

The recollection of events must also clearly state:

- Your full name: forename and surname (do not use initials).
- Current job title.
- Area of work.
- Role and place of work at the time of the event.
- The location, time and date of the incident for which the recollection of events relates.
- Who was on duty with you and any other persons present.
- NIMS Reference Number (if available to you).
- The date the recollection of events was recorded.

## Content of a recollection of events

The recollection of events should follow a chronological order and is a clear account of your involvement with the incident/person concerned; the content must be objective, factual and not contain comments or anecdotal matters reported to you by others subsequent to the incident.

It should be confined to your involvement with the service user or incident. It is essential to know the identity of others involved but you must not express opinions or criticise colleagues. (see example Box 1 below)

### Box 1.

*"At 09.35 I requested SN X to put out a cardiac arrest call."* This statement is factual and will enable the Review Team to follow up with SN X in relation to this.

*"At 09.35 I requested SN X to put out a cardiac arrest call and it would appear that she did not make that call."* This statement makes judgement about the actions of SN X. This assertion is at this point hearsay as it at this point is unexplored by the Review Team.

Your recollection of events must not contain any expressions of personal opinion about matters outside your field of expertise. It must not contain hostile, offensive or unnecessarily defensive comments.

The recollection should be written in the first person (e.g. "I saw ...")

The recollection should contain as much detail as you are able to provide and be as accurate as possible with regard to dates and times. If the recollection relates to an incident involving a service user, you may require access to the relevant clinical/care records which can be arranged through your manager or the review team contact.

The recollection should clearly indicate what you can and cannot recollect from memory (if you are unsure on something or can't remember then you can say this). If your recollection of events contains information taken from a record this should be noted in the recollection of events.

Make reference to any policies, procedures and guidelines **relevant to the incident**, that you were aware of at the time of the incident.

If you use abbreviations, ensure the full terminology is given at least once with the abbreviation in brackets following this. It is permissible to use technical terms but you should try and explain these in lay terms wherever possible.

You must sign and date each page of the recollection and indicate at the end of it if there are any enclosures.

A statement must come at the very end of the recollection of events. The wording to use is '*I believe that the information provided in this recollection of events to be true*'.

In summary, confine your written recollection of events to:

- Your involvement with the incident or situation.
- An objective and factual account of the incident.

## Further Advice

Further advice can be sought from a number of sources including:

- Your Departmental Manager.
- Your Trade Union or Professional Organisation.
- Quality and Risk Staff.

## Section 6 Reporting requirements external to the service where the incident occurred

Name of Body	What to report	How to report	Responsible Person
Child and Family Agency – Tusla	Staff who have concerns about a child's safety should discuss these with the Children First Designated Liaison Person in their organisation, or contact their local Child and Family Agency social work department for advice about reporting child protection concerns. Reporting child protection concerns is a statutory requirement since Dec 2017 for some staff.	<p>The Standard Report Form available on the Tusla website should be used when reporting child protection and welfare concerns. <a href="https://www.tusla.ie/children-first/report-a-concern/">https://www.tusla.ie/children-first/report-a-concern/</a></p> <p>If a report is made by telephone, this form should be completed and forwarded subsequently to Tusla</p> <p>If a child is in danger outside office hours you can contact the Gardai</p>	All staff working with children and staff designated as mandatory reporters under the Children First Act 2015
Coroner's Office	<p>The Second Schedule of the Coroners (Amendment) Act 2019 list the 25 instances in which death must be reported to the Coroner.</p> <p>These are also listed on the Coroners Service Website <a href="http://www.coroners.ie/">http://www.coroners.ie/</a></p>	<p>Directly to the relevant Coroner</p> <p>Each County has a designated Coroner(s) and these are listed on the Coroners Service Website <a href="http://coroner.ie/en/cor/pages/coronercontactdetails">http://coroner.ie/en/cor/pages/coronercontactdetails</a></p>	Doctors, and every person in charge of an institution or premises where the person who died was residing at the time of death have to inform the Coroner
Data Protection Commissioner	All incidents of loss of control of personal data in manual or electronic form by a data controller must be reported to the Data Protection Commissioner within 72 hours of the data controller becoming aware of the incident. Certain breaches relating to the loss of personal data must be notified to the Data Protection Commissioner. <a href="https://www.hse.ie/eng/services/publications/pp/ict/data-protection-breach-management-policy.pdf">https://www.hse.ie/eng/services/publications/pp/ict/data-protection-breach-management-policy.pdf</a>	By completion of a Data Breach Incident Form submitted to the Consumer Affairs Area Office (or equivalent) in the area where the breach occurred <a href="http://hsenet.hse.ie/GDPR/Data_breach_incident_reporting_form.pdf">http://hsenet.hse.ie/GDPR/Data_breach_incident_reporting_form.pdf</a>	The local Manager in the area where the breach occurred

Name of Body	What to report	How to report	Responsible Person
Garda Síochána	Events of an allegedly criminal nature involving staff or child protection concerns.	Directly to the local garda station	Senior Site/Service Manager
Health and Safety Authority	<ol style="list-style-type: none"> <li>1. The death of an employee/ other person if this is as a result of an accident at work or occurs within the workplace.</li> <li>2. The injury of any employee as a result of an accident while at work where the injury results in the employee being unable to carry out their normal work for more than three consecutive days, excluding the day of the accident.</li> <li>3. The injury of a person involved in an incident/accident within the workplace who dies or sustains injuries requiring medical treatment.</li> <li>4. Where an employee dies as a result of an accident at work within one year of that accident, even if you had already reported the accident.</li> <li>5. Designated incidents described as Dangerous Occurrences as listed by the HSA.</li> </ol> <p>For further information in relation to the above consult the HSA Website. <a href="http://www.hsa.ie/eng/Publications_and_Forms/Publications/Safety_and_Health_Management/Accident_and_Dangerous_Occurrences_Reporting.pdf">http://www.hsa.ie/eng/Publications_and_Forms/Publications/Safety_and_Health_Management/Accident_and_Dangerous_Occurrences_Reporting.pdf</a></p>	<p>IR1 form for items 1-4 and IR3 form for item 5</p> <p>Both forms available on-line from <a href="https://www.hsa.ie/eng/">https://www.hsa.ie/eng/</a></p> <p>Incident can also be reported to the HSA via their online reporting system. <a href="https://webapps.hsa.ie/Account/Login?ReturnUrl=%2f">https://webapps.hsa.ie/Account/Login?ReturnUrl=%2f</a></p>	Senior Site/Service Manager



Name of Body	What to report	How to report	Responsible Person
Health Information and Quality Authority – Disability Services	Residential Services for Persons with a Disability. There is a statutory requirement to notify certain prescribed incidents, events, or changes within registered centres to HIQA. Details of these can be found on <a href="https://www.hiqa.ie/guidance-providers/disability-services/notification-forms-dcd">https://www.hiqa.ie/guidance-providers/disability-services/notification-forms-dcd</a>	By email using the appropriate notification form, or  Via the on-line provider portal <a href="https://www.hiqa.ie/guidance-providers/provider-portal">https://www.hiqa.ie/guidance-providers/provider-portal</a>	The registered provider or person in charge of the designated centre
Health Information and Quality Authority – Older Persons	Residential Services for Older Persons. There is a statutory requirement to notify certain prescribed incidents, events, or changes within registered centres to HIQA. Details of these can be found on <a href="https://www.hiqa.ie/guidance-providers/older-peoples-services/notification-forms-dcop">https://www.hiqa.ie/guidance-providers/older-peoples-services/notification-forms-dcop</a>	By email using the appropriate notification form, or  Via the on-line provider portal <a href="https://www.hiqa.ie/guidance-providers/provider-portal">https://www.hiqa.ie/guidance-providers/provider-portal</a>	The registered provider or person in charge of the designated centre
Health Information and Quality Authority – Ionising Radiation Acute and Community Services	Acute and Community Services under the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019, undertakings have responsibility to submit statutory notifications to HIQA. Guidance on reporting requirements can be found on <a href="https://www.hiqa.ie/sites/default/files/2019-10/Guidance-notification-of-significant-events.pdf">https://www.hiqa.ie/sites/default/files/2019-10/Guidance-notification-of-significant-events.pdf</a>	By email using the appropriate notification form, or Via the on-line provider portal <a href="https://www.hiqa.ie/guidance-providers/provider-portal">https://www.hiqa.ie/guidance-providers/provider-portal</a>	Services are legally required to ensure that appropriate arrangements are in place to notify HIQA of significant events within three working days from discovery.
Health Products Regulatory Agency	Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.	Form and on-line reporting available at <a href="https://www.hpra.ie/homepage/medical-devices/safety-information/reporting-safety-issues">https://www.hpra.ie/homepage/medical-devices/safety-information/reporting-safety-issues</a>	Line Manager in whose area the incident occurred

Name of Body	What to report	How to report	Responsible Person
Health Products Regulatory Agency	<p>Incidents involving suspected adverse reactions. Health care professionals (including doctors, dentists, pharmacists, and nurses) are requested to report all suspected adverse reactions to the HPRA.</p> <p>Of particular importance to report are;</p> <ul style="list-style-type: none"> <li>■ All suspected adverse reactions to newly authorised medicinal products, including those subject to additional monitoring, identifiable by an inverted black triangle on the approved product information.</li> <li>■ Serious suspected reactions to established medicines.</li> <li>■ Any suspected increase in the frequency of minor reactions.</li> <li>■ Any suspected teratogenic effects.</li> <li>■ Any suspected reactions associated with the use of vaccines or medicines used in pregnancy.</li> </ul>	<p>Form and on-line reporting available at <a href="https://www.hpra.ie/homepage/about-us/report-an-issue">https://www.hpra.ie/homepage/about-us/report-an-issue</a></p>	Reporting by clinical staff in association with the Chief Pharmacist
Health Products Regulatory Agency	Serious adverse reactions and events (SARE) associated with Tissues and Cells	Form and on-line reporting available at <a href="https://www.hpra.ie/homepage/about-us/report-an-issue">https://www.hpra.ie/homepage/about-us/report-an-issue</a>	Responsible person designated under the legislation in whose area the incident occurred
Health Products Regulatory Agency	Serious adverse reactions and events (SARE) associated with human organs for transplantation.	<p>Downloadable report form available at <a href="https://www.hpra.ie/homepage/about-us/report-an-issue">https://www.hpra.ie/homepage/about-us/report-an-issue</a></p> <p>This form should also be emailed to Organ Donation Transplant Ireland <a href="mailto:odti@hse.ie">odti@hse.ie</a>.</p> <p>For more information see <a href="http://www.hse.ie/eng/about/Who/organdonation/qualityandsafety/">http://www.hse.ie/eng/about/Who/organdonation/qualityandsafety/</a></p>	Responsible person designated under the legislation in whose area the incident occurred

Name of Body	What to report	How to report	Responsible Person
Health Protection Surveillance Centre	Diseases identified by the HPSC as reportable. <a href="http://www.hpsc.ie/NotifiableDiseases/ListofNotifiableDiseases/">http://www.hpsc.ie/NotifiableDiseases/ListofNotifiableDiseases/</a>	Laboratories make their notifications directly via the CIDR reporting system. All other notifications should be made to the MOH/DPH in the local Department of Public Health using the relevant form. <a href="http://www.hpsc.ie/NotifiableDiseases/NotifyingInfectiousDiseases/">http://www.hpsc.ie/NotifiableDiseases/NotifyingInfectiousDiseases/</a>	All medical practitioners, including clinical directors of diagnostic laboratories, are required to notify the Medical Officer of Health (MOH)/ Director of Public Health (DPH) of certain diseases

Name of Body	What to report	How to report	Responsible Person
Maternal Death Enquiry (MDE) Ireland	<ol style="list-style-type: none"> <li>1. Maternal Deaths* which are defined as: "Deaths of women while pregnant or within 42 days of the end of the pregnancy* from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes"</li> <li>2. Direct maternal deaths which are defined as: "Deaths resulting from obstetric complications of the pregnant state (pregnancy, labour and puerperium), from interventions, omissions, incorrect treatment or from a chain of events resulting from any of the above".</li> <li>3. Indirect maternal deaths which are defined as: "Deaths resulting from previous existing disease, or disease that developed during pregnancy and which was not the result of direct obstetric causes, but which was aggravated by the physiological effects of pregnancy".</li> <li>4. Coincidental (Fortuitous) Maternal Deaths which are defined as: "Deaths from unrelated causes which happen to occur in pregnancy or the puerperium".</li> <li>5. Late Maternal Deaths which are defined as: "Deaths occurring between 42 days and one year after abortion, miscarriage or delivery that are the result of Direct or Indirect maternal causes".</li> </ol> <p>* This term includes delivery, ectopic pregnancy, miscarriage or termination of pregnancy.</p>	<p>Maternal Death Notification form available from:</p> <p>Maternal Death Enquiry Ireland office: Coordinator, Maternal Death Enquiry Office, 5th Floor, Cork University Maternity Hospital</p> <p>Wilton, Cork, T12 YE02</p> <p>Tel: 021 4205042</p> <p>E-mail: <a href="mailto:mdeireland@ucc.ie">mdeireland@ucc.ie</a></p>	Identified MDE hospital coordinators

Name of Body	What to report	How to report	Responsible Person
Mental Health Commission	<p>All mental health services are required to report to the Commission of quality and safety notifications relating to deaths, serious reportable events (Notifiable Events), child admissions, summary incident reports and overcapacity.</p> <p>In October 2018, the Commission launched a Comprehensive Information System (CIS) for various regulatory functions in Approved Centres.</p>	<p>Incidents are required to be reported to the Commission through CIS at the following (<a href="#">CIS</a>).</p> <p>The commission has produced Guidance for approved Centres on notifications (available at the following <a href="#">link</a> on the Commission's website) for notifications to be submitted through CIS.</p> <p>Death notifications and serious reportable events from other/ community mental health services, however, are still required to be reported to through the QSN6 form for deaths and the QSN8 form for SREs. (The relevant forms are available on the Mental Health Commission website at the following <a href="#">link</a>).</p>	

Name of Body	What to report	How to report	Responsible Person
National Haemovigilance Office	<p>Incidents relating to severe adverse reactions and events relating to blood component administration.</p> <p>Requirements for Hospital Blood Banks for Reporting Serious Adverse Reactions and Events to the National Haemovigilance Office. A working document is available at this time to assist hospital based haemovigilance staff in the reporting of serious adverse reactions and events to the NHO.</p> <p>Please contact the NHO for a copy of the working document – <a href="mailto:haemovigilance@ibts.ie">haemovigilance@ibts.ie</a></p>	<p>Notifiable to the NHO as soon as possible using the Initial Report Form (IRF). This is available on the NHO website access through <a href="http://www.giveblood.ie">www.giveblood.ie</a> clicking on clinical services tab and choosing National Haemovigilance Office. The NHO also has a Rapid Alert Notification System to be used in rare circumstances to initiate a recall of blood components, or to prevent the issue of the issue of blood components from a donor which may remain in stock. In this case notification is initially made by phone, followed by completion of an IRF. <a href="https://www.giveblood.ie/clinical-services/haemovigilance/reporting_to_the_nho/">https://www.giveblood.ie/clinical-services/haemovigilance/reporting_to_the_nho/</a></p>	Haemovigilance Officer and/or Quality Manager and/or Medical Scientist in Hospital Blood Bank.
National Haemovigilance Office	Serious adverse reactions and events associated with blood and blood components and SD Plasma, as well as serious adverse events associated with some blood-derived medicinal products.	<p>Form available from <a href="https://www.giveblood.ie/clinical-services/haemovigilance/reporting_to_the_nho/">https://www.giveblood.ie/clinical-services/haemovigilance/reporting_to_the_nho/</a></p> <p>For guidance on completion contact 01 432 2825/01 432 2741 or <a href="mailto:haemovigilance@ibts.ie">haemovigilance@ibts.ie</a></p>	Transfusion Surveillance Officer in conjunction with Consultant Haematologist/ Pathologist or Patient's Primary Consultant

Name of Body	What to report	How to report	Responsible Person
National Haemovigilance Office	All near miss events occurring in the Hospital Blood Bank (HBB).	Hospital Blood Bank Near Miss Notification Form  Form available from <a href="https://www.giveblood.ie/clinical-services/haemovigilance/reporting_to_the_nho/">https://www.giveblood.ie/clinical-services/haemovigilance/reporting_to_the_nho/</a>	Transfusion Surveillance Officer in conjunction with Consultant Haematologist/Pathologist or Patient's Primary Consultant
National Perinatal Epidemiology Centre (NPEC)	<p>Perinatal Mortality – All stillbirths, early and late neonatal deaths arising from births within the calendar year.</p> <p>Still births are defined as: “Baby delivered without signs of life from 24 weeks gestation or with a birth weight <math>\geq 500\text{g}</math>”.</p> <p>Early Neonatal Deaths are defined as: “Death of a live born baby occurring within 7 completed days of birth”.</p> <p>Late Neonatal Deaths are defined as “Death of a live born occurring after the 7th day and within 28 completed days of birth”.</p>	Electronic submission via the NPEC Perinatal Mortality online database or by paper format on the Perinatal Death Notification Form available on the NPEC website: <a href="http://www.ucc.ie/en/npec/npec-clinical-audits/">http://www.ucc.ie/en/npec/npec-clinical-audits/</a>	Identified NPEC hospital co-ordinator within maternity units
National Perinatal Epidemiology Centre (NPEC)	Vermont Oxford Network – Any live born infant whose birth weight is from 401 to 1500 grams OR whose gestational age is from 22 weeks 0 days to 29 weeks 6 days.	Electronic submission through Vermont Oxford Network eNiCQ database	Identified NPEC hospital co-ordinator within maternity units

Name of Body	What to report	How to report	Responsible Person
National Perinatal Epidemiology Centre (NPEC)	<p>Severe Maternal Morbidity – Any woman experiencing one of 16 reportable severe morbidities during pregnancy or within 42 days following the pregnancy end.</p> <p>Reportable morbidities are defined in the reference manual and include: major obstetric haemorrhage (<math>\geq 2,500</math> mls), uterine rupture, peripartum hysterectomy, eclampsia, renal or liver dysfunction, pulmonary oedema, acute respiratory dysfunction, pulmonary embolism, cardiac arrest, coma, cerebrovascular event, status epilepticus, septicaemic shock, anaesthetic complications, ICU admission and interventional radiology.</p>	Electronic submission via the NPEC Maternal Morbidity online database or by paper format on the Maternal Morbidity Notification Form available on the NPEC website: <a href="http://www.ucc.ie/en/npec/npec-clinical-audits/">http://www.ucc.ie/en/npec/npec-clinical-audits/</a>	Identified NPEC hospital co-ordinator within maternity units
National Perinatal Epidemiology Centre (NPEC)	Robson Criteria – Classification of all births according to the Robson Ten Classification System.	NPEC paper template – supplied by the NPEC	Identified NPEC hospital co-ordinator within maternity units
National Perinatal Epidemiology Centre (NPEC)	<p>Mid-trimester prolonged rupture of membranes: and delayed interval delivery in premature multiple pregnancy</p> <p>Cases of rupture of membranes occurring between gestations of 12 weeks, 0 days and 23 weeks, 6 days (inclusive) and which is of 24 hours or more in duration.</p> <p>Cases of delayed interval of delivery in premature multiple pregnancies defined as greater than or equal to 12 hours between the delivery of the first baby and the subsequent baby or babies.</p>	NPEC paper template – supplied by the NPEC.	Identified NPEC hospital co-ordinator within maternity units



Name of Body	What to report	How to report	Responsible Person
Office of Environmental Enforcement, Environmental Protection Agency	<p>Radiation incidents to staff or members of the public.</p> <ul style="list-style-type: none"> <li>Any incident involving the unintended exposure of a person arising from a design flaw, incorrect calibration or malfunction of a licensed item.</li> <li>Any incident arising from a diagnostic or therapeutic procedure in which a wrong patient* receives a dose exceeding the dose limits of a member of the public.</li> <li>Any incident in which a foetus receives a dose in excess of 1 mSv as a consequence of the licensee either failing to establish or adhere to appropriate procedures in relation to the determination of possible pregnancy of a patient undergoing either a diagnostic or therapeutic procedure.</li> <li>An inappropriate or unauthorised use of items subject to a licence or registration, such as staff or third parties taking or facilitating examination of themselves or others, without a referral from an approved prescriber or practitioner.</li> <li>The loss, theft or other misappropriation of any radioactive substance, nuclear device or x-ray equipment held by the licensee/registered person.</li> <li>Any incident involving a dose, or suspected dose, in excess of any of the dose limits for members of the public and workers specified in S.I. No. 30 of 2019.</li> <li>Any incident having off site consequences e.g., a release of radioactive material to the environment in excess of the disposal limits prescribed in the licence or by a disposal method other than as prescribed in the licence.</li> </ul>	<p>Contact the EPA, <a href="http://www.epa.ie">www.epa.ie</a></p> <p>Tel. (01) 268 0100</p>	<p>Radiologists in Charge, Radiation Safety Committee and/or relevant local processes</p>

Name of Body	What to report	How to report	Responsible Person
	<ul style="list-style-type: none"> <li>■ Failure of an interlock system, intended to prevent exposure to the operator or members of the public, which leads to the unintended exposure of a person.</li> <li>■ As a general guide, incidents involving workers, members of the public or the environment that are likely to give rise to public concern should always be reported regardless of their radiological significance.</li> </ul>		
Radiological Protection Institute of Ireland	<p>A range of radiological incidents are reportable in accordance with statutory and licensing requirements. These are required to be reported to the RPII within 24 hours from the time it is first realised that an incident has occurred. Full detail of these incidents and how to report them are contained in the Guidelines for Reporting Radiological Incidents to the Radiological Protection Institute of Ireland which can be accessed by the link below.</p> <p><a href="https://www.epa.ie/pubs/advice/radiation/RPII_Guide_Report_Incidents_03.pdf">https://www.epa.ie/pubs/advice/radiation/RPII_Guide_Report_Incidents_03.pdf</a></p>	Incidents may be reported verbally to the RPII which will, following consideration of the circumstances, advise whether formal reporting is required.	Radiologists in Charge, Radiation Safety Committee and/or relevant local processes
State Claims Agency	<p>Personal injuries (including clinical adverse events)</p> <p>Property damage (including motor vehicle)</p> <p><a href="http://stateclaims.ie/contact-us/reporting-events-or-incidents/">http://stateclaims.ie/contact-us/reporting-events-or-incidents/</a></p>	Via NIMS/NIRF	Local QPS/Risk Manager in whose area the incident occurred

# Section 7 Serious Incident Management Team (SIMT)

## Introduction

The SIMT is an important part of the governance arrangements for the management of Category 1 incidents.

The SIMT has two key responsibilities:

1. To meet on a scheduled basis to monitor and gain assurance in relation to the on-going management of all **Category 1** incidents within the service and;
2. To convene on an unscheduled basis and within 5 working days of a **Category 1** incident being notified to the SAO in order to gain assurance in relation to any immediate actions required and to conduct a preliminary assessment to inform the requirement for further review.

SIMTs must be chaired by the SAO in the relevant service area. In Community Healthcare Organisations this would equate to Head of Service whilst in Hospital Groups, depending on the management arrangement in place, the SIMT can either sit at a Hospital site level or at the Group Clinical Directorate level. In the National Ambulance Service this would be at Area level. In National Services, the SIMT is often located at the level of the national service.

At a minimum, the core membership of the SIMT should include nominated members of the executive management team, commonly the SAO (Chair), Clinical Director, Director of Nursing, Director of Midwifery and the QPS Advisor

When convened in response to a newly reported Category 1 incident, SIMT membership may be broadened to take account of the nature of the incident and the speciality in which it occurs e.g. if it relates to obstetrics in a general hospital the Consultant Lead for Obstetrics and Gynaecology may be invited to attend.

Members of the SIMT must be impartial and sufficiently removed from any incident being considered at any meeting of the SIMT. In the rare event a member is conflicted they must declare this and absent themselves from the deliberative and decision making process of the SIMT. Any decision taken by a member to absent themselves from discussion of an incident due to conflict must be recorded in the minutes of the meeting.

## 1. Role of SIMT when meeting on a scheduled basis

The SIMT will meet to review all active **Category 1** incidents. The maintenance of a **Category 1** incident log is useful to assist with this. At this meeting they will consider each active incident in order to;

- agree and monitor the management plan and timeframes for each incident;
- take/recommend action where the timeframes agreed are at risk;
- assure themselves that there is on-going communication with persons affected relevant person(s);
- receive the final draft review reports and consider in the context of the **Governance Approval Process for Finalising the Review Report (IMF Guidance Section 16)** and to recommend (or not) acceptance of the report to the SAO.;
- receive and review the adequacy of action plans developed by services to support the implementation of recommendations pertaining to completed reviews.;
- receive assurance that the action plans are being implemented within agreed timeframes;
- ensure where actions identified that are outside the control of the service that these are appropriately communicated in line with the accountability framework.
- consider how any learning opportunities identified as a result of incidents reviewed can be shared both within their service and with other services;
- Monitor KPIs relating to incidents and report on these as part of the services Performance Monitoring arrangements.

## 2. Role of the SAO and SIMT when notified of a new Category 1 incident

On notification of a new **Category 1** incident, the SAO will move to directly assure themselves in relation to the adequacy of immediate actions taken to manage the incident. They will also make an assessment in relation to the requirement to notify the occurrence of the incident to their line manager.

The SAO will then notify the SIMT of the incident and will convene the SIMT to discuss the incident.

The scheduling of this meeting allows decisions relating to the review of **Category 1** incidents to be made in a timely manner. Ideally this meeting should be convened within **72 hours** of notification of the incident to the SAO and at latest within one working week [5 days]. Depending on the nature of the incident the SAO may decide to convene this meeting earlier.

In order to assist decision making at the SIMT, the SAO on notification of the incident should assign a person, generally the Quality Patient Safety (QPS) Advisor or equivalent, to engage with relevant staff to identify and gather available factual information related to the incident and its immediate management. This person will use the information gathered to complete Part A of the **Preliminary Assessment Form (IMF Guidance – Section 8)**.

Apart from the SIMT's core membership and depending on the nature/subject of the incident it may be decided to invite others to this meeting in order to provide any specialist input that might be required e.g. clinical expertise relating to the incident, health and safety manager/officer etc.

Consideration should be given to also inviting the service user designated support person and the staff liaison person to this meeting. Though not part of the decision making process they will be central to the communication of the decision taken, to relevant stakeholder groups after the meeting.

### (a) At the SIMT Meeting

The role of the SIMT at this meeting is as follows;

1. To receive and consider Part A of the Preliminary Assessment Form completed in respect of the incident.
2. To gain assurance in relation to the immediate actions taken on identification of the incident (Step 2 of the incident management process), specifically the care and support provided to persons affected and the minimisation of risk of further harm to the person affected or others. Where adequate assurance is not provided, they should agree and communicate the need for any further actions that may be required.
3. To ensure that there are formal arrangements in place for on-going communication with persons and/or relevant person(s) affected (service users and staff). The importance of on-going communication and support at this time is critical as this is often the time when it may be perceived that persons affected have been left isolated by the service and are not aware of what is going on.
4. To consider whether the incident should be reviewed in line with the Incident Management Framework or whether referral for review/investigation under an alternate process is indicated. Reference to the **making decisions about appropriate investigation/review pathways guidance (IMF Guidance Section 3)** and the **just culture guide (IMF Guidance Section 4)** may support decision making in this regard.
5. To take a decision in relation to whether or not further review is required and
  - a. Where a decision is made that 'no further review is required' this should be documented along with detail of the rationale supporting this decision, on Part B of the **Preliminary Assessment Form (IMF Guidance – Section 8)**. These decisions must be referred to the relevant Quality and Safety Committee (or equivalent committee) for review where the decision can be ratified or referred back to the SAO.
  - b. Where a decision is made that 'further review is required' under the Incident Management Framework, the SIMT should then move to consider:
    - The level of review (including methodology);
    - The level of independence of the review;
    - The scope of the review, the makeup of the review team;
    - The names of those designated to provide support to persons affected.

6. In the case of multi-incident reviews or where there are other review/investigation processes running concurrently to a planned incident review e.g. a Look-Back Review, the SIMT should have oversight responsibility of these to ensure that each process though separate, can be governed as a whole. Where necessary, the SIMT should also make a recommendation in relation to the scheduling of these processes. **(IMF Guidance Section 3)**. This should be documented and endorsed by the SAO for implementation.
7. To identify the resources required to support the timely conduct of the review and to facilitate the allocation of the required resources.
8. In exceptional circumstances, a decision in relation to review or not to review, may not be reached at the SIMT meeting and it may be decided to defer the decision relating to this pending receipt of further information e.g. a **Healthcare Record Review (IMF Guidance Section 9)**. Arrangements must be made to obtain any information required for decision-making in a timely manner. Relevant parties should be advised of the need to obtain further information prior to a decision being taken. When the information is received the SIMT is reconvened to review this and make the decision.

#### **(b) Following the SIMT meeting**

Where the SAO accepts the recommendation of the SIMT that further review is required, he/she should move to commission and establish the review by developing the Terms of Reference and appointing the Review Team.

Persons affected should be advised of the intention to proceed with a review and:

- the level and approach to the review.
- that their perspective will be taken into account during the review process.
- where staff have not done so already, they should be encouraged to write a copy of their Personal Recollection of Events **(IMF Guidance Section 5)**.
- that any supports required to assist them will be put in place for the duration of the review process.

Where a decision is made that 'no further review is required' the relevant section of Part B of the Preliminary Assessment should be completed and referred to the relevant Quality and Safety Committee for their consideration. In circumstances where the relevant Quality and Safety Committee ratify a decision that 'no further review is required' arrangements should be made to communicate this to persons affected. Enter the decisions made at SIMT on relevant fields on NIMS review screens.

#### **(c) Monitoring Progress of a Review commissioned by the SAO**

The HSE has in place a timeframe of **125 days** for the completion of the review i.e. from date of occurrence of the incident.

To assist in achieving the relevant timeframe, the process for managing the incident should now be included for monitoring at the scheduled SIMT meetings.

## Section 8 Preliminary Assessment Form

**Note:** Guidance in italic font should be deleted on completion.

### Part A – to be completed in advance of the SIMT/Review decision making meeting

#### A. 1. Incident Details

NIMS Reference No:

Date entered on NIMS:

Date of Incident:

Incident Type (brief description)

Date Notified to SAO/LAO

Date of SIMT/Review decision meeting:

Date Report Completed

#### A.2 Background to Incident

*Include detail of:*

*The background to the service user e.g. their health status and reason for admissions/attendance*

*A brief chronology of the events leading up to the incident.*

#### A.3 Actions taken to date

*Include detail of the current status of the service user affected and assurance that the following have been addressed:*

- *The immediate care needs of the service user and that, if required, a plan for further care is in place.*
- *An assessment to identify any immediate actions required to prevent harm to others as a consequence of the incident.*
- *The immediate supports needs of persons affected i.e. service users, -relevant person(s) and staff*
- *Detail of any meetings held with the service user/-relevant person(s)*
- *That Open Disclosure has been initiated or if not that an explanation of why not, is provided.*
- *That a named service user/-relevant person(s) and staff designated support persons have been appointed*
- *Detail of any questions or issues raised by the relevant person(s) that require consideration by the SIMT/Review decision making meeting.*
- *That the incident has been factually documented in the service user's healthcare record.*
- *That any equipment or drugs implicated in the incident have been taken out of service and retained for examination.*
- *That the incident has been reported onto NIMS and to any other bodies/agencies external to the service.*

**A.4 Name and title of Person completing Part A**

## **Part B – Record of Decision (to be completed at the SIMT/ or review decision making meeting)**

### **B.1 Management of Incident to date**

*Based on Part A and discussions at the meeting include here an assessment of the adequacy of actions taken or planned in relation to the incident. Include also details of any further actions required.*

### **B.2 Appropriate Pathway for Review of Incident Reported**

Having considered Part A, is the SIMT/Review decision making meeting satisfied that the Incident Management Framework is the appropriate pathway for the management of this issue? Please select one option below:

☐ Yes ☐ No

If No, please indicate which alternative review/investigation route is most appropriate. (See making decisions about appropriate reviews/investigations pathways guidance – [IMF Guidance Section 3](#))

If Yes, AND it is also decided appropriate to also conduct a review/investigation using an alternative pathway, please document below the alternative pathway and recommendation in relation to scheduling of the two processes.

### **B.3 Information required for decision making in relation to review under the IMF**

Is further information required to assist a decision to review? Please select one option below:

☐ Yes ☐ No

If Yes, please indicate the type of information required

Healthcare Record Review ☐

Other Specify:

#### B.4 Approach to review

Please indicate the decision as to the approach of review to be conducted. Please select one option below:

Comprehensive Review ☐ If Comprehensive Review is selected, proceed to Part C

Concise Review ☐ If Concise Review is selected, proceed to Part C.

No further Review ☐ If No Further Review selected complete Section B.5 and refer to relevant Quality and Safety Committee for completion of B.6.

#### B.5 Sign off of decisions where No Further Review Required

If the decision is NOT to commission a Comprehensive Review or Concise Review, please set out below the reason or rationale for this decision and the evidence upon which it was based,

**Reason:**

Date:

Please outline below, any learning opportunities identified along with the arrangements required to ensure that these inform relevant care or management practice.

#### For Category 1 Incidents Senior Accountable Officer Details

Name:

Signature:

Date:

#### For Category 2 Incidents Local Accountable Officer (LAO) Details

Name:

Signature:

Date:

Decisions where No Further Review required must be:

- Submitted for review and ratification by the relevant Quality and Safety Committee or other equivalent committee
- Communicated to persons affected i.e. service user, relevant person(s) and staff.
- Entered onto NIMS and this should include the reason and rationale for same.

These incidents should be incidents in an Aggregate Review process.



## B.6 No Further Review Required – Ratification of Decision

Ratified by Quality and Safety Committee or equivalent committee Please select one option below:

☐ Yes ☐ No

If No is chosen please outline the reason for this below and submit this form to the SAO/LAO (as appropriate)

**Reason:**

Date:

## Part C – for Incidents where a decision to further Review has been taken, please complete this section.

### C.1 Comprehensive Review

A decision has been taken to commission a Comprehensive Review

☐ Yes ☐ No

Note: The Final Report of the Comprehensive Review must be accepted by the Review Commissioner within 125 days of occurrence of the incident.

### C.2 Concise Review

A decision has been taken to commission a Concise Review

☐ Yes ☐ No

If the decision is to commission a Concise Review, indicate whether this will be by way of any option below. Please select one below:

Multidisciplinary Team Review ☐

Approach to be used (tick appropriate box)

*Systems Analysis* ☐

*After Action Review* ☐

Incident Specific Review Tool ☐

Desktop Review ☐

The Final Report of the Concise Review must be accepted by the Review Commissioner within 125 days of occurrence of the incident.

### C. 3 Level of Independence attaching to the review.

Please select one option below

1. Membership of Team internal to the team/department/NAS Operational Region ☐
2. Membership of Team internal to the service/hospital/NAS Operational Area ☐
3. Membership of Team external to the service/hospital but internal to the CHO/HG/NAS ☐ Corporate Area
4. Membership of Team involve persons external to the CHO/HC/NAS Directorate ☐

### C.4 Scope of the Review

*This should set out the timeframe to be reviewed e.g. from admission to incident occurrence, from referral to incident, from X date to Y date.*

### C. 5 Composition of the Review Team

*Whilst it is not necessary to identify by name members of the Review Team at this stage the composition by title/profession should be listed.*

### C.6 Contacts in relation to the review process

#### **Review Commissioner (SAO – Category 1 Incidents or LAO – Category 2 Incidents)**

Name

Email

Telephone

#### **Service User Designated Support Person**

Name

Email

Telephone

#### **Staff Liaison Person**

Name

Email

Telephone

## Section 9 Healthcare Record Review

In the context of the incident management process it may be necessary to seek an independent expert review of a healthcare record by a person independent of the service for the purpose of providing an opinion in relation to the standard of care provided by the service to a service user. This may be done either:

- To support decision making as to whether a review is required e.g. where though there was a poor outcome for the service user but it is not clear if this resulted from an incident; or
- To support the conduct of a review where an independent expert is required to provide opinion on the timeliness and appropriateness of treatment/care provided by a service to a service user.
- To support the conduct of a review relating to a **Multi-Incident Events (IMF Page 33)**

It is therefore essential that in requesting the Healthcare Record Review, the person being requested to undertake this is clear about the purpose for which the report is being requested.

The focus is to support learning for systems and safety improvement and is not an assessment of the performance of any individual person. This is an important aspect of the request as other requests for independent reports may be made for a variety of other purposes which are not aligned to the Incident Management Framework e.g. to make determinations around the conduct and practice of individual clinicians or as a defence to litigation.

It is also important to note that a healthcare record review is limited to providing an opinion in relation to the standard of care provided by the service to a service user. Where issues with care are identified, it does not provide an analysis of why and what factors contributed to this. This is the purpose of the incident review.

The request for a Healthcare Record Review should therefore set out clearly the purpose and scope of the opinion required. The request must be approved by the SAO and the discharge of any costs associated with a request is the responsibility of the requesting organisation.

Irrespective of the reason for the request, it is essential that the person requested to carry out the review is appropriately qualified to do so and produces a report which provides the requestor with the required information in a structured format.

If the request for a Healthcare Record Review is being made in the context of a commissioned review the Independent Reviewer must also be given the Terms of Reference of the Review.

In order to ensure clarity in relation to the request for a Healthcare Record Review, the following template should be completed and provided to the person to whom the request is being made.

## Template request for an independent healthcare record review in the context of the IMF

**Note:** Guidance in italic font should be deleted on completion.

### Request for the provision of a Healthcare Record Review

**Name of service user to which the healthcare record relates:**

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**Requestor details:**

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#### Background to Request

*Brief description of the case and the concerns which prompted this request. Be clear here about the purpose and scope of the request (see note below)*

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#### Scope of the Request

1. To receive and consider the following documentation relating to the care of [Service User Name] from her/his admission on [dd/mm/yy]-to her/his death/discharge on [dd/mm/yy] (*list the documentation provided below*)
  - [Name of Document 1]
  - [Name of Document 2] etc
2. To consider the following (*you need to consider the specific areas that you want answered by the review e.g.*)
  - a. *to provide an opinion based on their review of the relevant records as to whether the aspects of care delivered that relate to their area of subject expertise were appropriate and/or reasonable in the circumstances,*
  - b. *The questions/concerns raised by the service user/relevant person(s) with the hospital/service and to what extent the care documented in the healthcare record can provide answers in relation to these.*
3. To provide a report to the requestor which sets out (suggested format below)
  - a. *The qualifications, experience and expertise of the reviewer.*
  - b. *The documentation that was made available.*
  - c. *The facts of the case upon which the opinion is given or any assumptions that were made.*
  - d. *The specific questions being asked in 2 above*
  - e. *The answers to each of those questions.*
  - f. *The reasoning that led to those answers.*
  - g. *Any further comments that occur to the reviewer (whether asked or otherwise).*
  - h. *References for other documentation referred to (for example, clinical guidelines, research publications or other documents that support the opinion being tendered which must be produced where it is practicable to do so and where the article is being relied upon by the reviewer).*

**Date:** (dd/mm/yyyy)

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**Note:** This request is being made in the context of the HSE's Incident Management Framework. The purpose of a review conducted in line with the IMF is to understand what happened, why it happened and what learning can be gained in order to minimise the risk of a similar incident occurring in the future. For the purpose of these reviews the actions of individual staff are examined within the context of the overall system.

## Section 10 Approaches to Incident Review

### Introduction

The review process should not be viewed as negative or adversarial; rather services need to move to a position where review is seen as the logical next step for the team in the aftermath of an incident so that they may learn from the incident. Ideally a review of an incident should be seen as part of a services day to day business.

This guidance seeks to set out detail in relation to a range of approaches to review that are endorsed for use within the HSE and HSE funded services. The range of approaches outlined aim to ensure that incident review can be carried out in a manner that is proportional to the individual incident.

**This guidance assumes that as part of the establishment of the review that there was been engagement with persons affected by the incident to include issues such as Open Disclosure (service users/relevant persons), support requirements (service users/relevant persons and staff), advising them of the plan for review and seeking their participation in the process (service users/relevant persons and staff).**

Regardless of the approach to review that is adopted, all commissioned reviews must have clear governance arrangements in place. This is essential for their establishment, for oversight during their conduct, for receipt of the final report and the development and monitoring of action plans required to implement any recommendations made as a consequence of them. Reviews relating to **Category 1** incidents must be commissioned by the SAO of the service within which the incident occurred. **Category 2** incident reviews are in the main commissioned by the LAO but may depending on the nature of the incident be commissioned by the SAO. The review of **Category 3**<sup>2</sup> incidents are the responsibility of the line manager in whose area of responsibility the incident occurs.

The approaches described seek to involve the multidisciplinary team within the service where the incident occurred, both in the analysis of issues which may have contributed to the event and the identification of solutions to improve safety. The involvement of the multidisciplinary team is to be encouraged as it has been shown to increase the understanding of staff in relation to why the incident occurred and consequently to gain their commitment to the implementation of actions that may be required to improve safety and reduce the risk of recurrence.

**Essentially incident review should be something teams do rather than something that is done to teams.**

### Incident Review (levels and approaches)

The HSE's Incident Management Framework identifies three levels of review as follows;

- Level 1: Comprehensive
- Level 2: Concise
- Level 3: Aggregate

Within each level a number of approaches to review are included. These are set out in Table 1 below;

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<sup>2</sup> The review of Category 3 incidents is normally done on an aggregate basis as part of the work of the MDT to inform service improvement and does not require the development of a formal review report.

Table 1.

Level of Review	Approaches to Review	Methodology underpinning approach
Comprehensive	1. Review Team	Systems Analysis
Concise	1. Facilitated Multidisciplinary Team approach 2. Desktop approach 3. Incident Specific Review Tool e.g. Falls and Pressure Ulcers	Systems Analysis or After Action Review (AAR) Systems Analysis Systems Analysis
Aggregate	1. Aggregate approach	Systems Analysis

With the exception of the Facilitated Multidisciplinary Team approach (concise level), which can be carried out using AAR or systems analysis methodology, all other approaches are underpinned by a **systems analysis** methodology ([IMF Guidance Section 13](#)). The use of systems analysis using a variety of approaches as set in Table 1 above enables a proportionate response to incidents of varying impacts and complexity.

Regardless of the approach adopted the focus is on finding out:

- What happened?
- How it happened?
- Why it happened?
- What the service can learn from the incident and the changes the service could make to reduce the risk of future harm arising from similar causes?

Due to its focus on vulnerabilities within the management and delivery of services, systems analysis seeks to identify the causes of incidents and the factors that contributed to these. This in turn allows for the identification of actions which when implemented will serve to reduce the risk of an incident recurring from a similar cause(s). Such an approach has been shown as most effective in improving safety.

This guidance provides services with an overview of each approach.

## Concise Reviews

Concise reviews are most commonly used for **Category 2 incidents** and for incidents of any category for which incident specific concise review tools are available e.g. Service User Falls and Pressure Ulcers.

There are three concise review approaches designated by the HSE:

- Facilitated Multi-Disciplinary Team approach (using systems analysis or After Action Review (AAR))
- Desktop Approach (using system analysis)
- Incident Specific Review Tool e.g. Falls and Pressure Ulcers (using systems analysis)

Unlike Comprehensive Reviews which require commissioning by the SAO, Concise Reviews can be commissioned by the manager of the service in which the incident occurred i.e. the LAO.

In using a concise review approach the Review Commissioner must at a minimum, agree a terms of reference which includes the scope of the review, detail of the person(s) conducting the review and the concise approach to be used.

### 1. Facilitated Multidisciplinary Team Approach

The Facilitated Multidisciplinary Team Approach recognises that incident review should be embedded as part of the normal business process of the multidisciplinary team. The approach engages with all members of the team, including those involved in the incident, in a dynamic problem solving approach in which all team members contribute equally.

The purpose of this approach is to facilitate the team to reach a consensus in relation to what happened and why, and to identify what actions may be required in order to prevent recurrence. The Review Lead should be a person possessing both, knowledge of the approach being applied i.e. systems analysis/After Action Review (AAR) and skills in group facilitation. To be objective this person must be sufficiently independent from the matter under review.

The outcome of the process tends therefore to result in an analysis that is 'owned' by the team and produces recommendations that team members commit to implementing. Its success relies on having a team that are open to meeting to discuss the incident in a collaborative and supportive manner and on good pre-meeting preparation by the agreed facilitator.

#### *Prior to an MDT meeting*

The Review Lead;

- Engages with the service user/relevant person(s) to outline the review process and gain their perspective on the event so that this can form an input into the process.
- Engages with the service manager to identify relevant staff to participate in the meeting and to gain their support in facilitating the attendance of these staff.
- Agrees with the service manager a date, time and suitable venue for the meeting. The time required for the facilitated session is dependent on the complexity of the issue to be reviewed and the number of staff attending but is generally between 1 and 3 hours.
- Ensures that relevant staff has been advised of the plan for review, the scope of the review and the arrangements for the MDT meeting. These staff should, depending on the methodology being used, be provided with the appropriate staff information leaflet i.e. either AAR or Systems Analysis.
- Where possible arrange for a person to be available to act as a scribe to note of key discussion points on a flipchart during the meeting.

**In preparation for MDT meetings that are using a systems analysis approach** the Review Lead ensures that a high level chronology of events is drawn up from available documentation along with any other relevant information e.g. the discussions held with the service user/relevant person(s) and staff. This is then provided on a private and confidential basis to staff scheduled to attend the meeting with a request for them, prior to the meeting to review this and feedback on any areas of inaccuracy. This enables gaps/inaccuracies in the chronology to be addressed and saves time at the meeting.

**In preparation for MDT meetings that are using an AAR approach** the Review Lead whilst not requiring a detailed knowledge of all aspects of the incident should receive a high level briefing from the review commissioner or a person nominated by them.

#### *At the meeting*

At the meeting the Review Lead

- Opens the session by introducing themselves and provides an assurance that this is a safe space for them to discuss and review the incident.
- Asks participants to introduce themselves by name and job title and to explain their role at the time of the event/in the service.
- Introduces the scribe and explain their role i.e. to capture key points to enable the development of a summary report (anonymised in relation to individual staff contributions) of the session and its outcomes.
- Lets them know that the draft report will be circulated to them within a stated time, after the meeting and that they will have two weeks to consider it and come back with any comments and/or factual inaccuracies.
- The Review Lead will then proceed to set the ground rules and ensure all participants indicate their agreement to them. The following ground rules are suggested:
  - Leaving hierarchy at the door – everyone in the room is equal right to be listened to and have their experience heard.
  - Everyone contributes and all contributions are respected.
  - The purpose of the meeting is to learn from the incident under review and is therefore improvement focused.
  - Discussing what happened objectively should not lead to assigning blame.
  - Everyone will have a different perspective to share about the same event.
  - Contributions should reflect what staff factually witnessed or experienced.
  - Respect time pressures but all must be fully present and engaged in the process.
  - Make no assumptions; be open and honest.

**For MDT meetings that are using a systems analysis approach** the aim is, through open discussion and using a systems analysis approach to:

- agree the chronology of events that led up to the incident.
- identify any findings that led to the incident occurring.
- analyse the findings using **relevant tools** to identify, the factors that contributed to the findings, any incidental findings and any areas of good/commendable practice. **(IMF Guidance Section 13)**
- address any questions/queries raised by the relevant person(s) that were not up to that point considered in the review process.
- consider the findings and the factors that contributed to these to identify recommendations that are required to improve safety and reduce the risk of an incident from similar causes occurring in the future.
- identify any learning from the review that can be shared with other services.

**For MDT meetings that are using an AAR approach** the aim is, through open constructive discussion and using the 4 AAR Questions to explore the incident and reach consensus on what happened, why it happened and what can be learned to address the cause and reduce the risk of a recurrence. The four AAR Questions are:

- What did we expect to happen?
- What actually happened?
- Why was there a difference?
- What have we learnt?



- The Review Lead starts the session by asking the first question and works sequentially through all four questions with the group. Encourages individuals to offer their perspectives as the most valuable learning often occurs through understanding the incident from differing perspectives. In some ways it is like getting a 360 degree view of the event.
- When all four questions have been asked to focus the attention of the group on the actions arising from what they have learnt i.e. what needs to change going forward. If possible agree with the group members who will take responsibility for each of the actions.

Irrespective of the approach being used it is important to encourage differing points of view and to acknowledge that these bring balance to the discussion and therefore the outcome. However in circumstances where behaviours are being exhibited that run contrary to the Ground Rules agreed by participants at the outset of the session, it is the role of the Review Lead to identify this and refer the group back to the Ground Rules and the need for them to be observed.

Close the session by thanking all those present for their honest and open participation in the process.

#### *Following the MDT meeting the Review Lead;*

- writes up a draft report (see page 93 for **Systems Analysis Report Template** and page 100 for the **AAR Report Template**).
- circulates the draft report back to the service manager to enable staff participating in the process to review this for factual accuracy and provide feedback.
- prepares a final draft report following consideration of any feedback received from staff
- with the service manager meets with the service user/relevant person(s) to discuss the final draft report and ensure that any issues raised by them have been considered and the outcome of this is reflected in the report.
- Finalises the report and submits it to the review commissioner.
- Arrangements agreed for the implementation of any actions agreed as a consequence of the review and whether there is learning identified that can be shared with other services.

#### *Following receipt of the report (systems analysis or AAR) the Review Commissioner;*

- Meets with the service manager to agree an action plan to implement the recommendations and this is reflected in the service's overall quality improvement plan for monitoring.
- Makes arrangements to share the report with the service user/relevant person(s) and staff.

#### *Strengths and Challenges of using a facilitated MDT approach (systems analysis or AAR)*

##### **Strengths**

- they use structured approaches to reviewing incidents in a way that is proportionate and responsive.
- they support patient safety by identifying how incidents occurred and what actions are required to reduce the risk of recurrence
- they engage with the team in a way which is inclusive, participative and solution focused.
- they assist in developing a culture of inquiry where safety management becomes a priority of the team
- the analysis of the incident and any improvements identified are 'owned' by the team which assists in supporting their implementation.
- the outcome of the process is used to develop a concise review report which can be provided to relevant stakeholders.

##### **Challenges**

- whilst focusing on a timely and proportionate response it may be perceived by service users/ relevant person(s) as not sufficiently independent.
- It may not be suitable for use in services if there is not a positive multidisciplinary team dynamic and an culture of openness to discuss incidents in a constructive manner.

## 2. Desktop approach (using systems analysis)

Application of systems analysis using a desktop approach is used for incidents which have occurred in the significant past where staff who were involved at the time the incident occurred are no longer available to contribute or if available such time has passed to render them reliant on the case notes available.

Where staff are still available they must be advised of the plan to conduct the review and invited to submit a written recollection of events if they wish.

The review will be conducted 'at the desktop' by a reviewer experienced in systems analysis who has been provided with a terms of reference outlining the scope and aims of the review.

In the case of clinical/service user care incidents, consideration should be given to whether an independent Healthcare Record Review of the clinical/care record would, in the context of no direct subject matter involvement, usefully augment the process. Similarly, in the case of non-clinical incidents, depending on the specialist nature of the subject matter under review, consideration should be given to obtaining an expert report to support the reviewer.

Service user/relevant person(s) involvement can be included through the reviewer meeting with the service user/relevant person(s) at the outset of the process to identify key issues that they wish to see addressed. This will also provide the reviewer with the opportunity to outline the process, the limitations on the process posed by the passage of time and the likely timeframe for completion of the review.

Having considered the available information the reviewer will:

- Develop a high level chronology of events that led up to the incident.
- Consider (if requested) the report arising from the independent Healthcare Record Review or other expert report.
- Identify any findings that led to the incident occurring.
- analyse the findings using **relevant tools** to identify, the factors that contributed to the findings, any incidental findings and any areas of good/commendable practice. **(IMF Guidance Section 13)**
- Identify any incidental findings.
- Identify any areas of good/commendable practice.
- Address any questions/queries raised by the service user/relevant person(s) that were not already considered in the review process.
- Identify any recommendations that may be required to improve safety and reduce the risk of an incident from similar causes occurring in the future.
- Consider whether the review findings highlight learning that can be shared with other services.
- Develop a draft concise report using the **Systems Analysis Review Report Template** (see page 93).
- Circulate the draft report in the first instance to any person who provided an independent Healthcare Record Review or other expert reports to ensure that their opinion has been accurately reflected in the report.
- Following this the draft report is circulated for factual accuracy checking-and comment to the relevant service manager, for review by and discussion with, any staff who may have been on duty at the time of the incident occurrence and are still available to the service. This includes all staff members who provided a written recollection of events.
- Following consideration of any feedback received from staff a final draft report is prepared.
- A meeting is held with the service user/relevant person(s) to discuss the report and ensure that any issues raised by them have been considered and the outcome of this reflected in the report.
- The report is finalised and presented to the person who requested the review e.g. the Commissioner.
- Arrangements are made for the Review Commissioner to provide a copy of the report to the service user/relevant person(s)
- The Review Commissioner ensures that an action plan is developed to implement the recommendations and this is reflected in their overall quality improvement plan for monitoring.

### Strengths

- It supports patient safety by identifying the causes of incidents and the factors that contributed to these.
- It identifies areas for quality and safety improvement.
- It results in a written report.

### Challenges

- The analysis is limited by the lack of direct testimony and the passage of time.
- It is dependent on the availability of good records.
- Whilst saving time and effort, the compromises involved in using a desktop approach may limit the review to known risks and that the more subtle causes of the incident or issue aren't detected and therefore aren't corrected.

### 3. Incident Specific Review Tool e.g. Falls and Pressure Ulcers.

These are tools that relate to specific incident types and are particularly useful for **Category 2 incidents**. They take a concise systems analysis approach and apply it to the best practice guideline for a specific area of practice e.g. pressure ulcers or falls. They are developed using a co-design approach involving persons with a subject matter expertise in the area to which they relate and persons with the technical knowledge of systems analysis. Currently, two concise tools are available i.e. pressure ulcers and service user falls. Both can be found on the [HSE website](#).

These tools include a preliminary assessment and decision making process to identify which incidents require review and then provide a standardised concise review process and report template. The tools are designed so that Part A of the preliminary assessment is carried out by a line manager. Part A of the preliminary assessment informs the decision making in relation to whether further review is required (Part B). Completion of Part B and the conduct of a review, if required, are carried out with the support of the local QPS advisor. The review focuses on identifying factors which contributed to the findings in order to identify recommendations to reduce the risk of recurrence.

Each tool contains guidance on its use including the involvement of service users/relevant person(s).

Review Teams should also consider whether the review findings highlight learning that can be shared with other services. If it is considered that such learning is identified the Review Team should reference and describe this in their Review Report.

### Strengths

- It supports patient safety by identifying the causes of incidents and the factors that contributed to these, using the relevant systems analysis tools.
- It provides a consistent approach which can be applied easily to the incident type to which it relates.
- It is quick to apply and results in a timely standardised report.
- The availability of a standardised approach facilitates the aggregate analysis of incidents across the specific incident type.

### Challenges

- Whilst saving time and effort, the compromises involved in using a specific tool may limit review to known risks and that the more subtle causes of the incident or issue aren't detected and therefore aren't corrected.

## Comprehensive Review

A comprehensive review is most commonly used for the review of **Category 1 incidents** and requires commissioning by the SAO. This type of review is carried out by a Review Team using a **systems analysis** methodology.

As the service context within which an incident occurs varies, rather than be prescriptive about the way the review is carried out, the approach outlined below is designed to enable services to conduct a robust and rigorous review in line with the principles upon which the IMF is based. This guidance, therefore, seeks to provide services with a set of core requirements to support the undertaking of a comprehensive review.

The core requirements that must be adhered to when undertaking a comprehensive review are that:

- Open disclosure has been carried out in line with the **HSE Open Disclosure Policy**
- A **SIMT** has been established to gain assurance in relation to any immediate actions required, consider the preliminary assessment and make a decision in relation to the need for further review – **(IMF Guidance Section 7)**
- Where the SIMT identify that further review is required, the SAO commissions this. Commissioning a comprehensive review includes the development of **Terms of Reference** in line with **IMF Guidance Section 11** and the appointment of a Review Team. The membership of the Review Team must include members relevant to the subject matter of the incident and a person who is experienced in the systems analysis process.
- The review process established is conducted in keeping with **fair procedures and natural justice (IMF Guidance Section 12)**
- Engagement with service users/relevant person(s) and staff affected is a feature of the review process from the commissioning of the review until the report is finalised.
- There is a designated support person for both service users/relevant person(s) and staff to keep them informed of the progress of the review and to arrange relevant supports required.

Outlined below are the features of the process to be applied when commissioning and conducting the review.

### Commissioning the Review

#### 1. *Assignment of the SU/Relevant Person(s) Designated Support Person and the Staff Liaison Person*

These persons provide a key link between persons affected and the review process. They should be available to both SU/relevant person(s) and staff affected as soon as possible after the incident and for the entire duration of the review process. Mechanisms will need to be agreed with the Review Commissioner for these persons to gain updates on the review process as it progresses. This is to enable them to keep the SU/relevant person(s) and staff informed of progress and to identify and report on or address any relevant issues that may arise. This may be best achieved by their attendance at the meetings of the SIMT and with direct liaison with the Review Team.

#### 2. *Appointing the Review Team*

Members of the Review Team must be sufficiently independent of the incident and not directly responsible for the management of the service in which the incident occurred e.g. a CNM responsible for the ward in which the incident occurred would be directly responsible for the management of the service but the ADON would not. Selecting Review Team members from within the Hospital Group/CHO/NAS Corporate Area or equivalent can speed up the appointment of the Review Team. However, it may be that, given the nature of the incident or the level of independence agreed by the SIMT as part of its Preliminary Assessment of the incident, that expertise will need to be sourced external to the Hospital Group/CHO/NAS Corporate Area.

It is important to remember that the level of independence required is critically linked to the level of trust that has been established and maintained with the SU/relevant person(s) Relevant Person(s) in the immediate aftermath of the incident. For further guidance on the issue of independence see the **IMF – Page 24** Independence attaching to the Review Process.

The Review Team will be provided with the **Terms of Reference** for the review and be aware of the scope and requirements of the review process. (IMF Guidance Section 11)

### 3. Engaging with SU/relevant person(s)

At the earliest opportunity, the SAO should ensure that there is a formal engagement with the SU/relevant person(s) so as to:

- Check how they are and to advise them of the plan for review and how they can engage with this if they wish.
- Provide them with information on what they can expect of the review process. The Service User Incident Review Information Leaflet provides an outline of this and should be discussed with and provided to the SU/relevant person(s) at this time. This leaflet also facilitates the opportunity to discuss the issue of their consent to both the conduct of the review and the sharing of learning from it. It is important to note that the obtaining of consent is a matter of best practice and any decision by a service user or relevant person not to provide this does not absolve the responsibility of the service to carry out a review if it is in the best interest of the safety of other service users to do so.
- If not already done, to introduce them to their Designated Support Person, to advise them of the role of this person and provide them with their contact details.

Engagement with SU/relevant person(s) at this point provides an opportunity to clarify:

- That the purpose of the review is to understand what happened, how and why it happened and to establish what can be done to reduce the risk of recurrence and make services safer. relevant person(s))
- The limitations of the Review i.e. whilst the Review Team will endeavour to answer questions posed by the SU/relevant person(s), that it may not be possible to find answers to all of the questions posed. For example it may not be possible to answer to a question due to a lack of available evidence.
- That the process is not designed to address issues such as civil litigation or professional regulatory issues. If these are the outcomes desired by the service user/relevant person(s) they should be advised of the alternate routes available for these.

The importance of this engagement with the SU/relevant person(s), within the shortest timeframe possible, cannot be understated as it provides the context for the review and provides an opportunity to be realistic about the SU/relevant person(s) expectations of the process to be undertaken.

Finally the Designated Support Person should also ascertain how and at what frequency the SU/relevant person(s) wish to be kept informed of the progress of the review i.e. telephone call, email, letter. They should also offer to facilitate the arrangement of an opportunity for the SU/relevant person(s) to meet with the Review Team at the outset of the review process.

### 4. Engaging with Staff

It is the responsibility of the Line Manager to:

- Advise relevant staff of the plan for the incident review
- Provide staff with the Systems Analysis Staff Information leaflet
- Inform staff that the Review Team may seek to engage with them to gain their perspective on the incident (see Conducting the Review section below).
- Introduce staff affected by the incident to their Liaison Person. This should be done early in the process to ensure that affected staff are made aware of and offered available supports.
- Request staff, if they have not already done so, to write a **personal recollection of events** so that it is readily available if required by the Review Team. (IMF Guidance Section 5).

### 5. Documentation Request

There are many sources of information that you can use when using a systems approach to review an incident. Your understanding of what happened will be informed by the information that you gather and your subsequent analysis of this. To support the work of the Review Team, the Review Commissioner should request the collation

of all documentation relevant to the issue under review e.g. healthcare records, relevant PPPGs, staff training records, staff rosters, equipment maintenance records, NIRF Form etc.

Consideration may also be given to obtaining a report from NIMS relating to the occurrence of similar incidents/near misses in the service. This may assist in identifying issues of recurrence which may indicate the presence of a systemic issue that may need to be addressed.

## Conducting the review

Though this guidance is set out in a sequential manner it is important to remember that in practice you might have to go back and forth between the steps when gathering and analysing information.

### 1. Engaging with SU/relevant person(s)

Whilst the SU/relevant person(s) will have been engaged with as part of the establishment of the review, a member(s) of the Review Team should also seek to meet with them as one of their first tasks. This meeting will enable the Review Team to listen to the perspective of the SU/relevant person(s) and seek to understand the questions that the SU/relevant person(s) wishes to have the review process answer.

This engagement also provides the Review Team with an opportunity to establish trust whilst re-emphasising the purpose and limitations of the review (see Engaging with service users/relevant person(s), in the section on commissioning the review).

It also provides an opportunity to enquire about how their support needs are being met and to reinforce the role of the SU/relevant person(s) designated Support Person.

Prior to engaging with the service user/relevant person(s) it is important that the Review Team are briefed in relation to the Open Disclosure process undertaken.

### 2. Developing the draft chronology

At this point in the process the Review Team must develop a draft chronology setting out a timeline of events from available documentation and the Review Team's engagement with the SU/relevant person(s).

Because the Review Team will use the draft chronology as a starting point for the analysis of the incident, it is crucial that it includes only the actual facts or processes as they occurred, and not stray into an analysis of what happened or what was supposed to happen.

### 3. Engaging with Staff

The Review Team will need to engage with staff to gain information required to finalise the draft chronology.

The availability to the Review Team of staff **Personal Recollections of Events (IMF Guidance Section 5)** at this point may allow the Review Team to identify key staff to meet with.

Meeting with staff who are familiar with the workplace where the incident occurred but not involved directly in the incident can also be useful in assisting the Review Team to gain an understanding of the normal workflow and environment. A visit to the location where the incident occurred can also assist in understanding the context of and any challenges that might have contributed to the incident.

Meetings with staff involved in the incident should focus on individual staff member's recollection of events. It is essential that from the outset the purpose of these meetings is clarified i.e. to gain an understanding of the detail of the event for the purpose of identifying learning to inform safety improvement. The designated staff support person has a role in ensuring that the purpose of these meetings is communicated appropriately to staff requested to meet.

The Review Team may initially decide on a core number of 'essential' staff to meet i.e. those who know the systems and processes, those who interact with the process and those involved in the incident. From information gained from these meetings the need to meet with other staff not previously identified might be recognised. The Review Team should decide who amongst them will meet with staff and make arrangements

for a note taker so that the member(s) of the Review Team present can focus on the conversation. A copy of any notes taken should be provided to the staff member for review and feedback.

Reviewers should use active listening skills and repetitively stress that the point of the meeting is fact finding and not fault finding. When meeting staff involved in the incident the process should commence by asking the staff member to outline the event from their perspective. The Review Team will demonstrate active listening by repeating back what they have heard or by asking any clarifying questions that may be required.

Whilst in the main meetings with staff are held on an individual basis the Review Team might decide to meet with staff as a group. This is largely dependent on the team's openness to meet as a group and it may not be appropriate in a service where there is a high level of team conflict or where a team which is hierarchical in nature and staff may find it challenging to engage in open discussion. Such a group meeting will require a competent facilitator to overcome any potential barriers for the group.

#### 4. Conducting the analysis

Having gathered and mapped the information required to finalise the chronology, the Review Team can commence the analysis phase of the review.

The Review Team will use the chronology of the incident (what happened), supported by the principles of systems and human factors theory, to understand the circumstances surrounding the incident. This will assist in the identification of the cause(s) of the incident (the findings) and the factors that contributed to these.

During the analysis, the Review Team will consider questions such as, "What discreet events associated with decisions or actions contributed to the incident? and to what extent were these events influenced by situational factors, local working conditions and latent factors?"

The goal is to focus on the interaction between the human and the system, and to look for the factors that influence that interaction. These factors may be related to the equipment, task and work environment, in addition to inherent human characteristics and limitations.

To assist with the analysis of the incident the Review Team will use a number of tools such as Fishbone diagrams, 5 Whys and the Yorkshire Contributory Factors Framework, [\(IMF Guidance Section 13\)](#).

Use of these tools shifts the focus away from individual performance, toward system performance and underlying factors. This will assist the Review Team to clarify its understanding of why the incident happened (findings) and what factors contributed to these thereby ensuring a thorough analysis of the incident.

Findings are expressed as Statements of Findings<sup>3</sup> which describe the relationships between the contributing factors and the incident and/or harm. The statements focus on the contributing factors and should be as specific as possible. The suggested statement format is as follows:

The contributing factor(s), within the context of the incident, increased/decreased the likelihood that this incident would occur.

The following are examples of Statements of Findings.

- No standardised internal process to ensure testing of defibrillators with accompanying documentation decreased the likelihood that the defibrillator would be identified as non-functioning prior to a cardiac arrest.
- The service user's cognitive impairment decreased the likelihood that she would be aware of the risk of leaving the facility.
- Evidence that pressure relieving equipment identified as required in the service user's risk assessment, was not made available in a timely manner increased the likelihood that the service user would develop a pressure ulcer.

Formatting findings in this manner will assist the Review Team with the framings of their recommendations.

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3 Statements of Findings replaces the term Key Causal Factors.



Findings that do not relate to the incident but are identified as areas requiring improvement are referred to as incidental findings. Whilst the review provides an opportunity to identify these as areas requiring improvement it is important to distinguish these from findings that are made arising from factors that contributed to the occurrence of the incident.

Having considered the analysis and in advance of making recommendations, the Review Team may seek through the Review Commissioner to engage with representatives of the service in which the incident occurred. Representatives may include clinical leads, subject matter experts and QPS staff. The goal of the meeting is to present and discuss the draft analysis with a view to, confirming and building consensus with those responsible for the service around what happened and what caused and contributed to the event. Building consensus around the event will enable an understanding not only of the event but also assist in the identification of any changes required to improve safety. Service representatives should be asked what actions or changes may be required of them to reduce the risk of recurrence. Such an approach can assist in gaining the services understanding of and commitment to; implement such changes that may be required when the Review Team makes its recommendations.

At this stage the Review Team are ready to consider any recommendations that may be required to reduce the risk of an incident occurring from similar causes.

## 5. Making Recommendations and Identifying Learning

Any **recommendations** made must link to the analysis of the incident and the findings. Recommendations are therefore focused on addressing any systems weaknesses that contributed to the incident and should not conflict with best practice, national policy or strategy relevant to the service (**IMF Guidance Section 14**).

Recommendations made should relate **only** to the service within which the incident occurred. Where a recommendation is made that relates to the service but outside the control of the service to implement e.g. where there are resource implications, this should be risk assessed and formally notified to the next organisational level via the performance and accountability framework. Responsibility for monitoring the implementation of recommendations sits with the Review Commissioner.

National recommendations cannot generally be made unless consultation has occurred with the key stakeholders at a national level. In circumstances where a national recommendation has been accepted, there must be clear governance structures in place for implementation and monitoring.

Whilst recommendations are in the main limited to the service within which the incident occurred, the Review Team may also identify learning arising from the incident which can be shared more broadly with other services. Such learning should be clearly set out in a separate section of the report. (**IMF Guidance Section 14**)



## 6. Drafting and Finalising the Report

The report should be drafted in line with the IMF **Guidance on Writing Review Reports** which includes report templates. (IMF Guidance Section 15) and finalised in line with the **Governance Approval Process for finalising a review report** (IMF Guidance Section 16).

The report once accepted by the Review Commissioner and shared with persons affected, should be uploaded in PDF format onto NIMS to enable national sharing and learning to be considered.

## 7. Providing the report to service users/relevant person(s) and staff

In the case of service users/relevant person(s), their designated support person should contact them personally to say that the report is finalised and to agree with them the arrangements required to provide them with a copy of the report. It is recommended, particularly in the case of a patient safety incident, that to respond to any clinical issues that may arise, a clinician is present at any meeting with the family.

Provision of the report in person at a meeting offers the service an opportunity to reiterate the apology and to enquire after their well-being and support requirements. The arrangements adopted in relation to this can vary depending on the relationship with the service user/relevant person(s). Where they have been involved in the process and kept up to date with the progress of the review, it is easier.

In relation to the staff, it is also vital that they are advised of the outcome of the review in a manner that is supportive. This will be best enabled where communication has been maintained with staff them since the review commenced.

Whereas staff can be advised of the outcome of the review individually, consideration should be given to holding a meeting to which they are all invited. The report and its findings can be presented to them in the manner of a learning session (slides are a useful way of summarising the report for presentation). Staff can also be provided with a copy of the report. The key to this meeting is to have it future focused and to place emphasis on the next steps, i.e. what is the learning and what are the plans for implementing the recommendations? Give time for discussion so that it is a consultative and inclusive process.

## Aggregate Review of Incidents: Systems Analysis Approach

In addition to individual incident analyses (comprehensive and concise), consideration should be given at departmental/service level to the aggregate analysis of incidents which are not subject to individual review (concise or comprehensive). One practical way of achieving this is by way of a scheduled MDT Incident Review meeting e.g. weekly/monthly.

This meeting is best supported or led by a person with facilitation skills and knowledge of systems analysis. It is recommended that an hour is set aside for the meeting and that it is generally held in the same location and time so that it becomes embedded as part of the normal business of the service e.g. part of the regular meeting of the MDT. Lunchtime meetings are ideal for this.

The purpose of the meeting is to review, on an on-going basis, incidents that do not warrant individual review but where learning can be identified to inform safety improvement.

In preparation for the meeting, the facilitator gathers the incidents reported since the previous meeting so that these can be discussed. A power-point presentation can be prepared setting out the core information relating to each incident – one incident per slide. Incidents to be discussed are presented in a manner that pseudo-anonymises service users and staff.

Using a systems based approach the facilitator leads the group in a discussion in relation to each incident.

The process is designed to assist the team to understand the cause of the incident and the factors which contributed to this rather than to make judgement about the actions of individuals at the sharp end of the incident.

Whilst this process does not result in a written report one member of the team is designated with the task of capturing actions agreed and persons responsible for ensuring implementation of these. An update in relation to actions closed and outstanding from previous meetings can be provided at the conclusion of the meeting.

### Strengths

- Assists teams in taking a proactive approach to reduce the risk of the occurrence of these incidents
- Assists teams to rapidly identify learning required for safety improvement
- Assists in building a culture of patient safety within the team
- Generates within the team an understanding of changes that may be required and assists in gaining their commitment to make these changes

### Challenges

- It requires strong and consistent senior leadership to ensure that there is a sustained commitment to holding the meetings on a scheduled basis
- It requires skilful facilitation to ensure that it remains focused on learning and the group does not rush to judgement or assign blame to individual team members.

## Other ways of applying Aggregate Analysis<sup>4</sup>

Aggregate Analysis can also be applied at an organisational or speciality level by the service to:

- A group of individual incidents that are similar in type and/or origin that may have caused varying degrees of harm (**Category 1**, **Category 2** and **Category 3 incidents**) e.g. service user falls in an older persons' residential setting.
- A group of patients that are impacted by a similar causal or contributing factor(s) e.g. inadequate clinical handover or failure to recognise and respond to clinical deterioration, and who experienced the same harmful incident (to greater or lesser degrees).
- A group of completed comprehensive and/or concise incident review reports.

Common features of any aggregate analysis include:

- Pre-defined theme or scope.
- Involvement of a multidisciplinary team.
- Use of quantitative and qualitative methodologies.

A benefit of aggregate analysis is it has the potential to reveal trends or patterns of causal findings and contributing factors that were not previously perceptible. These analyses can also reveal previous recommended actions that were or were not effective e.g. if despite the implementation of recommendations the frequency or severity of the incident occurring has not improved.

There is no hard and fast rule in relation to the level at which aggregate reviews are commissioned or requested. This depends on the nature of the incidents and their categorisation. It should therefore be decided on a case by case basis.

### Steps in Conducting an Aggregate Review

#### *Preparing for the review*

- Determine the theme and inclusion criteria.
- Gather applicable data.
- If applicable, conduct interviews with the service(s), patients/relevant person(s) and others with knowledge of the incidents and/or care processes involved in the incidents.
- Review literature and obtain expert opinions to collect additional background and contextual information to lend perspective to the analysis.
- Review other reporting and learning systems (such as the Global Patient Safety Alerts) to see if similar incidents have been studied by other organisations.
- Develop the analysis plan, which will include both qualitative and quantitative analysis elements.

#### *Conducting the Review*

- Review the incidents and/or previous comprehensive and concise analyses to look for common trends, patterns and issues. This will include comparing and contrasting timelines, causal and contributory factors and the recommendations from previous incident analyses.
- Process mapping can also be used to support the identification of system weaknesses when conducting an analysis of multiple incidents.
- Note the frequency of system issues or failure in control points and if applicable, recommended actions. This is the quantitative portion of the analysis and will include classifications such as: severity of harm, type of incident, service user diagnosis, etc.

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4 Adapted from the Incident Analysis Collaborating Parties. Canadian Incident Analysis Framework. Edmonton, AB: Canadian Patient Safety Institute; 2012.

- The qualitative analysis involves focusing on the identified causal and contributing factors as well as similarities that may not have been apparent through an individual incident review. Narrative descriptions are particularly helpful for this portion of the review. As common patterns are identified, the team may need to further sub-categorise to clarify trends or issues.
- When a group of comprehensive and/or concise analyses are reviewed, both the causal and contributing factors and the recommended actions may be included in the qualitative analysis.

### *Preparing the report*

- Summarise findings including causal and contributing factors (previously identified or identified as a consequence of the aggregate review) and previously recommended actions that may lead to system improvement. Include any trends, patterns of causal or contributing factors, and any other findings.
- Develop recommended actions that will lead to system improvement, giving consideration to available supporting information, including evidence-based guidelines and leading practices. Identify both short term and long-term strategies for effective recommended actions to reduce risk.
- The findings and contributing factors, trends and themes, recommended actions and their outcomes should flow into and be coordinated with the service's risk management and improvement processes, including processes for communicating and sharing learning.

## Learning from Reviews

Identification and dissemination of lessons learned from incidents is crucial in a patient safety system. Evidence shows that there is no one best way to achieve this and there is a need to consider a multimodal approach to share learning with the variety of relevant stakeholders i.e. from senior managers and clinicians to front-line workers.

Irrespective of the review approach used in the conduct of concise or comprehensive reviews, consideration should be given by Review Teams as to whether the analysis of the review can contribute to learning for other services. If it is considered that there are learning points such as these the Review Team should reference and describe these in their Review Report. From a patient safety and service improvement perspective learning relating to significant systems failures, avoidable harm, unusual events, evidence of excellence or what works well in patient safety practice or processes and recommendations with a strong evidence of improvement can be suitable.

On completion of the review report, services can then decide to complete and circulate the **learning summary template**. This template provides for a summary of the incident and the learning points identified from the review. Local learning summaries can be shared with staff and service users/relevant person(s).

In situations where it is considered that the local learning identified may have application nationally across other hospitals/services consideration should also be given to the submission of the learning summary to National Quality Assurance and Verification (QRS Team). On receipt of a learning summary a service should review and consider whether, in the context of their service, the learning applies and how it might be implemented.

Finally, it is important to recognise that sharing learning alone does not assure improvements in patient safety. Acting on key learning points from incident reviews is an essential part of risk prevention and improving service delivery for service users and staff.

# Section 11 Development of Terms of Reference (TOR) for incident reviews

## Introduction

The purpose of a review is to establish the sequence of facts around the incident in order to determine what happened, why it happened and what actions are required to reduce the risk of recurrence and improve safety through shared learning.

Terms of reference (TOR) form the foundation stone for the commencement of any review. They are the road map to the review and should be distinct and comprehensive. They should clearly and concisely set out the issue under review and the scope of the review as well as the core people, boundaries and methods to be utilised. Defining matters that are in the scope of the review are particularly important in ensuring that the review stays within those bounds. The importance of spending time debating and developing TOR for an adequate and appropriate review should not be underestimated.

The TOR should also seek to include the need to address any key issues or questions raised by the service user/relevant person(s) in the aftermath of the incident.

## Benefits of Terms of Reference

As well as establishing an understanding of what is required and by when, TOR can prevent pitfalls such as scope creep, misunderstandings, unintended breaches of privacy and negative effects on relationships. Sound TOR provide the means by which subjective or biased considerations can be eliminated from the review and also provide an excellent starting point for drafting a review plan.

In the rare event that matters that have been reviewed subsequently move into legal processes, TOR and constituting documents may be subject to significant scrutiny by courts or tribunals. The availability of a well-defined and expressed TOR in conjunction with evidence that the review process applied was in line with these can militate against challenge at a later stage.

## When should Terms of Reference be developed?

When TOR should be developed may depend on the category of the incident and the type of review planned but as a rule of thumb TOR should always be developed for the reviews commissioned by the SAO.

## What should Terms of Reference contain?

The TOR should contain the following elements;

### Introduction

The introduction provides a brief overview of the background to the incident being reviewed e.g. this is the Terms of Reference in relation to *[insert incident type here]* which occurred in *[insert location here]* on *[insert date here]*. It also identifies that that Review will be carried out in line with the HSE's Incident Management Framework and sets out detail of the Review Commissioner.

### Purpose

The purpose of the review details the rationale and sets out what the review is required to examine. It may be described in terms such as:

*"To establish the facts relating to [insert detail of incident type, date of occurrence and to whom it relates here], to identify any findings which caused and factors which contributed these findings and to make recommendations which when implemented would serve to reduce the risk of a similar incident occurring in the future."*

### Scope

The scope sets out the bounds of the review. Determining the scope, or the issues that are to be reviewed, is a critical component of any review. Defining and maintaining a clear understanding of the review's scope, and effectively conveying that to relevant parties, is essential to an effective review. Without a statement of scope, the reviewer/review team may be tempted to take the review into areas that are not necessarily material to the original incident and the review may lose direction.

When determining scope, it is important to cast the net wide enough to ensure that the review elicits all relevant facts. Therefore, the scope should be framed around the central focus of the incident with sufficient breadth to take account of events leading up to it e.g. "from admission of the service user to her death" or "from time of referral to time of diagnosis".

### Membership of the Review Team

This should provide detail of the names and titles of the team and identify the Chair. It may also include a sentence regarding to the ability of the Review Team to engage with the Commissioner to seek access to any additional expertise or advice that might be identified as required to complete the review.

### Objectives

The objectives set out the actions and deliverables required by the review and should contain the following detail:

- The process and methodology to be applied e.g. engaging with the service user/relevant person(s), determining the chronology of events, analysing the incident using a systems approach, determining findings and making recommendations.
- The need to ensure that the review adheres to the principles of natural justice and fair procedures and data protection requirements.
- The preparation of a report to the Review Commissioner providing details of the incident, findings and recommendations. Where a collaborative approach to the development of recommendations is being used (**IMF Guidance Section 13**) consideration may be given to reflecting this here.

### **Timeframe for the completion of the review**

This should include the expected timeframe for completion of the review and also set out the need to advise the Review Commissioner of any issues that might result in a delay to achieving completion within the stated timeframe.

### **Communications during the conduct of the review**

The following should be considered for inclusion;

If during the course of the review, the Review Team identifies any issues of immediate concern these will be escalated for action to the Commissioner.

A service user/relevant person(s) designated support person and Staff Liaison person will be appointed for the purpose of communicating information pertaining to the review to the service user/relevant person/staff member(s) affected by and/or involved in the incident.

Communications queries made by any external party during the conduct of the review will be directed to the Review Commissioner for response.

### **Revisions to the terms of reference**

Whilst it is not desirable, in some limited circumstances there may be a need to amend or modify aspects of the TOR in the course of conducting a review e.g. due to unanticipated events or the availability of new information. The availability of a review/amendment clause may therefore be advisable. If it is decided to include such a clause, then the process attaching should be explicit e.g. following discussion and agreement with the Review Commissioner and that all parties will be informed of the change.

# Section 12 Principles of Natural Justice and Fair Procedures

## Background

The HSE's Incident Management Framework requires managers to consider on receipt of an incident report whether the issue reported is appropriately managed under the IMF or whether an alternate review/investigation process is more appropriate. The HSE's **Guidance on making decisions about appropriate review/investigation pathways (IMF Guidance Section 3)** should be referred to if clarification is required. Use of the **Just Culture Guide (IMF Guidance Section 4)** may also assist managers in making such decisions.

The purpose of an incident review conducted under the IMF is to examine the effectiveness of the systems and processes in place to prevent the incident and identify actions can be taken to reduce the risk of a similar incident occurring in the future. Whilst the actions of individuals are examined in the context of the overall system, the focus of an incident review is to identify learning to inform safety improvement and should not be used as a mechanism to apportion individual blame.

Irrespective of the pathway chosen, there is a common requirement for all reviews/investigations to comply with the principles of natural justice and fair procedures for those participating in the review process.

## What is meant by Natural Justice and Fair Procedures?

Natural justice is legal language for two ancient rules from the Romans who believed that some legal principles were self-evident and did not require a statutory basis.

The first is a rule against bias is known as “nemo iudex in causa sua”. It means that no person can judge a case in which they have an interest. This is why those being asked to conduct a review must be sufficiently removed from the incident i.e. have no direct management responsibility for the area within which the incident occurred. The level of independence required for members of the Review Team will also depend on the seriousness of the matter under review.

“Audi alteram partem” means “hear the other side too”. It is most often used to refer to the principle that no person should be judged without a fair hearing in which each party is given the opportunity to respond to the evidence against them. The principles of natural justice represent the basic requirements of fair procedure.

## What is required to ensure that reviews carried out under the IMF comply with these principles?

Adherence to these principles is ensured by the review:

1. Having a clear **terms of reference (IMF Guidance Section 11)** which set out the matters under review, the scope of the review, membership of the Review Team, Review Commissioner etc.
2. Advising staff involved in the incident of the terms of reference and what is required of their involvement in the process e.g. submitting a personal recollection of events, attending a meeting with members of the Review Team, the right to be accompanied if required to attend the meeting.
3. Advising persons harmed e.g. service user/relevant person(s)/staff of the decision to carry out a review and meeting with them to explain the process, to listen to their perspective and take note of issues that they would like to see the review consider.
4. That staff members participating in or affected by the outcome of the review process will be provided with an opportunity to review the draft report and provide feedback in relation to issues of factual accuracy..
5. That any report arising from the review will be pseudo-anonymised to protect the identity of service users/relevant person(s) and staff.



6. That the service user/relevant person(s) will have an opportunity to consider the draft report and to provide feedback in relation to matters of factual accuracy.
7. That there is a system in place to govern the acceptance of the final report to ensure that it has been developed in line with the terms of reference and carried out in line with fair procedures and natural justice.

Feedback to staff and service users participating in the review process should be a graduated process where participants are provided with the report in the following order:

1. That where there are any issues of criticism (implied or actual) relating to a staff member or where the findings of the review might be seen to adversely affect an individual staff member that, prior to circulation of the draft report to other participants, the staff member:
  - a. be advised of these,
  - b. be provided with detail of the manner these are reflected in the draft report, and
  - c. be provided with an opportunity to refute the finding or to explain or mitigate the criticism.

Based on feedback received any required changes must be made to the draft report prior to circulation to other persons participating in the review. The person must receive feedback on all items raised by them in their feedback, along with reasons for the basis of why these are accepted or rejected. A copy of the amended report should be provided to them with this feedback.

2. The draft report when amended is then provided to all staff, organisations and the service user/relevant person(s) who participated in the review. They are requested to provide feedback on matters of factual accuracy. Issues relating to factual inaccuracy, for which there is evidence, must be changed. Where feedback is received that does not relate to issues of factual accuracy, the Review Team may, having considered this decide, either to make changes to the draft report or leave as is. It is recommended that participants receive a response on all items of their feedback along with an explanation in relation to why these are accepted or rejected.

The following deals in more detail with the key issues of hearings, bias and evidence as they relate to natural justice and due process.

### Hearings – audi alteram partem

- An staff member must know the detail of any adverse findings or criticism (implied or actual) made against them and the evidence in support of those findings.
- They must be allowed an opportunity to present their case and defend themselves with evidence and arguments.

### Bias – nemo iudex in causa sua

- The Review Team must be unbiased throughout the review and when making any findings which may adversely affect a person.
- The Review Team must act without bias in all procedures connected with the making any findings which may adversely affect a person.
- The Review Team must be impartial and must make a decision based on a balanced and considered assessment of the information and evidence without preference for one person over the other.
- The Review Team should avoid conflicts of interest and anything that would appear to be biased.

### Evidence

- Any decision taken by the Review Team must be based upon logical reasons or evidence.
- The Review Team should not base their decisions on gossip, speculation or suspicion.
- The Review Team should be able to show the evidence on which their findings or recommendations are based and if required to provide this to persons referred to in the report.

# Section 13 Systems Analysis Guidance

## Introduction

The HSE Incident Management Framework (2018) sets out three levels of review (comprehensive, concise and aggregate) and the approaches to review available for each level. With the exception of After Action Review<sup>5</sup> (AAR), all approaches to use a systems analysis methodology.

So what is system analysis and how is this beneficial for reviewing incidents? To answer these questions it is important to understand:

- (a) What is a system?
- (b) What is systems thinking?
- (c) How the system and systems thinking relate to patient safety.
- (d) Models explaining systems errors or accidents
- (e) What is systems analysis?

## What is a system?

A system is defined as a set of things working together as parts of a mechanism or an interconnecting network; a complex whole.<sup>6</sup>

Peter Senge defines a system as 'a perceived whole, whose elements hang together because they continually affect each other over time and work towards a common purpose.'<sup>7</sup> According to Senge, life teaches us to be systems thinkers as we are part of systems in all aspects of our lives. On a personal level, families are systems and in our professional lives, the teams and organisations that we work in are systems.

The HSE and HSE funded services are complex organisations or in other words, complex systems where people and technology work together to provide health and social services to the population of Ireland. This system is made up of a diverse range of complex services provided by multi-disciplinary staff and administrative and management functions; these functions 'hang together' to deliver the organisational goals and targets set out in the Corporate Plan and other organisational plans. Elements of the system within the health and social care settings might include:

- Service users: individuals and families who use services.
- Staff members: the people providing the services.
- Services: the separate services provided and the individual tasks performed to deliver them.
- Teams: local and national teams where individual staff members work.
- Management: the overall organisational/management structure.
- Equipment: the technology and equipment used to carry out tasks associated with service provision.
- External environment: legislation, regulators, standards, political etc.

## What is systems thinking?

In a world of increasingly complex problems, systems thinking allows us to understand how elements of a system fit together so that we understand how to make changes to improve the system. It is a way of thinking that encourages reflection. Reflection is necessary as it opens people up to thinking together to collaboratively solve any problems. Systems thinking supports us to take a big picture view rather than trying to understand problems individually or in isolation.

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5 An after action review is a facilitated discussion analysing what happened, why and what can be done better.

6 <https://en.oxforddictionaries.com/definition/system>

7 Senge P et al (1994) *The Fifth Discipline Fieldbook* UK, Nicholas Brearley Publishing.

*Systems thinking is a way of thinking about and a language for describing and understanding the forces and interrelationships that shape the behaviour of systems. This discipline helps us to see how to change systems more effectively.<sup>8</sup>*

Systems thinking is useful for:

- Complex problems that involve helping people to see the big picture and not just their individual part of it.
- Recurring problems or those that remain unresolved despite past attempts to fix them.
- Issues where an action affects (or is affected by) the environment surrounding the issue
- Problems where solutions aren't obvious.

Using systems thinking allows you to get a better understanding of the real causes of the complex behaviours that occur in systems so you can try to predict them and ultimately adjust their outcomes.

## How the system and systems thinking relate to patient safety

When seeking to make health and social care services safer, a good place to start is by analysing the elements of the system to identify where improvements can be made. A systems view of health care recognises that we need to move from 'silos' to an appreciation that in order to be effective, each element of the system must recognise its dependence or influence on other elements so that the performance of the system as a whole is strengthened. In the same way, individual team members as part of that system must recognise their dependence and influence on other team members.

All the components in systems are interrelated and interact with each other. These complex interactions can lead to positive or negative outcomes. Positive outcomes happen when the system is working well. In a health and social care setting, this might mean that staff are using evidence based approaches and working in line with national policy and legislation to provide services. In turn, service users benefit by living fulfilled lives and being as healthy as they can.<sup>9</sup> However, a negative outcome might mean a particular intervention or approach hasn't worked and this may have consequences for the service user, sometimes fatal consequences. In cases where a reported incident has resulted in a negative outcome, we need to look at the system to see if there are any improvements that we can make to prevent or minimise the risk of further adverse outcomes. Conversely it is also valuable to look at the system where the outcomes are consistently good in order to identify those elements that are critical to that outcome.

Factors in the wider system, often outside the control of the health and social care delivery system, also influence the work and function of these services. These are commonly political, environmental, and sociological factors which influence the manner in which health and social care services are required to operate. Changes in one part of the system can have a positive or negative effect on another part. For example, changes made in the political arena such as budget allocations or legislative change can affect service provision downstream.

## Swiss cheese model of accident causation

A British psychologist, James Reason, developed a model to help explain how incidents or accidents happen from a systems perspective. This model is commonly referred to as the Swiss cheese model.

This model explains that systems have many layers of defence. Some of these are engineered defences (e.g. alarms or physical barriers). Others rely on people and others again depend on procedures and administrative controls. This model proposes that failures, such as patient safety incidents, are rarely caused by isolated errors at the point of care delivery. Instead it is a combination of factors which taken together conspire to create an environment where incidents can occur<sup>10</sup> at the point of acute delivery.

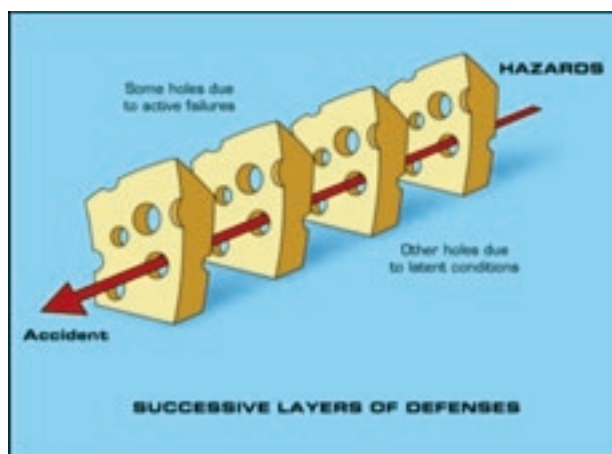
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8 <http://www.thwink.org/sustain/glossary/SystemsThinking.htm>

9 <http://www.hse.ie/eng/services/publications/corporateplan/>

10 See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1298298/> and <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1117770/>.

Figure 2: Swiss cheese model



On the whole, the defences we put in place to prevent incidents occurring are effective. However, in complex systems like healthcare there are always weaknesses which mean that adverse events/incidents will occur. In this model, the weaknesses are depicted as the holes in slices of Swiss cheese. The presence of holes in any one slice does not normally cause a bad outcome but this can happen when the holes in lots of layers line up to allow the opportunity for error.

The holes in defences arise for two reasons: active failures and latent conditions. Active failures are unsafe acts (e.g. mistakes, slips, deviation from policy) carried out by people who are in direct contact with service users – people at the ‘sharp end’ of the system. For example, this might be the nurse who gave the patient the incorrect drug or the surgeon who performed the wrong procedure.

On the other hand, latent conditions are underlying factors or organisational influences which contribute to error. These are at the blunt end and refer to the many layers of the health system that don’t have direct contact with service users. They can include policy makers, management and manufacturers of equipment or technology and other people and forces which affect how health and social care services are delivered. According to Reason, latent conditions can include time pressures, staffing deficits, fatigue, inexperience and poorly maintained equipment.<sup>11</sup> Latent conditions can create long lasting holes or weaknesses in the system increasing the risk of error. They can also lie dormant for a while until they combine with active failures to trigger opportunities for error. Unlike active errors, latent conditions that pose risk can be identified and remedied before an adverse event occurs. Understanding this emphasises the need to adopt a more proactive management of risk.

If we followed an approach to incident review that focuses on the actions of an individual (i.e. person approach to review), we would focus on the person at the sharp end. This approach aims to ‘fix’ the people rather than the system within which they operate. However, this type of approach reinforces a blame culture and fails to address weaknesses in the system that would seek to reduce the risk of a similar incident occurring in the future. The weakness remaining in the system would serve to facilitate similar errors to occur involving other staff members as far from being random; errors tend to fall into recurrent patterns. A useful analogy is to think about road safety and accident black spots. The focus in these situations isn’t on individual cars or drivers rather it is on other measures that need to be put in place. These measures might include prominent signage warning motorists and improvements to the road surface. There may also be national campaigns to reduce speed and ensure all vehicles meet certain safety requirements in an effort to reduce the number of road traffic accidents. In this way there is a whole system of road safety that includes safe roads, safe vehicles and safe road users.

## What is Systems Analysis?

The HSE’s Incident Management Framework defines systems analysis as:

<sup>11</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1117770/>

*A methodical review of an incident which involves collection of data from the literature, records (general records in the case of non-clinical incidents and healthcare records in the case of clinical incidents), individual interviews with those involved where the incident occurred and analysis of this data to establish the chronology of events that led up to the incident, identifying findings that the reviewers considered had an effect on the eventual harm, the contributory factors, and recommended control actions to address the contributory factors to prevent future harm arising as far as is reasonably practicable. The principles of systems analysis can be applied using a comprehensive, concise or aggregate approach.*

A systems analysis approach is useful as it ensures that the system as a whole is reviewed not just the incident in isolation so that all of the factors that contributed to the incident occurring in the first place are established.

A common patient safety incident can illustrate why a systems analysis approach is useful. A recent HIQA report suggests that there could be as many as three million medication errors in Irish public hospitals every year.<sup>12</sup> Giving the wrong drug to a patient can lead to devastating consequences for the service user but also for the staff member concerned. If we respond to this incident by looking at the incident in isolation and telling the nurse who gave the patient the wrong drug to be more careful next time, we won't see what other factors contributed to this error.<sup>13</sup> However, if we expand our view to look at the system rather than just the individual we will be able to see the bigger picture. For example, we will see other contributory factors which might include prescribing or dispensing errors and/or staffing deficits. Conversely in addition to identifying areas relating to systems failures or weaknesses, systems analysis can also identify areas of the system which either did serve to prevent the incident occurring (a near miss) or reduced the impact of the incident when it occurred. The review of the system should therefore not just focus on 'what when wrong' but also 'what went right'. We need to understand a system before we can change it. This 'big picture' thinking is the reason that health care organisations use a systems approach to make services safer.

This guidance has been prepared to support staff undertaking incident reviews using a systems analysis approach. It provides information on systems analysis and aims to help staff to carry out a methodical, systemic review whether a concise, comprehensive or aggregate review approach is being used.

This guidance used in conjunction with the **Approaches to Incident Review** guidance (**IMF Guidance Section 10**) will support the review of incidents by outlining the steps to follow in order to gather information, analyse it and generate recommendations. It will support the review to be systemic by guiding the reviewer to consider all aspects of the system rather than just focusing on the point of occurrence of the incident. This means that the outcome of the review will facilitate systemic improvements rather than focusing solely on the incident or staff member involved.

The use of systems analysis in this way therefore:

- Supports reviewers to look beyond single acts or omissions as immediate reasons for an adverse event and identify the multiple factors or series of events that contributed.
- Is structured and systematic which helps to ensure that reviews are carried out consistently.
- Promotes a Just Culture by creating a climate of openness facilitating systemic improvements rather than assigning blame.

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12 <https://www.hiqa.ie/sites/default/files/2017-02/Guide-Medication-Safety-Monitoring-Programme.pdf>

13 <https://www.ncbi.nlm.nih.gov/pubmed/11442680>

## Tools to assist in the conduct of a systems analysis

### Chronology of Events

Key factual information is collated from a variety of sources including documentation gathered and engagement with key individuals (service user/relevant person(s) and staff) in the form of a chronology of events. It is important that the chronology include only the actual events or processes as they occurred, and not what was supposed to happen.

The chronology simply sets out information relating to the incident in the sequence that the event occurred. It is useful to have a basic chronology prepared from available documentation before engaging with staff so that the Review Team can use the engagement to confirm your understanding of what happened and to address any gaps in the chronology that might exist. As more information is added the chronology will become more detailed with information drawn from a number of sources.

All information presented must be anonymised but can include sufficient detail about staff members such as profession, grade and clinical/care speciality.

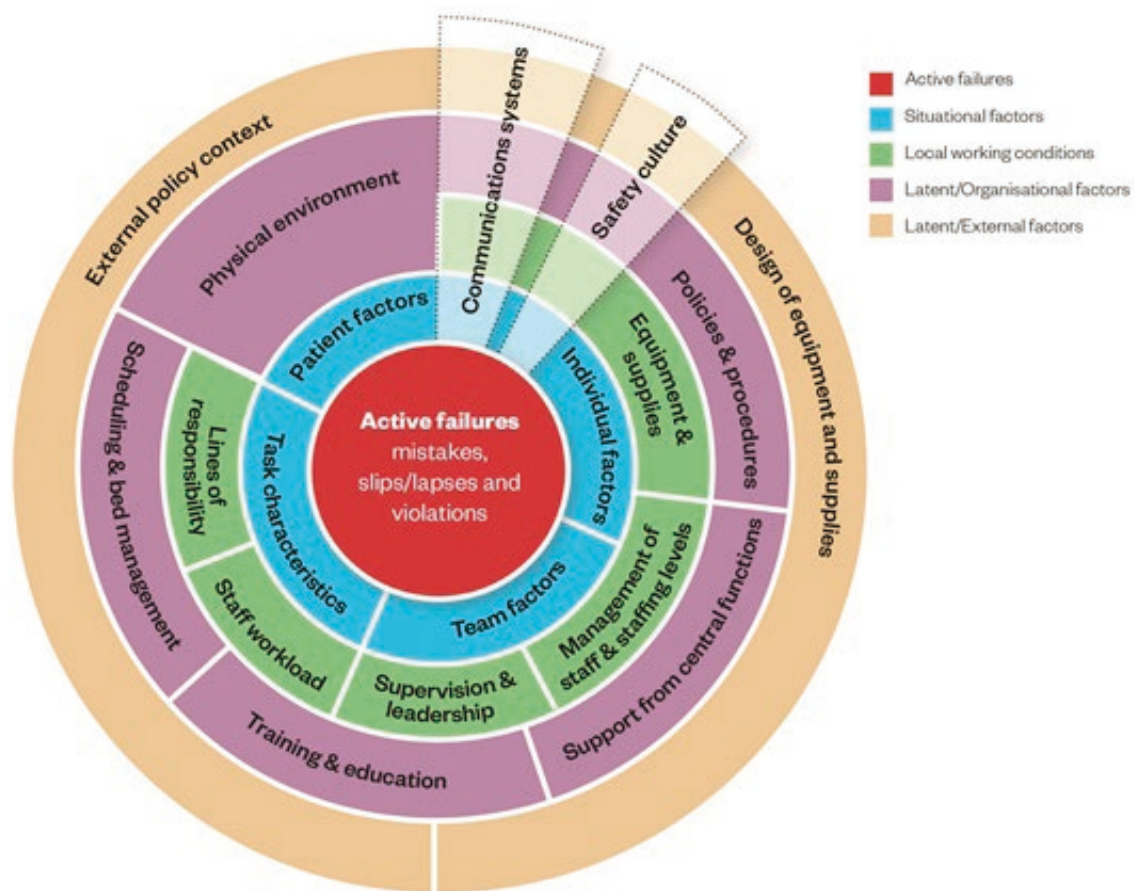
**Table 1: Example of tabular chronology**

Date	Time	What happened?	Source
12 January 2018	14.20	Patient A presented to XX Hospital Emergency Department complaining of shortness of breath.	Medical record.
12 January 2018	14.40	S/he was triaged as serious but stable and allocated to see a doctor within an hour.	Medical record/ engagement with Staff Nurse A

This simple chronology is provided above as an example of how a Review Team can map information relating to the incident. In a complex incident review chronologies can be lengthy but are an invaluable tool to support the subsequent analysis of the incident. The tabular format and inclusion of a 'source' column assists the Review Team to view the timeline and keep a note of where the information was identified from.

In terms of the eventual review report, the chronology included may be reduced to include only the date and time of key events/decision points. In such instances the full chronology should be retained as part of the Review Team records.

## Yorkshire Contributory Factors Framework



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The Yorkshire Contributory Factors Framework (YCFF) is a tool which has an evidence base for optimising learning and addressing causes of patient safety incidents by helping clinicians, risk managers and quality and safety advisors to focus of their review of patient safety incidents on 'systems factors' or 'latent failures' rather than 'active errors'

The YCFF, illustrated above, depicts the contributory factors domains that should be considered when reviewing the active failures (mistakes, slips/lapses and violations) associated with an incident. This diagram helps to illustrate the domains and the extent to which a domain is proximal to the active failure. When reviewing incidents teams often have a tendency to focus primarily on the proximal causes of the incident e.g. active failures and situational factors and less on the working conditions and latent factors and how these influence the occurrence of the incident. Adopting a limited focus on the less proximal factors can lead to a failure to address the underlying issues. It is often these which if left unaddressed that can result in the recurrence of incidents.

The table below provides an outline of what is contained in each of the contributory factor domains.



Contributory Factor Domain	
Situational Factors	These refer to the situation that pertained at the time of the incident and includes such things as team factors (goal alignment, respect, delegation and feedback), individual staff factors (fatigue, stress, distraction and experience), task factors (task familiarity, complexity or repetitive tasks) and service user factors (language barrier, complex, compliance etc).
Local Working Conditions	These refer to the local working conditions at the time the incident occurred and include such things as workload and staffing, leadership and supervision and issues relating to the availability of suitable equipment, devices and medication.
Latent/ Organisational Factors	These refer to the physical environment in which the care is delivered, the support from other departments required to provide care, scheduling and bed management, staff training and education and the availability and workability of relevant PPPGs.
Latent/External Factors	These refer to factors external to the organisation that may influence error e.g. the design of equipment, supplies and drugs or the external policy context which influences the delivery of care.
General Factors	These are illustrated in the diagram above as factors that have an influence across the domains and relate to Safety Culture and Communication Systems (written and verbal).

The underlying aim of this tool is not to ignore individual accountability for unsafe care, but to try to develop a more sophisticated understanding of the factors that cause incidents. These factors can then be addressed through changes in systems, structures and local working conditions. Finding the true causes of patient safety incidents offers an opportunity to address systemic flaws effectively for the benefit of all our future service users.

Though the primary use of the YCFF relates to the review of individual service user incidents, if applied in a standardised way to a group of service user incidents it can assist in the conduct of aggregate analysis to identify common trends and features of groups of incidents of the same type.

To support staff in applying the framework in practice, it has been adapted in the format of a pragmatic two page framework guidance document which suggests a series of questions relating to the contributory factors domains that you might want to ask of those involved in the incident. This document is set out below.

As the contributory factors domains and their related elements identify the areas that should be considered for any type of incident i.e. service user and non-clinical, the YCFF can also be adapted for use in considering non-clinical/care incidents. When doing so the user should consider “examples” for each contributory factor domain and their related elements in the context of the particular incident they are reviewing.



## A Framework for Patient Safety Incident Review Yorkshire Contributory Factors Framework (YCFF)



Prompting Question	Relevant to Incident?	CONTRIBUTORY FACTOR DOMAIN
		Situational Factors
Did the staff involved function as a team?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Team Factors – For example: <ul style="list-style-type: none"> <li>■ Conflicting team goals</li> <li>■ Lack of respect for colleagues</li> <li>■ Poor delegation</li> <li>■ Absence of feedback</li> </ul>
On the day of the incident, how did you feel?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Individual Staff Factors – For example: <ul style="list-style-type: none"> <li>■ Fatigue</li> <li>■ Stress</li> <li>■ Rushed</li> <li>■ Distraction</li> <li>■ Inexperience</li> </ul>
Did the task features make this incident more likely?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Task Characteristics – For example: <ul style="list-style-type: none"> <li>■ Unfamiliar task</li> <li>■ Difficult task</li> <li>■ Monotonous task</li> </ul>
Were there any reasons this incident was more likely to occur to this particular service user?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Service User Factors – for example: <ul style="list-style-type: none"> <li>■ Language barrier</li> <li>■ Uncooperative</li> <li>■ Complex medical history</li> <li>■ Unusual physiology</li> <li>■ Intoxicated</li> </ul>

Prompting Question	Relevant to Incident?	CONTRIBUTORY FACTOR DOMAIN
		Local Working Conditions
Did staff provision match the expected workload around the time of the incident?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Workload and Staffing issues – For example: <ul style="list-style-type: none"> <li>■ High unit workload</li> <li>■ Insufficient staff</li> <li>■ Unable to contact staff</li> <li>■ Staff sickness</li> </ul>
Did everyone understand their role?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Leadership, Supervision and Roles – example: <ul style="list-style-type: none"> <li>■ Inappropriate delegation</li> <li>■ Unclear responsibilities</li> <li>■ Remote supervision</li> </ul>
Were the correct drugs, equipment and supplies available and working properly?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Drugs, Equipment and Supplies – e.g. <ul style="list-style-type: none"> <li>■ Unavailable Drugs</li> <li>■ Equipment not working</li> <li>■ Inadequate maintenance</li> <li>■ No supplies delivery</li> </ul>
		Latent/Organisational Factors
Did the ward environment hinder your work in any way?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Physical Environment – e.g. <ul style="list-style-type: none"> <li>■ Poor layout</li> <li>■ Lack of space</li> <li>■ Excessive noise/heat/cold</li> <li>■ Poor visibility (e.g. position of nurses' station)</li> <li>■ Poor lighting</li> <li>■ Poor access to service user</li> </ul>
Were there any problems from other departments?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Support from other departments This includes support from IT, HR, porters, estates of clinical services such as radiology, phlebotomy, pharmacy, biochemistry, blood bank, physiotherapy, medical or surgical subspecialties, theatres, GP, ambulance etc.
Did any time of bed pressures play a role in the incident?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Scheduling and Bed Management – e.g. <ul style="list-style-type: none"> <li>■ Delay in the provision of care</li> <li>■ Transfer to inappropriate ward</li> <li>■ Difficulties finding a bed</li> <li>■ Lack of out-of-hours support</li> </ul>
Were there any issues with staff skill or knowledge?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Staff Training and Education – e.g. <ul style="list-style-type: none"> <li>■ Inadequate training</li> <li>■ No protected time for teaching</li> <li>■ Training not standardised</li> <li>■ No regular/yearly updates</li> </ul>
Did local policies, protocols and Procedures help or hinder?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Local Policies, Protocols or Procedures – e.g. <ul style="list-style-type: none"> <li>■ No protocol exists</li> <li>■ Protocol too complicated</li> <li>■ Lack of standardisation</li> <li>■ Contradictory policies exist</li> </ul>

Prompting Question	Relevant to Incident?	CONTRIBUTORY FACTOR DOMAIN
		Latent/External Factors
Is there any characteristic about the equipment, disposables or drugs used that was unhelpful?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Design of Equipment, Supplies and Drugs – e.g. <ul style="list-style-type: none"> <li>■ Confusing equipment design</li> <li>■ Equipment not fit for purpose</li> <li>■ Similar drug names</li> <li>■ Ambiguous labelling and packaging</li> </ul>
Have any national policies influenced this incident?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	national policies – e.g. <ul style="list-style-type: none"> <li>■ Commissioned resources</li> <li>■ National Screening Policy</li> <li>■ Interference by government organisations</li> <li>■ National medical/nursing standards</li> <li>■ National Performance Targets</li> </ul>
Prompting Question	Relevant to Incident?	CONTRIBUTORY FACTOR DOMAIN
		General Factors
How would you describe the culture of your clinical/care areas in relation to service user safety?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Safety Culture – e.g. <ul style="list-style-type: none"> <li>■ Service User Safety awareness</li> <li>■ Fear of documenting errors</li> <li>■ Attitude to Risk Management</li> </ul>
Were the notes available, accurate and readable? Did poor or absent verbal communication worsen the situation?	<input type="checkbox"/> Yes <input type="checkbox"/> Maybe <input type="checkbox"/> No	Communication – written and verbal – e.g. <ul style="list-style-type: none"> <li>■ Poor communication between staff</li> <li>■ Handover problems</li> <li>■ Lack of communication/notes</li> <li>■ Unable to read notes</li> <li>■ Inappropriate abbreviations used</li> <li>■ Unable to contact correct staff</li> <li>■ Notes availability</li> </ul>

Acknowledgement: Yorkshire and Humberside Improvement Academy. Creative Commons Bradford Teaching Hospitals NHS Foundation Trust.

## 5 Whys

The use of '5 Whys' can be used in conducting the analysis. '5 Whys' is a simple tool which focuses on repeatedly asking the question 'Why?'

The '5 Whys' tool can help to determine the cause-effect relationships in a problem such as an incident. It can be used whenever the real cause of a problem is not clear. As the most obvious explanation as to why an incident has occurred often does not identify underlying problems, by repeatedly asking the question 'Why?' a Review Team can peel away the layers of issues and symptoms and identify the real cause. The 5 whys however may not be a suitable tool if you need to tackle a complex or critical problem as it can lead you to pursue a single track, or a limited number of tracks, of inquiry when, in fact, there could be multiple causes. Its use therefore should be considered in the context of the complexity of the incident being reviewed.

Start with a statement of the situation and ask why it occurred. Then turn the answer to the first question into a second Why question. The next answer becomes the third Why question and so on. By refusing to be satisfied with each answer the odds of finding the underlying cause of the event increase. Though this technique is called '5-Whys', five is a rule of thumb. You may ask more or less Whys before finding the cause of a problem. Many people start into a 5-Why analysis by using a 5-Why Table as illustrated in Fig X below. With each Why question they put in an answer and then ask the next Why question. This continues until the Review Team agrees the cause is found. It must not be forgotten that an incident can be produced by multiple causes and multiple combinations of causes. If it is considered that there may be multiple causes the tool can be used to explore these too.

## 5 Why Table

**Problem Statement: A service user in an Older Persons residential unit fell on her way to the bathroom at night**

Why Questions	Why Answers (what, when, where, how)	Solution
1. Why did she fall?	Because she tripped over a chair	Check for trip hazards in rooms before bedtime
2. Why didn't she see the chair?	Because her room was dark and there was no nightlight	Ensure functioning nightlights are in all rooms
3. Why was there no nightlight in her room	Because it was not part of her care plan	
4. Why was it not part of her care plan?	Because she was not risk assessed for falls on admission	Routinely audit resident admissions to ensure that they have a falls risk assessment and that required controls identified are put in place.
5. Why did she not have a falls risk assessment on admission?	Because the admitting nurse was new to the service and was not familiar with service policy on falls.	Ensure that induction for all new nurses includes training on admission procedures.

## Fishbone diagrams

These are used to explore and display all the factors that contributed to the cause(s) of an incident (the finding(s)). It is a more structured approach than the Five Whys tool. It can be helpful to use it in conjunction with the YCFF.

A fishbone diagram graphically displays the relationship of the contributory factors to each other and the finding. When complete this type of diagram can help a team focus on where the areas requiring improvement may lie and so assist in identifying evidence-based recommendations that link to the finding.

The finding is displayed at the "head of the fish". Possible contributing causes are listed on the smaller "bones" under various contributory factor domains set out in the YCFF). A fishbone diagram can be helpful by directing the team to look at the domains and think more broadly about the system.

### Directions:

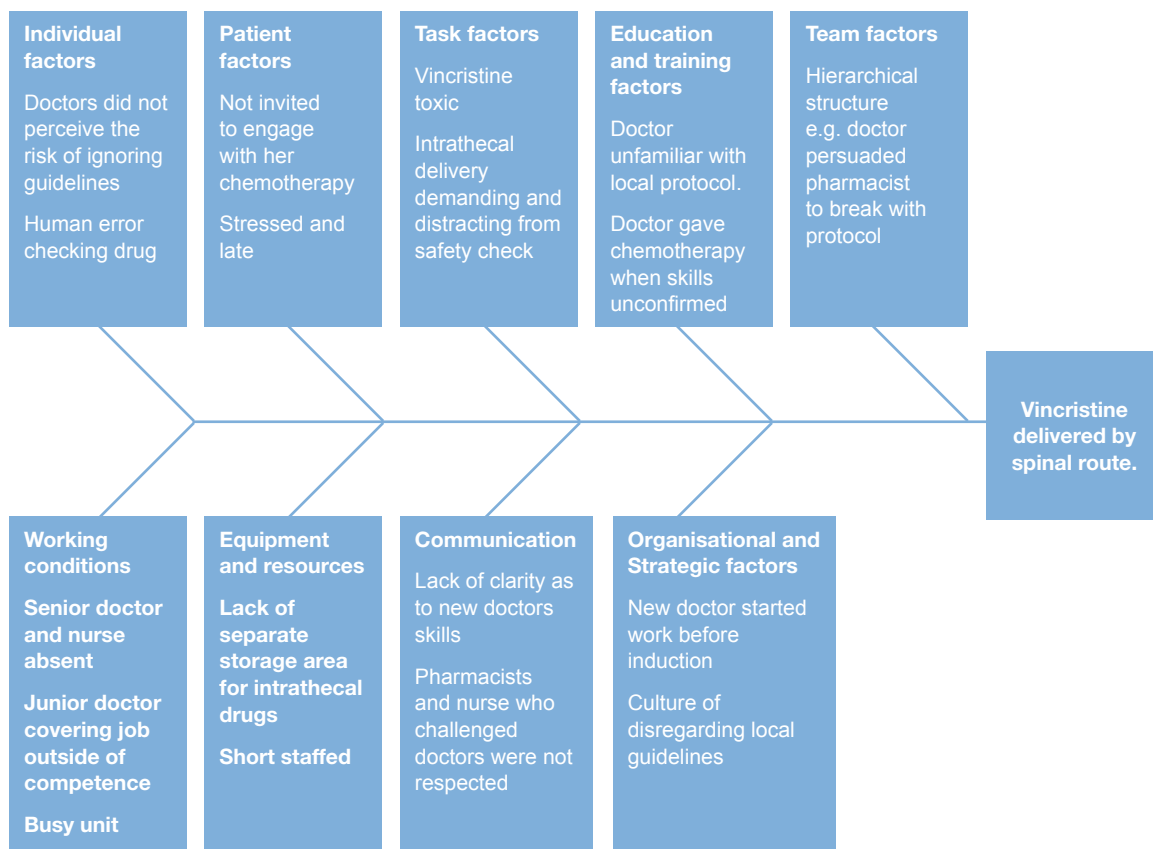
- The team using the fishbone diagram tool should carry out the steps listed below.
- Agree on the finding that you wish to explore (the effect). This is written at the 'head of the fish'.
- Set out the contributory factors domains on the bones of the fish.
- Brainstorm the finding by asking "Why does this happen?" The prompting questions for each contributory factor domain in the YCFF can assist with this. The facilitator writes the answers on the appropriate contributory factor category on the fishbone diagram.
- For each contributory factor identified the question "Why does this happen?" should be asked again. The answers to these questions will assist the Review Team in moving towards the solutions that they may wish to recommend.

### Tips:

- Use the fishbone diagram tool to keep the team focused on the finding, rather than the symptoms. Consider drawing your fish on a flip chart or large dry erase board.
- Make sure to leave enough space between the contributory factor categories on the diagram so that you can write on it or use sticky notes that can be moved if required.
- The "five-whys" technique can be used in conjunction with the fishbone diagram.
- As each category is explored, teams may not always identify problems in each of the categories.

The fishbone diagram illustrated below relates to a finding relating to the delivery of the drug Vincristine through the wrong route and is taken from a WHO teaching resource. It relates to a video case study which can be accessed through the following link.

[https://www.who.int/patientsafety/education/learning\\_from\\_error/en/](https://www.who.int/patientsafety/education/learning_from_error/en/)



## Time Person Grid

A time person grid is a tabular mapping tool that enables you to track the movements of people (staff, service users, visitors, contractors) before, during and after an incident, therefore enabling the Review Team to clarify where all persons were at key points in the incident.

### When to use a Time Person Grid

- You have a number of personnel involved in an incident and you need to ascertain where they were as the incident was occurring (e.g. child abduction, absconson, unexpected clinical emergency, violence and aggression)
- It is particularly useful for short time frames when a lot seems to be going on and many peoples are involved in the delivery of care. This tool enables you to clarify timings and placement of people and identify areas requiring clarification.
- Can be mapped into a timeline to examine a specific time frame in more detail.

It is unlikely that you would use a time person grid for the whole of an incident, unless it is very short e.g. less than 30 minutes.

### How to complete a Time Person grid

- Create a table composed of a number of rows and columns, see below.
- In left hand column list all the staff involved in the incident. Title this column “staff involved” or something similar
- The following column headings should be time stamped e.g. 09:00 hrs, 09:05 hrs, 09:10 hrs etc. These must run for the duration of your incident, or for the period you have decided to analyse using this technique.
- At each point in time, ascertain where each member of staff was e.g. at 09.08 hours the SHO CNM2 and Staff Nurse were all with the service user.

Staff involved	09:02 hrs	09:04 hrs	09:06 hrs	09:08 hrs
SHO	With service user	In Dr’s office	In Dr’s office	With service user
CNM2	At the nurses’ station	At the nurses’ station	With service user	With service user
Staff Nurse	With service user	With service user	With service user	With service user

### Positive Attributes of the Time Person Grid

- Quick and efficient tool to identify where all staff were when events within an incident were happening
- A useful mechanism for identifying where you have data or information gaps
- It maps onto a timeline effectively

### Negative (challenging) Attributes of the Time Person Grid

- It can only be used for short timeframes
- People cannot always remember where they were at specific times, especially if the case did not seem particularly significant to them at the time
- Focuses on individuals

# Section 14 Developing Recommendations

## Introduction

The purpose of conducting a review of an incident is to find out what happened, why it happened and what actions are required to reduce the risk of an incident from similar causes occurring again. This will support improvement(s) both in the area where the incident occurred and enable the sharing of learning in the wider system. It is therefore essential that recommendations made and learning identified as a consequence of the review are presented in a manner that is clear and relate to the findings identified in the analysis. Recommendations made this way flow logically from the findings.

From the service's perspective clear recommendations will assist in ensuring that any consequent action plan developed targets the areas where improvement is identified as required. This in turn will enable and support the process of monitoring implementation of these actions.

It is important to note that recommendations may, in some instances, not be purely confined to factors directly related to the incident being reviewed. Such recommendations may relate to issues identified in the course of the review which indicate areas where service improvement may be required but which the reviewers consider did not impact on the outcome i.e. incidental findings.

## Why make recommendations?

Recommendations are often the medium by which services effect change. They are the result of expert analysis carried out by the Review Team when they are reviewing an incident.

Recommendations represent the best course of action in a given situation and are made so that HSE and HSE funded services put in place actions identified as required following an incident. The monitoring and evaluation of actions required to implement recommendations form the basis for assurance and verification of implementation. This provides assurance for service users/relevant person(s), staff, managers and policy makers. In essence, making and monitoring effective recommendations makes it more likely that safety improvements will be implemented.

## Problems with some recommendations

A retrospective analysis of incident review reports will often indicate a wide variance in both the style and the clarity of recommendations made. Common problems identified include;

### Recommendations that are vague and non-specific

Recommendations in this category are those where there is not an obvious linkage between them and the analysis and findings relating to the event. Such recommendations can be open to misinterpretation and are generally more difficult to develop an action plan for and consequently for a service to provide evidence of implementation. For example, many recommendations do not differentiate between what is to be done and how to do it. This makes it more challenging to identify the action to be taken and how to monitor and evaluate the outcome.

### Recommendations are impractical in nature and out of line with economic, professional and social realities

Recommendations that are aspirational in nature and not grounded in professional, economic and social realities are likely not to be implemented. From a professional perspective recommendations must be based on and reference the evidence or best practice which underpins them.



Whilst not intending that recommendations must be cost neutral or not requiring practice change, cognisance needs to be taken in relation to the realities of the environment that services operate. For example, a recommendation may need to be made that has budgetary implications that will require additional funding. However, such recommendations should be made within the context of discussions with the service to determine if there are alternate ways to achieve the desired outcome and if not they should be considered in the context of future planning and/or the service's risk register.

#### **The quantity and prescriptive nature of recommendations may be counterproductive**

The need to implement a large number of recommendations may prove a significant challenge to many services. This may result in a tendency to focus on the recommendations that might be amenable to implementation in the short term. As a consequence, less focus may be placed on more challenging recommendations which may have the greatest potential to improve safety.

Recommendations that are very prescriptive will require the organisation to address them in a manner that does not take account of the context for implementation. Whilst it may be appropriate to be prescriptive when it relates to compliance with regulatory and statutory requirements, being overly prescriptive can also be counterproductive. Allowing an organisation to decide, within its context, the best way to achieve the outcome desired by the recommendation can foster innovation and increase ownership.

#### **Perceived relevance of recommendations to those responsible for their implementation.**

Commitment to implementation often relates to the degree to which those responsible for implementation understand the relevance of the recommendation and 'buy in' to the need for action. Collaboration with services at the time of developing recommendations can overcome this challenge and could be considered.

#### **Expecting that recommendations made in the context of one service have general application in all services.**

Recommendations made as a consequence of a review should apply primarily to the context within which the incident occurred. Learning from a review however can form a valuable source of information for other services where there may be a risk of a similar incident occurring. It is therefore appropriate for review reports to contain both recommendations for the service where the incident occurred and a short description of learning identified from the review.

Such learning when shared with other services acts as a prompt for them to ask the question; 'What controls (systems and processes) do we have in place to reduce the risk of a similar incident occurring here and how assured are we that these are effective?'

National recommendations or recommendations for other services are therefore not generally included unless consultation has occurred with the key stakeholders to which the recommendation relates. In circumstances where a recommendation which applies outside the service where the incident occurred has been accepted for inclusion, there must be clear governance structures agreed with the relevant stakeholders to enable both implementation and monitoring.

## Use of collaboration with the service in the development of recommendations

The concept of collaborating in the development of recommendations is aimed at the production of relevant and focused recommendations. This approach will support rather than conflict with the capacity and willingness of the service to make meaningful and sustained change. It also ensures that the intention of a recommendation is clearly understood and that they are feasible and realistic and owned by the service to which they relate.

Accepting that some may feel that the concept of collaboration may compromise the independence of the Review Team it is proposed that the need for collaboration is designed in from the outset and if so may also be reflected in the terms of reference. There are a number of ways to address collaboration e.g. it can be achieved by the nomination of appropriate staff drawn from a range of relevant disciplines, to act as an advisory panel to the Review Team. Any collaboration in the development of recommendations would be managed, directed and controlled by the Review Team.

## Making good recommendations

The best approach to drafting recommendations will vary depending on the topic or service. However, there are some basic principles that apply to all recommendations.

- Recommendations should be based on best available evidence or practice and aligned where relevant to organisational strategy/policy. These should where possible include a reference to support this.
- There should be a clear linkage between recommendations and the findings made following analysis of the incident.
- Recommendations should focus on a measurable change so that they can be monitored
- Recommendations need to be realistic. For example, making a recommendation that is contrary to agreed strategic direction or impacts on service plan commitments is counterproductive. Such recommendations also may not be within the capability or capacity of the service to implement.
- Engaging or collaborating with relevant stakeholders about recommendations can make them more robust and realistic.
- Recommendations should be made for the service within which the review is conducted and not generalised to all services of that type.
- The use of a model for framing recommendations such as CLEAR can assist with writing recommendations which are easier for services to interpret and implement.

### What is the CLEAR Model for framing recommendations?<sup>14</sup>

CLEAR is an acronym used to describe the key elements/features that a recommendation should have to support successful implementation i.e. **C**ase for Change, **L**earning Orientated, **E**vidence, **A**ssign, **R**evue.

The CLEAR model aims to support people to draft recommendations that set out the case for change, learning points, the evidence upon which the change is based, it assigns responsibility for the change and enables review. This model was developed to address a balance between learning and recommendations and is particularly suitable for use in the context of incident reviews.

Focusing on learning promotes reflective practice while outlining a case for change and drawing on an evidence base can address any review findings and their associated contributory factors.

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14 Buckley H and O’Nolan C (2014) ‘Child death reviews: developing CLEAR recommendations’ at <https://onlinelibrary.wiley.com/doi/full/10.1002/car.2323>.

## The elements of the CLEAR Model explained

### Case for change

It is important that anyone tasked with implementing a recommendation understands why the change is necessary. This means that your report needs to set out the case for change clearly. Any investigation or review that uses an appropriate methodology and links its findings with recommendations will do this.

When framing recommendations, the CLEAR model suggests that it will be helpful if you are explicit about the issues that give rise to the need for change and outline what will happen if no change occurs.

This model also suggests that proposed changes are contextualised within any policies, procedures, protocols or guidance (PPPGs) that already exist or are in development. This will show how the change proposed in the recommendation fits with current or planned PPPGs. It also ensures that cases for change are well informed, which should facilitate cultural change as changes may also be needed in norms, perspectives and behaviours.

Some services that use the model only make a recommendation if there is a convincing case for change. The evidence for such a change might come from an identified gap in practice or policy, which became apparent as a result of the complaint investigation or incident review. Alternatively, there may be research that demonstrates the need for a change in practice or policy.

For example, reviewers might be aware that a recommendation that they want to make has been made before but has not been implemented. Rather than repeat the recommendation, they should set it out in the context of the issues identified that give rise to the need for change and the consequences which might accrue should no change occur. If the recommendation relates to the absence of a policy then arrangements should be made to develop this. Alternately if the recommendation relates to a current policy or a policy which is known to be in preparation it should be framed within this context.

The likelihood that changes identified as required occur in practice is greatly increased if, from the outset of the review process, the principle of cooperation is present between the work of the review team and the service to which the review relates. This will assist in both linking the findings and proposed solutions to an evidence base and ensuring that any recommendations made are feasible and realistic for the service to implement. The service will, through such a process, also gain an increased understanding of the need for and benefits accruing from implementation. This in turn will increase the likelihood that the recommendations will be implemented.

### Learning oriented

It is important for reports and recommendations to highlight key learning so that it can be shared. The CLEAR model suggests using a separate section of the report to elaborate on key learning. This can be useful particularly if any research or theory referenced is easily available to anyone reading the report or a learning notice developed to support shared learning from a report. Reports also provide an excellent opportunity to share examples of good practice.

### Evidence based

The CLEAR model suggests that recommendations should draw on three different types of evidence when identifying a solution to any policy and practice deficits identified.

1. They should flow from evidence of any gaps in policy or practice identified by the investigation or review.
2. They should demonstrate knowledge of the context where the recommendations are to be implemented.
3. Changes to PPPGs should only be made if evidence exists and can be cited that their implementation will effectively address and remediate the deficits identified. This ensures that recommendations are aligned with best practice.

## Assign responsibility

Recommendations are most effective when they clearly specify which discipline, directorate or organisation should implement them. If a multi-agency response is required, each individual discipline or organisation required to respond should be identified, as well as a leader to carry responsibility for coordinating and overseeing implementation. This should enhance ownership and reduce the likelihood that responsibility will fall between two stools.

Recommendations are unlikely to be implemented unless someone takes responsibility for them. This ownership is facilitated if people drafting recommendations engage with key stakeholders prior to finalising recommendations.

## Review/evaluate

Learning points and recommendations that follow the format proposed in this approach (i.e. set out the case for change, emphasise learning, make the link between findings and learning and assign responsibility) should be amenable to review. It should also be feasible to link recommendations to regulatory processes and standards and quality benchmarks so that there are external benchmarks by which to measure their implementation.

## Examples of CLEAR Recommendations

Recommendation	CLEAR Recommendation
Incidents should be reported once.	<p>The information gathered as part of this review indicates that some incidents of pressure ulcers are being reported twice. Evidence highlighted that this is happening because staff in Community Service A, are completing incident forms for pressure ulcers that patients have on admission from Acute Hospital B.</p> <p>Existing pressure ulcers do not need to be reported on NIMS but should be reflected in the patient's healthcare record with actions to prevent further deterioration.</p> <p><b>Recommendation</b></p> <p>The Director of Nursing should ensure that line managers inform all staff about the practice change where there is no requirement to complete an incident report form (NIRF) for pressure ulcers identified as present at the time of a patients admission. Reference: HSE's Pressure Ulcers: A Practical Guide for Review (2018).</p>
The service should be GDPR compliant.	<p>The information gathered as part of this review indicates that there was a failure to ensure that all information shared with a third party provider was suitably anonymised.</p> <p><b>Recommendation</b></p> <p>The service manager should review the service's policy on data sharing to ensure that its obligations to protect the anonymity of persons are compliant with the requirements of GDPR.</p>

## Monitoring recommendations

The ultimate goal of any recommendation is to effect change for service improvement. The service should develop an action plan based on recommendations and/or key learning the implementation of which will provide assurance that the quality and safety of the service has improved. Actions need to be time framed and assigned to a specific person or group so that it is clear who is responsible for implementation. It is therefore important that monitoring is not just a compliance exercise on whether a recommendation has been implemented or not. Monitoring needs to consider if and how the change has improved the safety of the service.

Framing recommendations that are CLEAR will facilitate the development of the action plan. For appropriate governance and assurance, action plans should be integrated into service's Quality and Improvement Plan (QIP). This allows services to monitor recommendations and/or learning points from a number of reports rather than trying to monitor them individually. Services must keep a record of which recommendations are aligned with which action in their QIP. This will enable the compilation of monitoring reports if required. The governance arrangements for monitoring the achievement of QIP must be clear. For example a service's QIP might be overseen by their Quality and Safety Committee, reporting to the SAO/Management Team.

Services should also consider aligning improvement plans to themes in national standards. This type of mapping exercise can help services to demonstrate to regulatory inspectors how they have linked reactive processes such as incident management with their proactive safety and quality improvement process.

Reviews are identified in the HSE's Integrated Risk Management Policy as reactive-internal sources for risk identification. This is of particular importance where it is identified that similar recommendations are being made in relation to similar recurring incidents. Consideration should therefore be made whether the report has identified a risk which needs to be assessed and managed and monitored on the service's risk register.

### Top Tips for making recommendations

The purpose of a recommendation is to make demonstrable improvement so ask the following questions when making recommendations;

1. Is the recommendation written using the CLEAR model?
2. Will it be effective in reducing or eliminating the identified risk?
3. Is it objective and balanced and free from judgement?
4. Is it reasonably practical?
5. Are potential improvements roughly proportional to the impact of the change required?
6. Will it be seen as relevant to those who will be affected by implementation?
7. Will it be sustainable over time?
8. Does it introduce new risks in another area? E.g. could it have unintended consequences?
9. Is it based on good evidence and practice?
10. Have you considered engaging or collaborating with people e.g. staff and service managers about recommendations that you are making?
11. Is the implementation of some recommendations more urgent than others – would it help if you prioritised these ones?

## Section 15 Writing Review Reports

The quality of the report is critical both from the perspective of those affected by the incident and also the service within which it occurred. It provides an opportunity to reflect on what happened and why it happened and to set out the recommendations for change to reduce the risk of recurrence. A well written report can assist in gaining closure on the incident; conversely a poorly written report can leave questions unanswered in relation to the incident or a lack of clarity for services in relation to the need and basis for change.

Perhaps the biggest challenge with writing a report is that you don't get a second chance and if you lose your reader, it is difficult to get them back. This is why there is a need to pick and choose words carefully, and present the points in a style, manner and sequence that best suits the message being delivered. With this in mind it is important to consider the following three issues:

### 1. Purpose

Whilst the key purpose of a review report is to provide an outline of what happened, why it happened and to set out recommendations to reduce the risk of recurrence, it is not the only purpose. Another and equally important purpose is the opportunity that exists to address concerns/questions raised by the service user/relevant person(s) some of which may be not directly related to the incident e.g. issues relating to aspects of care either before or subsequent to the incident.

### 2. Audience

There are three key audiences to consider when writing a report, the service user/relevant person(s), the staff who participated in the process and the service who will be receiving the report. All three audiences want to understand what happened, why it happened and what improvements are required to reduce the risk of recurrence. The report therefore needs to be written in a manner which is accessible to all groups with the use of jargon and technical terms minimised in so far as is possible. The layout should be logical so that the reader can easily be brought through the report from the background to the incident, the incident and its outcome, the immediate actions taken, the commissioning of the review, the approach to review adopted, the sequence of events, the analysis, the findings and the recommendations. Though reports are a key output of the process efforts should be made to keep these succinct and not overly complex or lengthy. Whilst there will have been considerable material both collected and created e.g. a detailed chronology, there is no need to include all of this in the main body of the report. Such material can either be included in appendices or held on file in the event there is a query, for example in relation to the evidence upon which a finding is made.

### 3. Tone

Tone refers to the style or manner of expression used in speech or writing. Just like in a conversation, the tone you use in your writing affects the way a reader interprets and responds to the message. Many reports can be 'technically' correct but lack empathy and given that the audience for the report includes those people that have been impacted by the incident it is important to get this right.

Using the appropriate tone will

- prevent alienating the reader – the use of a tone that is too casual may cause offence. Similarly, using a tone that's too formal could appear "high-handed" and unfriendly.
- positively influence the reader's attitude – Using the right tone can help set the mood and form the attitude of the reader. This makes it more likely you'll get the desired response to the message.
- help the reader connect with the message – By using the right tone and carefully choosing the words, it can help readers "hear your voice." It can make them feel more connected to what the review report is about.

To assist with the writing of reports two report templates are included below

- Template 1. For use with Systems Analysis Review Reports
- Template 2. For use with After Action Review Reports.

## Template 1. Systems Analysis Review Report Template

### Systems Analysis Review Report

**Confidential**

Date of Incident
NIMS NUMBER
Hospital Group/CHO/NAS/Other
Review Commissioner
Chair of Review
Date Report Completed

Note: Guidance is provided throughout the template in italicised text – please ensure that this is deleted before finalising the report.

## Contents

<b>1.0</b>	Executive Summary	xx
<b>2.0</b>	Acknowledgement	xx
<b>3.0</b>	Overview of the Review Process	xx
<b>4.0</b>	Persons involved in the conduct of the Review	xx
<b>5.0</b>	Background	xx
<b>6.0</b>	High Level Chronology of Events	xx
<b>7.0</b>	Aftermath of the incident	xx
<b>8.0</b>	Analysis and Findings of the Review Team	xx
<b>9.0</b>	Review Outcome	xx
<b>10.0</b>	Other issues raised by the service user/relevant person not addressed by the systems analysis	xx
<b>11.0</b>	Recommendations	xx
<b>12.0</b>	Learning	xx
	Appendix 1: Terms of Reference	xx
	Appendix 2: Definitions and Abbreviations used in the report	xx



## 1.0 Executive Summary

*To include: Detail of the incident type, detail of the person affected, and the circumstances of the incident, and the impact on the service user/relevant person(s) (use codes i.e. do not use names)*

*Purpose of the review*

*Timeframe taken to conduct the review.*

*That the Review Team were independent of the matters under review i.e. not directly involved in the incident.*

*A summary of the key findings and that recommendations have been made to address the factors that contributed to these.*

*Consider writing this summary in a manner that it can be adapted as the basis for sharing learning with other services.*

## 2.0 Acknowledgement

*Acknowledgement – to the persons affected e.g. service user/relevant person(s) staff, service for their participation in the process.*

## 3.0 Overview of the Review Process

*How was the review commissioned and by whom? What was the remit of the review (consider including the terms of reference as an appendix) Include detail of how the service user/relevant person(s) was involved in the process e.g. was there a meeting with them to outline the plan for review and to ask them if they had any particular questions that they would like to see the review address? Consider providing detail of the questions identified by the service user/relevant person(s) here.*

*Document the approach used and what information/material was considered e.g. documented reviewed (incident report, review of health records (medical case notes, nursing records, laboratory and radiological reports), site visits, use of written recollection of events from staff, interviews with staff (if any), duty rotas, PM/Coroner reports, equipment reports including serial number, relevant local or national PPPGs.*

*Outline that an analysis of this was conducted to identify the findings and the relevant systems analysis tools were used to identify any factors that contributed to the findings.*

*Outline that the outcome of this analysis has resulted in the identification of a number of recommendations to reduce the risk of recurrence. Make reference to the process used to ensure natural justice and fair procedures was guaranteed for all parties.*

## 4.0 Persons involved in the conduct of the Review

*Name and title of lead reviewer and others who assisted in the process, including any subject matter experts (if involved)*

## 5.0 Background

*Provide brief detail relating to the background of the service user and relevant detail of their care episode leading up to the incident e.g. the service user was an elderly person with a history of multiple admissions for treatment of chronic respiratory problems. S/He was admitted 5 days prior to the incident for ... and outline what happened.*

## 6.0 High Level Chronology of Events

*Though the Review Team will have developed a detailed chronology of events the inclusion of this within the report is not required as many chronologies are lengthy and serve to interrupt the flow of the report. Consider therefore outlining here a high level chronology which focuses on key events leading up to the event. The more detailed chronology may be held as part of the review file or included in an appendix to the report.*

## 7.0 Aftermath of the incident

*Outline what happened following identification of the incident and provide detail of the immediate management of the incident to include how persons affected (service user/relevant person(s)/staff) were cared for/supported, whether and when open disclosure occurred, what steps were taken to identify and address any immediate risks that may have affected others.*

## 8.0 Analysis and Findings of the Review Team

*To include:*

*Statement(s) of Findings and the Factors that contributed to each of these (see **Systems Analysis Guidance (IMF Guidance Section 13)**)*

*Incidental Findings (note anything that requires attention but which had no real impact on the event e.g. illegible/untimed records, procedures not followed)*

*Good/Notable Practice – Highlight any good practice identified e.g. good record keeping, the service's immediate response to the incident, the support for persons affected etc.*

## 9.0 Review Outcome

Indicate which ONE of the following outcomes best applies and delete ALL others

Appropriate care and/or service – well planned and delivered, unavoidable outcome and no findings identified.

Indirect system of care/service issues – no findings identified but Incidental Findings were identified i.e. improvement lessons can be learned but these were unlikely to have affected the outcome.

Minor system of care/service issues – a different plan and/or delivery of care may have resulted in a different outcome, for example systemic factors were identified although there was uncertainty regarding the degree to which these impacted on the outcome.

Major system of care/service issues – a different plan and/or delivery of care would, on the balance of probability, have been expected to result in a more favourable outcome, for example systemic factors were considered to have an adverse and causal influence on the outcome.

## 10.0 Other issues raised by the service user/family not address by the systems analysis

*Cross check to see the extent to which the questions posed by the service user/relevant person(s) at the outset have been covered in the report to this point and if the answers to some or all have not been explicitly covered provide detail here.*

---

## 11.0 Recommendations

What is recommended to address the findings and contributory factors? **Guidance on Developing Recommendations (IMF Guidance Section 14)**

- 1.
  - 2.
  - 3.
- 

## 12.0 Learning

*Consideration should be given to the inclusion of learning from the review of the incident that may indicate an opportunity for service improvement with a potential for application in other services. This can act as a prompt for other services to ask the question; 'What controls (systems and processes) do we have in place to reduce the risk of a similar incident occurring here and how assured are we that these are effective?' **Guidance on Developing Recommendations (IMF Guidance Section 14)***

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**Appendix 1: Terms of Reference**

<include a copy of the terms of reference here>

**Appendix 2: Definitions and Abbreviations used in the report**

Definitions
Abbreviations

Review Report – Pseudoanonymisation Codes

**Note:** Whilst it is important to maintain the confidentiality of persons and locations referred to in the report, it is also important to have on file detail of the names of people and locations referenced **by code** in the report.

**Please complete the table below but do not attach to the final report. This page should be provided directly to the Review Commissioner by the Chair of the Review Team and should not be filed with the report.**

NIMS Number relating to the Review:

CODE	Name of Person/Location to which the code relates



## AAR Summary Report Template

The responses included in italics below are sample text only. Please replace with your own responses.

### After Action Review Learning Report

NIMS Number:

---

Date of meeting:

---

### Background to AAR

*Provide a brief summary of the issue to which the AAR relates and a narrative summary relating to the outcome of discussion to the first three AAR questions.*

---

### Key Learning Points Identified

*Provide a brief summary of the learning points – these can be both items that worked well and those which could be improved. It is important to acknowledge both*

---

### Actions Agreed

*The actions agreed should be linked to the learning points identified above*

- 1. Set out the actions agreed here*
  - 2. etc*
-

## Section 16 Governance approval process for finalising a review report

Prior to finalising the report, it is essential that it is quality assured in a number of respects including that:

- The report has kept within the scope outlined in the Terms of Reference<sup>15</sup>.
- That the process applied was consistent with the requirements of the approach taken for the review<sup>16</sup>.
- There are clear linkages between the analysis, the findings and any recommendations that are made.
- The recommendations made are practical and proportionate to the findings and designed to facilitate the development of an action plan which can be monitored to ensure implementation and provide assurance to service managers.
- The process applied has adhered to the principles of natural justice and due process.

Though the ultimate signoff process occurs with the Review Commissioner it is essential that the Review Team consider the above points throughout the review process and in the development of the review report.

To ensure that reviews are completed within designated timeframes the time taken to carry out this process must be considered in the planning and conduct of the review. The purpose of the final stage of the governance approval process is as outlined above but it is critical that it is not perceived as a mechanism to interfere with the content of the report or its findings.

Reports relating to the review of **Category 2** incidents can be considered and signed off by the review commissioner.

Reports relating to the review of **Category 1** incidents must be considered by the SIMT prior to sign off. If for any reason a member of the SIMT has also been a member of the Review Team to which a report being considered relates they should absent themselves from the discussions and decisions relating to sign off. Such absences must be recorded in the minutes of the meeting. Risk of perceived bias can be further addressed by the Review Commissioner absenting him/herself from this process. This is worthy of consideration as he/she is the ultimate decision maker in relation to the acceptance of the report. In circumstances where the Review Commissioner absents themselves from this part of the process this should be recorded in the minutes.

In the event that the SIMT is satisfied that the report has met the criteria for final sign off they recommend acceptance of the report to the Review Commissioner. Where it is determined that the report has not met the criteria for sign off it is referred back to the Review Team with a rationale as to which of the criteria outlined above it has not met. The Review Team are requested to address any deficits in the process and to resubmit the report or provide a clear rationale as to why this is not possible.

In the rare circumstance that a Review Team is unable or unwilling to address issues identified, the Review Commissioner is notified and a decision taken in relation to further actions required to conclude the review process, up to and including stepping down the Review Team. Decisions to step down a Review Team must be formally escalated to the Review Commissioner's line manager for discussion in relation to next steps required.

A summary of the overall governance approval process is outlined in Figure 1 below and a check list for use by reviewers and those governing the review process e.g. the SIMT, in the finalisation and acceptance of review reports can be found on [page 103](#) of this section.

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15 It should be noted that the TOR may in exceptional circumstances be amended in the course of the review and in such cases it is the amended TOR that should be considered.

16 Whereas the checklist is designed to cover all aspects of a comprehensive approach to review the application of the checklist should be adapted for use when considered the requirements of concise reviews.

Figure 1. Governance Approval Process for Final Report





## Systems Analysis Review Report Checklist

This checklist has been designed to guide reviewers and those governing the review process e.g. the SIMT, in the finalisation and acceptance of review reports so as to ensure that:

- The report has kept within the scope outlined in the Terms of Reference<sup>17</sup>.
- That the process applied was consistent with the requirements of a systems analysis review.
- There are clear linkages between the analysis, the findings and any recommendations that are made.
- The recommendations made are practical and proportionate to the findings and designed to facilitate the development of an action plan which can be monitored to ensure implementation and provide assurance to service managers.
- The process applied has adhered to the principles of natural justice and due process.

## Review Details

---

**NIMS Number**

---

**Date Checklist Completed**

---

**Checklist Completed by**

---

---

<sup>17</sup> It should be noted that the TOR may in exceptional circumstances be amended in the course of the review and in such cases it is the amended TOR that should be considered.

## Areas for Consideration when Reviewing the Report

Pseudo – Anonymisation	Y/N/Partial/n/a	Comment
Does the report use codes in order to pseudo-anonymise the report in terms of persons/ gender and location?		
Is the Review Report – Pseudo-anonymisation codes form completed? <b>Note:</b> this is to be returned separately to the Review Commissioner and not filed with the report.		
Plain English	Y/N/Partial/n/a	Comment
Is the report written in plain English and is there an explanation, provided by way of an appendix, of any medical and technical terms and abbreviations used? Definitions used should be referenced.		
Does the report have a logical flow that will enable the reader to engage with the report and clearly understand the sequence of events leading up to the incident, the process of review, the analysis and how the reviewers reached their findings and recommendations?		
Bias	Y/N/Partial/n/a	Comment
Is the review report balanced and fair or does it appear biased – either towards an individual or as a result of hindsight bias or outcome bias or in terms of the language used?		

## Checklist for Body of Report (by Section)

Title Page: Are the following items included?	Y/N/Partial/n/a	Comment
Date of Incident		
Is it marked confidential?		
NIMS Number		
Location of Incident i.e. Hospital Group/CHO/NAS		
Title Page: Are the following items included?	Y/N/Partial/n/a	Comment
Name of Review Commissioner		
Chair of Review Team		
Report Completion Date		
Contents Page	Y/N/Partial/n/a	Comment
Is a contents page included?		
Executive Summary	Y/N/Partial/n/a	Comment
Is the purpose of the review stated?		
Is the timeframe of the review stated (i.e. length of time taken to undertake the review)?		
Does the executive summary state who conducted the review?		
Does the executive summary state that the reviewers were not involved in the incident and that they do not directly manage the service within which the incident occurred.		
Does the executive summary summarise the key findings of the report and the recommendations to address these?		

Acknowledgement	Y/N/Partial/n/a	Comment
Is an acknowledgement included in the report		
Overview of the Review Process (methodology)	Y/N/Partial/n/a	Comment
Is there detail included in relation to who commissioned the review and the remit or scope of the review?		
Is there detail of how the review was conducted including reference to the approach used?		
Is there detail provided in relation to the documents/records considered as part of the process?		
Is there detail in relation to how the person(s) harmed/relevant persons (as appropriate) were involved and supported in the review?		
Is there detail in relation to how staff were involved and supported in the review?		
<p>Is there detail in relation to how the principles of natural justice and fair procedures were observed? E.g.</p> <ul style="list-style-type: none"> <li>Does the report state if persons participating in the review were allowed the opportunity to comment on the draft report in terms of its fairness and factual accuracy?</li> <li>Does the report state if feedback in relation to matters of inaccuracy identified by persons asked to review the draft report was incorporated into the final report?</li> <li>Does this review report include details of a legal review? <b>Note:</b> this is only required if complex legal issues arose during the review or if it is the condition of the involvement of an individual external expert used.</li> </ul>		

Persons involved in the conduct of the review	Y/N/Partial/n/a	Comment
Does the report contain detail of the name of those who conducted the review and others who assisted in the process, including any subject matter experts (if involved)?		
Background	Y/N/Partial/n/a	Comment
Is there a brief summary of events leading up to the incident?		
Is it concise and does it avoid repetition?		
High Level Chronology of Events	Y/N/Partial/n/a	Comment
Is there a high level chronology included which sets out sequentially the key events leading up to the event and immediate actions taken to mitigate harm.		
Aftermath of Incident	Y/N/Partial/n/a	Comment
Is there a summary of the immediate aftermath of the incident?		
Does this section reference the Open Disclosure process?		
Is there a summary of what happened in the longer term after the incident?		

Analysis and Findings of the Review Team	Y/N/Partial/n/a	Comment
<b>a) Findings</b>		
Does the report set out Statements of Findings or does the report state that none were identified following the analysis of the chronology?		
If the report states that no findings were identified is there evidence to support this?		
If the report identified findings is the context in which these occurred explained and is each finding adequately supported by evidence within the report?		
<b>b) Contributory Factors</b>		
Does the report show that the reviewers used the relevant systems analysis tools to identify the Contributory Factor(s) for each finding?		
Is each identified Contributory Factor clearly linked to the relevant finding?		
If no Contributory Factors are identified does the report state a reason for this?		
<b>c) Incidental Findings</b>		
Does the report identify issues that while not impacting on this incident highlight an area for service improvement?		
<b>d) Notable Practice</b>		
Does the report identify areas of notable practice either prior to the incident occurring, in the management of the immediate aftermath of the incident or during the conduct of the review?		

Review Outcome	Y/N/Partial/n/a	Comment
Does the review identify one of the four available outcomes listed?		
Other issues raised by the family	Y/N/Partial/n/a	Comment
Does the review address any issues raised by the family not covered already in the report?		
Recommendations	Y/N/Partial/n/a	Comment
Are recommendations included in the report?		
Are the recommendations linked to the Contributory Factors highlighted in the review?		
Do the recommendations include all actions necessary to ensure that the risks associated with the Contributory Factors are reduced as far as is reasonably practical so that the incident is unlikely to recur?		
Does the report state who has responsibility for implementation of the recommendations? (This may already have been covered in the terms of reference.)		
Learning	Y/N/Partial/n/a	Comment
Does the report identify any learning from the review of the incident that may provide an opportunity for improvement to be shared with other services?		
Appendices (whilst a review may require the addition of a number of appendices the two most commonly included are referred to in this checklist).	Y/N/Partial/n/a	Comment
Are terms of reference included in the review report?		
Is there a list of definitions and abbreviations used in the report included?		

Notes:

## Section 17 Retention of Records relating to an incident review

For ease this guidance has been divided into two sections

1. Documents gathered to support the review
2. Documents created as part of the review process

As the management of medical devices associated with an incident and its return to use is a query that comes up from time to time, a section on this is also included in this guidance.

**Note:** Arrangements required for the retention of records relating to an incident review are the responsibility of the Review Commissioner and not the Review Team.

### Documents gathered to support the review

Whilst original copies of records should not be disposed of, the documents in this section are copies of documents which exist in their own right, gathered to support the conduct of the review and are subject to retention by others.

Where the Review Commissioner is satisfied that these documents are subject to appropriate retention by the service and that they can be accessed again if required, any **copies** used by the Review Team can be disposed of after the review. Where such documents contain personal data they must be disposed of by shredding using an approved mechanism.

A log of the records accessed should however be retained, which includes a dated numbered version of any non-personal records and detail of the disposal mechanism and date.

### Examples of documents gathered to support the review

- Copy of the individual's Health or Social Care Record
- Copy of Radiology or Laboratory Tests
- National Regulatory Standards
- National Clinical Guidelines
- HSE Policies or Procedures (local and national)
- Copy of Staff Rosters
- Governance organograms
- Copy of Staff Training Records
- Copy of Incident Report Form
- Copy of Letters of Complaint received by service which may have triggered the need for the review
- Copy of Equipment Maintenance Records
- HPRA Alerts



### Documents created as part of the review process

As a rule of thumb all documents created as part of the review process should be retained for a period of seven years. The exception to this is cases relating to children where the statute of limitation for personal injury claims is two years less a day from the date of their 18<sup>th</sup> birthday.

The other query that staff have relates to the retention of draft review reports and in this case there is a need to distinguish between draft reports created that;

- have not been circulated beyond members of the Review Team and
- have been circulated outside of the Review Team e.g. for factual accuracy checking.

Draft reports which **have not been circulated** beyond the members of the Review Team can be deleted at the time of creation of the next draft.

Draft reports that **have been circulated** beyond the Review Team e.g. as part of the factually accuracy process, should be retained, along with any feedback received, for seven years following completion of the review. This is required both for audit purposes and in the event of legal challenge as it may be necessary to provide evidence of changes made as a consequence of feedback received. It is important that all drafts retained are both dated and version controlled.

Prior to disposal of any documents created a check should be made with the SCA that a case has not been lodged which the service may be unaware of. Disposal of documents created as part of a review must be disposed of by shredding using an approved mechanism.

If clarity is required on an individual case legal advice should be sought.

### Examples of original documents created as part of the review process

- Personnel Recollections of Events written by staff
- Notes of interviews with staff, patients or their relevant person(s)
- Photographs taken of the physical layout where the incident occurred
- Draft Reports

## Medical Devices associated with an incident

The European commission guidelines on a Medical Devices Vigilance System defines medical device related incidents as;

*“Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.”*

Where a medical device is assessed by an appropriately qualified person e.g. Clinical engineer, device manufacturer or distributor and it is determined that there is no suspicion or evidence that the device contributed to the reported incident, the device is to be certified for return to use by an appropriately qualified person. The return to use certification report should be recorded and retained locally together with referencing the specific device make, model and serial number and outline of reported incident. Device-related problems or minor failures and discrepancies that are not reportable to the Health Products Regulatory authority (HPRA) should be recorded locally by the service to provide failure history and assist in trend analysis.

Where a medical device is assessed by an appropriately qualified person e.g. clinical engineer, device manufacturer or distributor and it is determined that the device is suspected to be a contributory cause of the reported incident, the device is to be removed from immediate use and quarantined including the associated accessories so that examination, if deemed necessary, can be carried out at a later date. The suspected device issue is to be reported to the device manufacturer either directly or via their authorised agent. It is strongly encouraged that at the time of reporting to the manufacturer, the user also informs the competent authority the Health Products Regulatory authority (HPRA). The suspected device will then be subject to further examination by the device manufacturer and the HPRA. The HPRA will review all documentation and information resulting from the investigation and determine if proposed actions outlined by the manufacturer is the most appropriate or may advise to carry out further action to supplement the manufacturer's action for return to use.

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