Incident Management Framework

Care | Compassion | Trust | Learning

2018

Seirbhís Sláinte
Níos Fearr
á Forbairt

Building a
Better Health
Service

Foreword

The majority of services provided by health and social care organisations are safe and result in good outcomes, both for those receiving and for those providing these services. There are times when things go wrong. These incidents occur due to a combination of factors including the vulnerability of those receiving care, the fallibility of those providing care and the dynamic and complex nature of the health care environment.

Incidents when they occur can cause harm. These incidents range from the need for additional medical treatment or an extended hospital stay, to more significant harm, up to and including death.

Whereas those directly affected bear the primary burden of this harm, staff whose primary motivation is to assist and support patients and users of our services, can also be significantly impacted in these situations. There are other incidents where it is our staff who are harmed. It is therefore incumbent on health and social care providers to respond to incidents once they occur, in a manner which seeks to support those affected. This includes patients, users of our services, their families and staff. This support is not confined to the immediate aftermath of the incident, but should extend throughout the period when the incident is being reviewed. Timely reviews will in turn allow us to understand what happened, why it happened and what needs to change to reduce the risk of its recurrence.

When an incident occurs, we have the opportunity to demonstrate the HSE's Values of Care, Compassion, Trust and Learning and this should be marked by openness and transparency. From the time of the incident and throughout the management process, the response of managers, clinicians and other frontline workers must be to seek to demonstrate these values so as not to damage the confidence and trust of any person affected by the incident.

This Incident Management Framework 2018 replaces the HSE Safety Incident Management Policy 2014. It is designed to provide services with a practical and proportionate approach to the management of incidents and seeks to place a particular emphasis on supporting the needs of service users, families and staff in the aftermath of an incident.

Services at all organisational levels are required to align their processes for incident management with the requirements and processes set out in this Framework. The Quality Assurance and Verification Division will lead, in partnership with other Divisions and our service organisations, on the development of further resources to assist and enable implementation.

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 development of the Framework. In particular, I would like to extend my appreciation to the patients and staff who shared their personal stories. In acknowledging the painful experiences they shared, it is my hope that through implementing this Framework, we will in some way be able to demonstrate that their experiences have brought about real change.

Tony O'Brien
Director General
Health Service Executive

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Introduction

This Framework has been co-designed in collaboration with representatives from all levels of service and has been informed by listening sessions carried out with staff and service users.

The aim of this approach was to ensure that the Framework was informed by learning from the experience and perspective of persons affected by incidents from the point of occurrence and through the lifecycle of their subsequent management. Persons affected by incidents include service users, families and staff.

The requirements of the National Standards for the Conduct of Reviews of Patient Safety Incidents, Part 4 of the Department of Justice and Equality's Civil Liability (Amendment) Act 2017 which provides for Open Disclosure and the Safety, Health and Welfare at Work (Reporting of Accidents and Dangerous Occurrences) Regulations 2016 (S.I. No. 370 of 2016) were taken into account in the development of this Framework.

The Framework sets out detail in relation to 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 Framework places particular emphasis on the need, in the aftermath of an incident, to adopt an empathetic, person centred and practical response to persons affected by the incident. To assist in providing context and illustrating the importance of this, Patients for Patient Safety Ireland have developed a series of **patient stories** and a number of staff have kindly agreed to develop **staff stories.** Staff at all levels in the organisation are encouraged to read and reflect on these **(**see **IMF Patient and Staff Stories)**.

The development of a consistent and effective response to the management of incidents also requires that there are appropriate systems of governance and management in place within services. This document outlines the key requirements for these and provides reference to more detailed guidance in respect of a number of these.

Members of the Co-Design Group have also worked closely with the National Incident Management System Steering Group to align the National Incident Management System with the process outlined in this Framework. This will assist both in relation to data capture at all stages in the incident management cycle and will support learning and improvement.

The collaborative approach used in the design of this Framework will continue in relation to its implementation. In particular the development and provision of training, tools and guidance required to assist with the Framework's implementation will be informed by service and service user need.

Key Definitions used in the Incident Management Framework

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

Incident	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. Incidents can be clinical or non-clinical and include Incidents associated with harm to: ■ patients, service users, staff and visitors ■ the attainment of HSE objectives ■ ICT systems ■ data security e.g. data protection breaches ■ the environment
Harm	**Harm to a person:** 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 a patient safety incident. (see Terms and Definitions document for a more detailed definition) *(As adapted from the World Health Organization's Conceptual Framework for the International Classification of Patient Safety, 2009.)* **Harm to a thing:** Damage to a thing may include damage to facilities or systems, for example, environmental, financial, data protection breach etc.
Open Disclosure	Where a health services provider discloses, in accordance with Part 9 of the Department of Justice and Equality's Civil Liability (Amendment) Act 2017, at an open disclosure meeting, to: (a) a patient that a patient safety incident has occurred in the course of the provision of a health service to him or her, (b) a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient concerned, or (c) a patient and a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient, that disclosure shall be treated as an open disclosure by the health services provider of that patient safety incident and *section 10* shall apply to: (i) the information, in respect of the patient safety incident, provided to the patient or relevant person (or both of them) at the open disclosure meeting, additional information provided at the additional information meeting and information provided in a clarification under *section 19*, (ii) an apology, in respect of the patient safety incident, where an apology is made at that meeting, or the additional information meeting. Open disclosure: information and apology not to invalidate insurance; constitute admission of liability or fault; or not to be admissible in proceedings *(Department of Justice and Equality's Civil Liability (Amendment) Act 2017)*
Incident Review	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.

Serious Incident	An incident that results in a rating of major or extreme as per the HSE's Risk Impact Table.
Serious Reportable Event	Serious Reportable Events 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.
Service User	The term "service user" used throughout this Framework includes patients and clients of the HSE and of services funded by the HSE.
Family	An individual who is a parent, guardian, son, daughter, spouse or civil partner of the service user, is cohabiting with the service user, or has been expressly identified by the service user to the service provider as an individual to whom clinical information in relation to the service user may be disclosed. (Adapted from the definition of a connected person as per the *General Scheme on Open Disclosure-Periodic Payment Orders 2015*.) Family involvement is in line with the expressed wishes of the service user.
Staff	(a) a person who: (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 (ii) is (or was) placed for the purpose of vocational training with the health services provider, and (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. (In line with the definition of Employee as defined in the Department of Justice and Equality's Civil Liability (Amendment) Act 2017)
The National Treasury Management Agency (NTMA)	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.

Acronyms used in this document

AAR	After Action Review
CHO	Community Healthcare Organisation
CORU	Multi-Professional Regulator established under the Health and Social Care Professionals Act 2005 (amended)
HSE	Health Service Executive
HG	Hospital Group
HIQA	Health Information and Quality Authority
HR	Human Resources
HSA	Health and Safety Authority
LBR	Look-Back Review
MHC	Mental Health Commission
NAS	National Ambulance Service
NIMS	National Incident Management System
NIRF	National Incident Reporting Form
QAVD	Quality Assurance and Verification Division
QSR	Quality Safety and Risk
SAO	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. **S**pecific, **M**easurable, **A**chievable, **R**easonable/**R**ealistic, **T**ime-bound.
SRE	Serious Reportable Event
TOR	Terms of Reference
YCFF	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. Incidents will be disclosed in accordance with the requirements of the Department of Justice and Equality's Civil Liability (Amendment) Act 2017 and the National Open Disclosure Policy (2013) and related guidance.

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

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

Purpose

The purpose of this Framework 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. It replaces the HSE's Safety Incident Management Policy (2014) 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 Incident Management Framework a number of practical tools and guidance documents have been developed and these are referenced throughout the Framework.

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

Scope

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

- Hospital Groups
- Community Health Organisations
- National Ambulance Services
- National Services e.g. National Screening Services, National Transport Medicine Programme
- HSE Funded Care e.g. Section 38/39 agencies

The above services are required to set out their governance arrangements for incident management in a manner which is consistent and in compliance with the approach outlined in the Framework. Compliance with key elements of the Framework will be subject to verification audits.

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.

Detail of the roles and responsibilities of staff, managers, and Senior Accountable Officers in HSE and HSE funded agencies in relation to this Framework 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 addressing any inherent weakness in the system rather than focusing solely on an individual's actions or inactions. The focus of this framework 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 this Framework. 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, 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 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 Incident Management Framework is only used when its use 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/investigation.

A 'no wrong door[1]' 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 2)**

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1 '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 of an issue may not indicate the appropriate route for management of the issue

Source

Confidential Recipient	Protected Disclosure	HSA/ Dangerous Occurrences	Complaint	Audit	Incident	Regulatory

Identify the Dominant Concern to Determine Appropriate Route for Management
(see examples below)

Concern	Action
Concern related to individual competence, behaviour or accountability?	Consult Human Resources
Concern related to the need to identify any/all individuals potentially harmed by a hazard	Consider the need for the conduct of a Look-Back Review
Concern related to a hazard or risk that could, if not managed result in an incident occurring	Consider as part of the service's Risk Management Process
Concern related to an allegation of service user abuse of any kind	Consider for management under Trust in Care or the Safe-Guarding Policy
Concern related to an incident of intentional harm of a service user not related to abuse	Conduct preliminary screening supported by use of the Incident Decision Tree (IMF Guidance Section 3) and take appropriate action
Concern related whether the care provided to a service user was appropriate and timely	Consider requesting an independent opinion in relation to the standard of care provided e.g. a Healthcare Record Review
Concern related to a formal complaint as defined by the Your Service Your Say Policy	Refer to Complaints Officer for management in line with Your Service Your Say Policy

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. When parallel investigations are complete the learning generated from each process can be valuable for informing improvement.

Principles upon which the Framework is based

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HSE Values

Principle	Description	Features of application
Person Centred	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 required.	All immediate care needs have been met in a manner that is caring, compassionate and respectful. Where harm has occurred that a designated service user/family liaison person has been assigned. Where harm has occurred that a designated staff liaison person has been assigned.
Fair and Just	That all persons affected (service users, and staff) are treated in a manner which is fair and just. Where issues of individual accountability are identified that the service responds to these in a manner which is proportionate and safety focused.	Persons affected are listened to, have an opportunity to contribute to the review process and are advised of the outcome. 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. 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.
Openness and Transparency	That all persons affected by an incident are aware of the incident and the steps to be taken to learn from it.	Open and honest communication (Open Disclosure) is initiated as soon as practicable after the incident has been identified. That the planned review process has been described and communicated to all persons affected.
Responsive	That the actions taken following the identification of an incident are taken in a timely and proportionate manner.	That persons affected are aware of the actions to be undertaken and the timeframe for these has been communicated to them. In the event that there are unavoidable delays that the reasons for these are communicated immediately to persons affected.
Improvement Focused	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.
Learning	That the incident management system is focused on learning both locally and within the wider service.	That there are a range of tools and methods used to share learning from incidents at local, directorate/service and organisational levels.

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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. The Senior Accountable Officer is responsible for monitoring of performance in relation to the effective management of incidents to include, monitoring of key performance indicators, verifying compliance with policy and process, having in place systems to monitor the implementation of recommendations, sharing learning for improvement and the governance of information arising from incident management processes.

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, serious incident escalation, notification to external agencies and arrangements for 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. This should include details of delegated accountability, responsibility or authority. An organisation chart should be available setting out these arrangements.

Governance arrangements for incident management must be integrated with the service's overall governance 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 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 NIMS for management of data and information relating to incident management is required.

Process for managing an incident

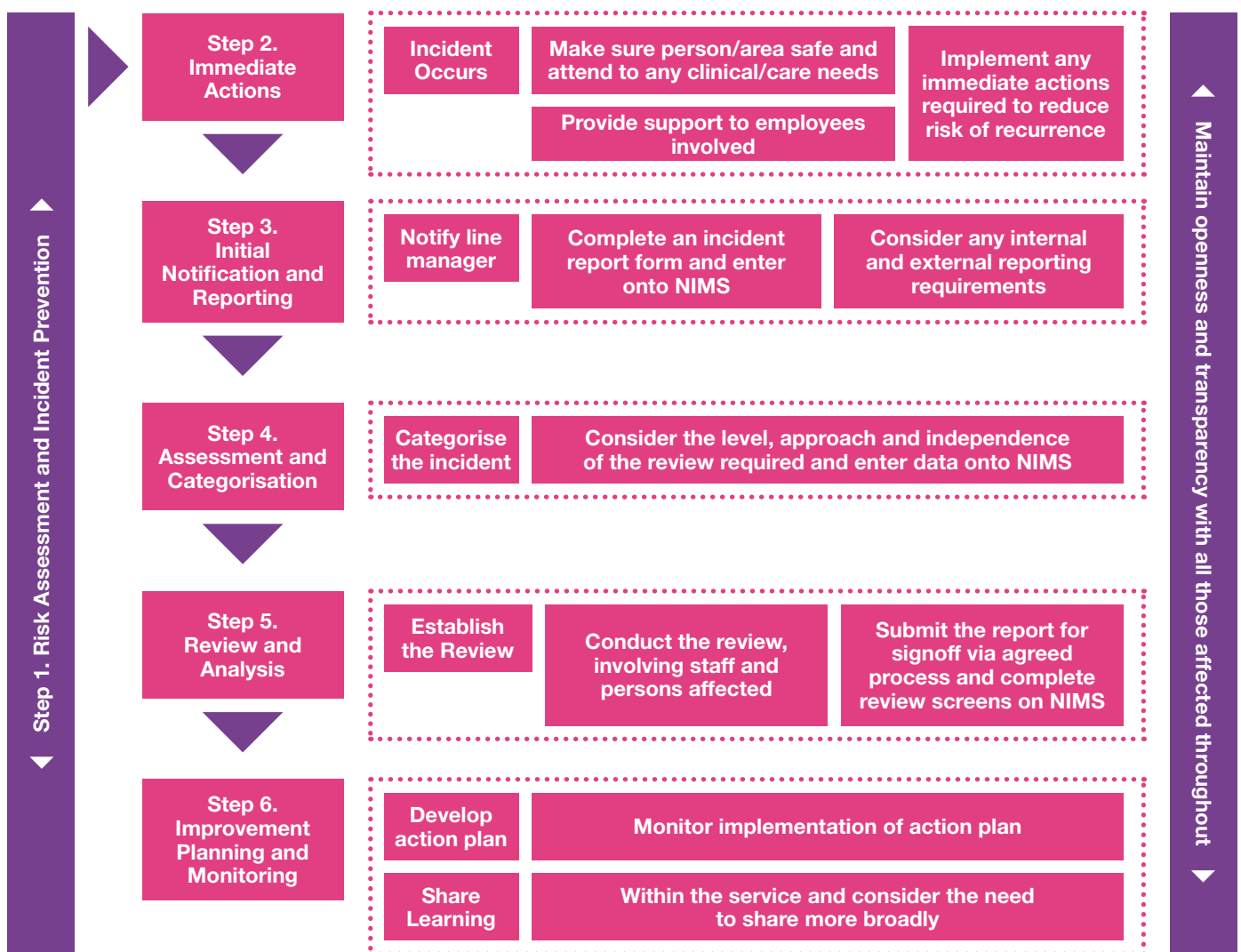Incidents, regardless of their impact, require management in line with the following steps:

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. Risk Assessment and Incident Prevention

Step 2. Immediate Actions
- Incident Occurs
- Make sure person/area safe and attend to any clinical/care needs
- Provide support to employees involved
- Implement any immediate actions required to reduce risk of recurrence

Step 3. Initial Notification and Reporting
- Notify line manager
- Complete an incident report form and enter onto NIMS
- Consider any internal and external reporting requirements

Step 4. Assessment and Categorisation
- Categorise the incident
- Consider the level, approach and independence of the review required and enter data onto NIMS

Step 5. Review and Analysis
- Establish the Review
- Conduct the review, involving staff and persons affected
- Submit the report for signoff via agreed process and complete review screens on NIMS

Step 6. Improvement Planning and Monitoring
- Develop action plan
- Monitor implementation of action plan
- Share Learning
- Within the service and consider the need to share more broadly

Maintain openness and transparency with all those affected throughout

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 to provide feedback to staff on incidents reported and how these are used to identify opportunities to improve the quality and safety of services.

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 (2017)** 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 incidents, complaints, claims management, coroners 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 has a key role in promoting, monitoring and sharing learning from the services' quality and safety processes.

Key messages

1. The importance of clear leadership at all service levels is important to support a culture of quality and safety.

2. Anticipate and manage risk which may lead to incidents.

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 (for persons affected and to minimise risk of further harm to others)

The immediate actions taken by services following 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*[2] 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 it should trigger a cascade of immediate responses to those (i) directly involved in the incident, the person affected and staff, (ii) to those who are not directly involved in the incident but who may be affected by what has happened, i.e. the person affected's family and other members of the healthcare team/ organisation and (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 families:

When an incident occurs/is identified, the first response must be to the person directly affected. It is important to focus first and foremost on the affected person's physical 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: Attention and effort must also be given at this time to prompt, open and transparent communication with the person affected and their family (as appropriate) 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 families 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 family'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.

Liaison Person: Service users and other persons who have suffered harm will likely need emotional and psychological support and this should arrive seamlessly. The assignment of a named liaison person(s) at this stage is important to ensure that the person affected/family and staff do not feel isolated and that their support and communication needs in respect of the plans for the management of the incident (including review) are identified communicated and addressed. These liaison persons should have the necessary skills and experience required to fulfil their role.

The HSE's Open Disclosure Policy and Guidelines and webpage www.hse.ie/opendisclosure 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.

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2   Conway J, Federico F, Stewart K, Campbell MJ. *Respectful Management of Serious Clinical Adverse Events (Second Edition)*. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2011. (Available on www.IHI.org)

(ii) Immediate Responses to Staff:

Harm to a service user or colleague is the last thing that health care staff want to happen in the delivery of care. Similar to persons directly affected and their families, staff may be significantly impacted, emotionally and functionally, following an incident which causes harm.

When an incident occurs 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 absence of a structured support system can have a longstanding and detrimental impact on a staff member's ability to provide care following an incident. 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.

Services should have information leaflets available for both service users/families and staff which outline information in relation to the approach to the management of incidents and supports available for them.

(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 implicated 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, families and staff, should be identified and supported.
> 4. The open disclosure process must be initiated promptly.
> 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/family and staff liaison persons are to be appointed.

Step 3. Initial reporting and notification

When any immediate action has been taken, the staff 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.

It is also the responsibility of the staff to complete the appropriate National Incident Report Form (NIRF) as soon as is practicable after the event occurs and within one working day. 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 completing a NIRF staff must ensure that they provide all information and complete all mandatory fields required by the NIRF and ensure that any information provided is factual and not subjective. This is important as it assists in supporting a just and fair culture. Services must clearly identify the route for submission of the NIRF for input onto the National Incident Management System (NIMS). The entering of an incident onto NIMS fulfils the service's obligation to inform the State Claims Agency.

Local polices must identify the route and process for notification of serious incidents to the Senior Accountable Officer (SAO) within 24 hours of occurrence. For incidents relating to service users this route is often via the Quality and Patient Safety Office. The process should distinguish both the arrangements for notifying incidents within and outside normal working hours. As these incidents may be subject to a formal review process staff involved should be advised by their line manager at this time to prepare a **written personal recollection of events**[3] **(IMF Guidance Section 4)**.

Services also have an obligation **to notify specific incidents external to the service where the incident occurred, (IMF Guidance Section 5)** 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
- Gardaí
- Commercial Insurers (this may be applicable where the incident relates to an area not covered by the State Claims Agency)

The Senior Accountable Officer (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.

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3 The main purpose of writing a personal recollection of events is for employees 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 employee interviews that are required.

Key messages

1. Incidents should be reported by the staff identifying them within in a timely manner having regard for the immediate needs of persons affected i.e. within 24 hours of their identification, on the relevant National Incident Reporting Form.

2. Notification of Serious Incidents to the SAO must occur within 24 hours of occurrence.

3. Report all incidents on the National Incident Management System (NIMS) as soon as possible. NIMS is the primary reporting system across HSE and HSE funded agencies.

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.

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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, as part of the completion of the National Incident Report Form (NIRF), 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.

The above categorisation is also auto-generated on NIMS when the outcome of the incident is entered from the NIRF.

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 at **Appendix 2**[4].

In relation to **Category 2** incidents, the completion of Part A of this form i.e. the Case Report is the responsibility of the line manager 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 6)** 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 identification 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 a Case Officer(s), for example the QPS Manager, who will engage with the Clinical Director/Service Lead or person nominated by them to identify and gather the information required for the completion of Part A of the Preliminary Assessment Form i.e. the Case Report. The Case Officer(s) will present this information at the SIMT meeting in order to assist in framing the discussion relating to review.

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.*

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4   Where an incident specific review tool is being used, the preliminary assessment and record of decision making is a constituent part of that tool and should be used in place of the form at Appendix 2.

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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 4)**.

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 7)** of the case. Such a review will clarify whether the care provided was appropriate and timely or whether there was an issue 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.

A Healthcare Record Review may also be requested to provide an expert report to support the conduct of a review. 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 Senior Accountable Officer 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 an **Approaches to Incident Review Guidance (IMF Guidance Section 8)** 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
Comprehensive	1. Systems Analysis (Review Team approach) 2. Systems Analysis (Review Panel approach)
Concise	1. Systems Analysis (Facilitated Multi-Disciplinary Team approach) 2. Systems Analysis (Desktop approach) 3. Incident Specific Review Tool e.g. Falls and Pressure Ulcers 4. After Action Review
Aggregate	1. Systems Analysis (Aggregate approach)

Systems Analysis: 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 the Key Causal Factors 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.

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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 approach, AAR can also be used to de-brief with staff following a Category 1 incident for which a Comprehensive review is planned.

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.

There are 4 options for independence available to services, ranging from the lowest level to the highest level of independence. This is illustrated below in relation to how it would apply to Hospital Groups, Community Healthcare Organisations and the National Ambulance Service (NAS).

Option	Organisational level at which the review process is led/facilitated	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 at Step 2 of the process i.e. the immediate actions taken following the identification of the incident.

The importance of initial and continued attention to supporting and communicating with persons affected by the incident (Step 2) cannot be over-emphasised. The level of independence required is often a factor of 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.

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 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 with some being commissioned internal to the service/hospital 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 role that the team has played in the immediate management of the incident 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. 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 following the identification of the incident to ensure the safety of persons affected and to address any immediate risk to others (see actions required at Step 2).

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"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

The review team should, where possible, be convened from within the level of the organisation within which the incident occurred.

Timeframes for completion of reviews

To assist with a responsive and timely approach to review and with building a culture of safety the following timeframes are required for reviews.

Option	Organisational level at which the review process is led/facilitated	Timeframe
1.	Internal to the team/department.	As soon as possible after the incident.
2.	Internal to the service/hospital.	125 calendar days from notification to the SAO.
3.	External to the service/hospital but internal to the CHO/Hospital Group.	125 calendar days from notification to the SAO.
4.	External to the CHO/Hospital Group.	6 months from notification to the SAO.

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 family member of a service user

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 9)**. A **terms of reference (TOR) (IMF Guidance Section 10)** setting out the background to the incident, Commissioner, purpose, scope, team membership, approach, timeframe, outcome i.e. report and recommendations and detail of liaison persons (service user/family and staff) is agreed. The availability of terms of reference is essential for all comprehensive reviews and is recommended as best practice for concise reviews, as it clearly sets out the scope and authority of the process.

The level at which a review is commissioned will depend on the category of the individual incident with **Category 1** incidents being commissioned by the SAO.

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

Where it is 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 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 line manager in whose area/service the incident occurred. Persons affected i.e. service users, families and staff, must be advised of the decision to proceed or not to proceed with a review.

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.

When decisions have been taken in relation to the commissioning of the 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.

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 or SRE that decision, supported by the reason or basis for the decision must be signed off by the SAO and reviewed at the relevant Quality and Safety Committee.

4. Persons affected i.e. service users, families 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.

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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 in relation to quality improvement. There is a need to understand not just what happened at the point of occurrence of the incident e.g. at the point of care delivery, but to understand the factors that contributed or influenced the occurrence. It is therefore important that the approach to review seeks to examine the systems in place in order to understand the factors that contributed to the incident. The actions of staff are therefore 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 of staff are identified these must be brought to the attention of the Senior Accountable Officer by the Chair of the review team. Performance issues should be managed with an appropriate and proportionate Human Resources response.

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.

Regardless of which approach to review is taken there is a need to apply it in a systematic and structured way which looks beyond the particular incident.

> *"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

To do this successfully all those affected by the incident i.e. service users, families and staff must be confident that the process is applied in a supportive manner that is open and fair and follows the **the principles of fair procedures and natural justice (IMF Guidance Section 9)**. These principles must be seen to work in practice at all stages in the process i.e. from commissioning 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 and the areas of good performance. It should not be viewed as a wholly negative process.

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Methodology

All commissioned reviews irrespective of the approach chosen require the establishment of the following:

1. The management of the review within the context of the service's governance arrangements for quality and safety.

2. A terms of reference as set out in section 4.

3. A multidisciplinary review team with clearly defined roles i.e. a technical lead who is trained in the approach to review chosen and a person with subject matter knowledge in the area under review. The team should be 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).

4. The review team should have access to appropriate expertise relevant to the area under review.

5. Service user/families and staff liaison persons should be identified and communicated to these parties. As the role of the liaison person is critical to the maintenance of trust between parties every effort should be made to ensure the continuity of this person throughout the incident management process. The service user/family liaison person should be in a position to advise the service user/family in relation to independent advocacy services available to support them. Staff liaison persons should also ensure that relevant staff are requested to complete their **written personal recollection of events (IMF Guidance Section 4)** and where to seek advice in so doing. The role of the liaison persons is to advise those affected of the plan for review and to provide for effective and on-going communication and support in relation to the review process.

6. The review team should have access to all documentation relevant to the issue under review e.g. healthcare records, relevant PPPG's, staff training records, staff rosters etc.

7. Systems for the management of documentation and information relevant to or created as part of the review is established and maintained. In the case of reviews the recommended timescale for retention of documentation and information is 7 years. Final reports should be retained indefinitely.

8. Systems for monitoring the progression should be established to ensure that it is completed within timeframes or in the event of unavoidable delays that these are identified to the Commissioner and managed.

Analysis

Whilst it is important when reviewing an incident to understand what happened, to truly understand the cause of an incident and work out what actions are required, services need to understand why it happened and the role human factors play in creating a quality system.

Human factors can be defined as:

"Enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities and application of that knowledge in clinical settings" (Catchpole (2010)

The **Yorkshire Contributory Factors Framework** (YCFF) **(IMF Guidance Section 11)** is an evidence based tool which can be used by services to optimise learning and address causes of patient safety incidents through the identification of those factors that contribute to incidents occurring in clinical and care services.

The YCFF is a pragmatic 2 page framework that includes all domains which have been shown to contribute to incidents occurring and suggests questions that review teams might want to ask of those involved in the incident. 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 future service users.

Any review being undertaken must therefore go beyond simply setting out a chronology and identifying any key actions or omissions that led to the incident e.g. the failure to monitor, the administration of the wrong drug etc, it must address the WHY? Use of the YCCF will enable services to answer this question.

Though designed primarily for use in relation to service user safety incidents the domains and related contributory factors contained in the YCCF are in the main also relevant to non-clinical incidents.

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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 12)** that these are clearly linked to the factors that contributed to the incident. To support implementation the recommendations must be:

1. Framed in a manner that conform with SMART[5] principles

2. Capable of supporting any changes in practice required

3. Where possible aimed at changing systems (both at delivery and organisational levels) 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.

> "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

Acceptance of the final report by the Commissioner

Prior to accepting the final report the Commissioner needs to have in place a **governance approval process for the final draft report. (IMF Guidance Section 13)**. From the perspective of the 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
- That the scope of the review was in keeping with that set out in the terms of reference
- That the process applied conforms to the approach identified in the terms of reference
- That there is evidence that the process conformed to the principles of fair procedures and natural justice
- That there is clear linkage between the findings and the recommendations made
- That recommendations made are consistent with SMART principles, are consistent with the policy framework within which the service operates and when implemented (either in the short or longer term) will seek to address any systems weaknesses identified
- That it conforms with relevant legislative requirements e.g. Data Protection.

If the report conforms to the requirements of the governance approval process it should be accepted by the Commissioner. In circumstances where the report does not conform to the requirements of the governance approval process the Commissioner should outline to the review team the reason for this decision, request that they address any issues and following this resubmit the report.

In the exceptional circumstance where the review team indicate that they are unable/unwilling to address the deficiencies identified the Commissioner can decide to step down the review team and move to appoint a new team. The reason for this should be documented and available for audit.

When the report is accepted, NIMS data fields relating to the outcome of the review process must be completed.

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5   SMART is an acronym used to describe the key elements/features that a recommendation should have to support successful implementation i.e. Specific, Measurable, Achievable, Reasonable/realistic, Time-bound.

Provision of the report to persons affected (a service user/family 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.

> *"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

The Commissioner should agree the process for providing the report to persons affected and nominate a person(s) to engage/meet with them.

With regard to service users/families, the service user/family liaison person should contact them personally to say that the report is finalised and to make arrangements to provide them with a copy of the report. Provision of the report in person at a meeting offers the service an opportunity to reiterate any apology contained in the report and to enquire after their well-being and their support requirements. The arrangements adopted in relation to this can vary depending on the relationship that has been developed with the family. Where they have been involved in the process and kept in the loop around 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 facilitated where the nominated staff liaison person has maintained a good relationship with them since the incident was identified. 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). They should 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, so what is the learning and what are the plans for implementing the recommendations etc. Give time for discussion so that it is a consultative and inclusive 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

Dissemination/Publication of the review report or its findings/recommendations

Dissemination of the report

Dissemination relates to sharing learning and the extent to which any report or its findings are disseminated should be decided on a case by case basis. At a minimum, services must arrange to have final reports discussed at their Quality and Safety Committees to ensure that any findings or recommendations are shared internally. Consideration should also be given to dissemination beyond the service and this may be achieved by way of provision of a copy of the full report or limited to a summary of the incident along with findings and recommendations to relevant stakeholders, for example to relevant National Divisions, Clinical Programmes etc.

Publication of the 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 family and as such are not generally published.

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 should come through the Commissioner in consultation with the review team. 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 nominated person(s). This includes providing service users/families with information about advocacy services that may be of assistance in providing support to them.

7. Recommendations made must be SMART and focused on avoiding recurrence.

8. A formal process for acceptance of the final report by the 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.

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 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. Dissemination and publication of reports or findings are separate processes and require consideration when reports are finalised.

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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 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 Commissioner must ensure there is separation between the processes to ensure that each process remains robust and retains the integrity 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 (2015)**.

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 identified 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 terms of reference, review team and the service taking the lead should be jointly agreed. Systems should be put in place to ensure the seamless conduct of the review including 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 or Investigations being carried out by agencies external to the HSE/HSE funded services

An incident review may also be carried out while external investigations are on-going or anticipated, relating to the incident. 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/families and staff to ensure that the review takes place in a timely and responsive manner.

In cases where there is a civil action on-going in relation to a matter undergoing internal review it is important to clarify with the indemnifier (SCA or other insurer) that the review does not compromise any existing civil action.

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.

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If a criminal investigation is on-going and it is agreed with An Garda Síochána that the review should proceed, the Commissioner must ensure that nothing is done in carrying out the review that may compromise/prejudice the criminal investigation. Requests to defer a review by An Garda Síochána are only likely to occur in a minority of cases and decisions in relation to the same will be made on a case by case basis by the review Commissioner in consultation with An Garda Síochána.

Reviews relating to Multi-Incident Events

Multi-incident events may arise where a cluster of similar complaints/concerns are received by a service, often 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 both service users, families and staff.

The pressure placed on a service by external demands for an immediate response and the need for a considered and effective review process from the perspective of affected persons must be carefully balanced. It is important therefore that the pace of the process is informed primarily by the needs of the person(s) harmed and not in response to the pressures from the public and the media for quick answers.

The success of the approach therefore lies with the assignment of a person to manage and coordinate all aspects of the process along with the assignment of a liaison person to develop a relationship with persons affected so that they will have confidence that the review will take account of their opinion and provide them where possible with the answers they require. Whilst the issue of timeliness is important to persons affected, experience has shown that where a realistic timeframe is provided and persons affected have confidence in the process a satisfactory outcome is more likely.

A formal line of communication should be established with each person affected. This provides an opportunity to establish personal contact and empathy, to ascertain a clear understanding of their issues, to advise them of the steps to be taken in deciding how best to progress their issues, to provide them with a likely timeframe for decision making and to confirm that when a decision is taken that they will be appraised of that decision. The adoption of such an approach at this stage will be important in framing expectations.

Commonly, there is variety in relation to the type of complaints/concerns that are expressed by service users/ families. These can range from issues relating to the way they were communicated with, to issues relating to deficits or errors in clinical care. There is therefore a need to adopt a differentiated approach[6] to the management of all complaints/concerns received. In some cases there may be an opportunity to resolve some of these issues at an early stage. The process should allow for the early evaluation of each complaint/concern so they can be triaged in a manner that supports their management in an effective and proportionate manner.

The use of Aggregate Review of Incidents for multiple incidents **(IMF Guidance Section 8 – Approaches to Incident Review)** that are identified by a particular theme should be considered.

Decisions taken in respect of the cases identified should be communicated back to the service user/family through the designated liaison person. Consideration should be given to how this communication takes place i.e. by phone or in person and this will depend on the nature and sensitivity of the case and the relationship developed at the outset.

The further management of the totality of cases should be the subject of a formal management plan the delivery of which is monitored by the SIMT.

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6   Some issues may be best addressed through the Complaints procedure and others may require management under the Incident Management, Look Back or other procedure.

Step 6. Improvement planning and monitoring

It is the responsibility of the Commissioner to ensure that an action plan to support 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 and implementation monitored through this. This is of particular importance where a number of reviews have made similar recommendations. In cases where actions are being monitored through the service improvement plan a note should be kept, along with the review report of the actions on the service improvement plan which relate to recommendations in the review report. This will assist in the services ability to report on implementation of actions relating to an individual report if this is 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. Progress on implementation of actions must be reported to the relevant 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 this framework 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, 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 unit level and at organisational level through the relevant 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, a 'master' 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

This Framework has been co-designed in collaboration with representatives from all levels in the service delivery system. This has assisted greatly in ensuring that it provides a practical approach which is aligned to best international practice. This model of working will continue in the provision of the support services require for its implementation.

The Quality Assurance and Verification Division (QAVD) will therefore continue to work with relevant National Divisions and services to design and develop tools and guidance required by services to operate in line with the requirements set out in this Framework. Prioritisation of additional tools or guidance required will be agreed in collaboration with services. An emphasis will be placed on developing guidance and tools that are relevant, practical and add value.

Training programmes will be reviewed to ensure that they are aligned to the requirements of the Framework and associated Guidance. Where indicated, these will be developed on-line and where training is skills based e.g. that relating to approaches to review, these will be designed by QAVD and either delivered directly by members of the QAVD, by commissioning with relevant organisations or through the development of capacity in services using a train the trainer approach.

The QAVD will continue to monitor the quality of reviews and conduct aggregate analysis of reports to identify and share learning across services. The process for the aggregate analysis of information will involve relevant stakeholders e.g. clinical and care programmes. This will inform the planning and design of initiatives aimed at improving quality and safety.

QAVD plans to build knowledge networks and communities of practice where supports for the implementation and operation of the Framework can be accessed and learning can be shared. These mechanisms will enable services to share learning about:

- Improvement initiatives that have taken place in response to incident review that could have potential national application
- Innovative or alternate approaches to the management of any aspect of the incident management process which could form the basis of new tools or guidance
- Notices aimed at alerting services to a risk identified in one part of the organisation which can act as an early warning notice to others.

QAVD will, in collaboration with the QPS leads in the Office of the Chief Operating Officer, develop and deliver events at which sharing of learning from incident reviews and best practice will be presented.

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 Senior Accountable Officers in HSE and HSE funded agencies in relation to this Incident Management Framework are as follows.

Staff responsibilities (including temporary and contracted staff)

It is the role and responsibility of all staff to:

- Comply with the services procedures established in compliance with this Incident Management Framework
- Ensure that incidents are reported in a timely manner
- Participate in and co-operate with reviews conducted in accordance with 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.

Manager responsibilities

It is the role and responsibility of all managers to promote compliance with this Incident Management Framework by:

- Ensuring that they and staff reporting to them are aware of their obligations in respect of this Framework
- Facilitate training for staff including the training of reviewers
- Facilitate staff trained are reviewers to practice including providing protected time to do so
- Monitor compliance with the Framework in their area of responsibility
- Ensure that incidents are reported and managed in line with the requirements of the Framework including logging of required information onto the National Incident Management System (NIMS)
- To ensure that actions required as a consequence of recommendations made in reviews, relating to their area of responsibility, are included in their services Quality Improvement Plan
- To monitor the service's Quality Improvement Plan and to take corrective action, where required, to ensure achievement of required actions within agreed timeframes
- To follow the correct HSE processes relating to Freedom of Information requests, Data Protection access requests, parliamentary questions, media queries and briefing documents in the management of safety incidents.

Staff liaison responsibilities

This person is a contact point at service delivery level for the staff member involved in a patient safety incident. The staff liaison may facilitate communication between the staff member and the incident management team and or the incident review team, as appropriate during the review process. They may also facilitate access to support services. The staff liaison is impartial and sufficiently removed from the incident.

Service User liaison responsibilities

This person is a contact point for the service user involved in a patient safety incident. The service-user liaison may facilitate feedback between the service user and the incident management team and or incident review team, as appropriate during the review process. They may also facilitate access to support services. The service-user liaison is impartial and sufficiently removed from the incident.

Senior Accountable Officer responsibilities

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.

It is the role of the Senior Accountable Officer (or his/her senior nominee) to:

- Have overall executive accountability for the management of patient safety incidents at the relevant governance level
- Be impartial and sufficiently removed from the incident
- Ensure that the services for which he/she is responsible have in place and comply with a procedure for the management of incidents that is in line with the requirements of the HSE's Incident Management Framework
- Ensure that the appropriate review into patient safety incidents is conducted in an effective and timely manner
- Have clear systems of governance in place to manage incidents of all categories
- Be accountable for quality and safety within services under his/her governance
- Ensure that robust structures and processes are in place to both proactively and retrospectively enhance quality and safety systems throughout their organisation or service
- Have clear systems of governance in place to implement actions required as a consequence of recommendations made following the review of incidents in their area of responsibility.

In relation to Category 1 incidents specifically to:

- Assure themselves that all care has been provided to any person affected/harmed as a result of the incident
- To notify the relevant National Director of the occurrence of these incidents in accordance with agreed pathways
- To convene the Serious Incident Management Teams for these incidents
- To receive and consider recommendations of the SIMT in relation to the commissioning of reviews
- To commission reviews of incidents where applicable
- To receive monitoring reports from the SIMT in relation to the progress of reviews and to take corrective action required where a review is experiencing delays
- To have in place a process for acceptance of final review reports which they have commissioned.

Responsibility of the Quality Patient Safety Advisor/Manager

The Quality Patient Safety Advisor/Manager is responsible for the provision of support and advice to staff and managers in their area of responsibility. The purpose of this is to enable staff and managers to comply with the requirements of the Incident Management Framework. They also commonly fulfil the role of the 'case officer' in the context of incidents notified to the SIMT for management.

Responsibilities of the Serious Incident Management Team

The Serious Incident Management Team (SIMT) are an established standing group and includes senior staff who are responsible for overseeing the management of patient safety incidents and reporting into the relevant Senior Accountable Officer at regular intervals to update on the progress of reviews. Members of the incident management team are impartial and sufficiently removed from the incident.

The SIMT has a particular role in relation to leading and overseeing the management of Category 1 incidents.

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Their role therefore includes the following:

1. To meet within 5 working days of the notification of the incident to the SAO. **Note:** Depending on the nature of the incident the SAO may decide to convene this meeting earlier than 5 working days.

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 others. Where adequate assurance is not provided, they should agree and communicate the need for any further actions that may be required.

3. To receive and consider the report of the Case Officer e.g. Quality and Safety Advisor.

4. To make recommendations to the SAO in relation to the further management of the incident in line with the requirements of the HSE's Incident Management Framework.

5. Once a review is commissioned, to receive monitoring reports on their progress to ensure they are completed within the prescribed timeframe. Where delays are identified to recommend remedial action and where required to advise the SAO of issues requiring his/her attention.

6. To receive the final draft report of the review and consider in the context of the **Governance Approval Process for Finalising the Review Report (IMF Guidance Section 13)** whether to recommend (or not) acceptance of the report to the Commissioner.

7. In the case of multi-incident reviews or where there are other review/investigation processes running concurrently to an 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.

Responsibilities of the Review Team

The review team is responsible for conducting the review of the assigned incident. Membership of the incident review team is determined by the SIMT in the context of the incident under review and reviewers are to be impartial and sufficiently removed from the incident. The lead reviewer reports into the SIMT. If in the course of the conduct of a review, an immediate risk to safety is identified, it is the responsibility of the lead reviewer to bring this directly to the attention of the SAO.

Responsibilities of the relevant QPS Committee (in relation to incident management)

The reporting relationship of the QPS Committee is to the Senior Accountable Officer.

It is the responsibility of the QPS Committee to:

- Obtain assurance that the processes for incident reporting and management (including Serious Reportable Events) are being adhered to

- Receive, review and ratify decisions taken 'not to review' Category 1 incidents and SREs

- Make recommendations to the SAO where they do not agree to ratify the decision 'not to review' a Category 1 or SRE

- Oversee the implementation of recommendations and actions from incident reviews

- Receive and review completed incident review reports so as to identify learning and ensure this is appropriately disseminated within relevant services

- Monitor how the learning from reviews is shared and used to prioritise areas for safety and quality improvement

- Evaluate training programmes on the conduct of reviews of patient safety incidents within their area of responsibility.

Appendix 2 Preliminary Assessment to assist review decision making

(Guidance in Green Font should be deleted on completion)

Part A – Case Report – to be completed in advance of the SIMT/ Review Decision Making Meeting

Incident Details	
NIMS Ref No:	Date entered on NIMS:
Date of Incident:	Incident Category:
Date Notified to SAO/Local Manager:	
Date of SIMT/Review decision meeting:	

Situation	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 support needs of persons affected i.e. service users, families and staff. ■ That Open Disclosure has been initiated or if not that an explanation of why not, is provided. ■ Detail of any questions or issues raised by the family 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. ■ That named service user/family and staff liaison persons have been appointed. ■ Detail of any meetings with the service user/family.
Background	Include detail of: ■ The background to the service user e.g. their health status and reason for admission/attendance ■ A brief chronology of the events leading up to the incident.
Assessment	Include a summary assessment of the above focusing on the adequacy of the actions taken to date. The purpose of this is to identify any areas where action is outstanding or required to provide assurance that the incident is being adequately managed.
Recommendation	Based on an assessment of the information above provide here a recommendation to the SIMT/review decision making meeting for further action required including the level and approach to the review and the level of independence attaching to the process to be adopted.
Name of Person completing Part A	

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Part B – Record of Decision (to be completed at the SIMT/or Review Decision Making meeting)

Management of incident to date

Based on the report of the Case Manager and discussions at the meeting include here an assessment of the adequacy of actions taken or planned in relation to the incident. Include also detail of any further actions required.

Appropriate Pathway for Review of Incident Reported

Having considered the case report is the SIMT/review decision making meeting satisfied that the incident is to be reviewed under the Incident Management Framework?

Yes ☐   No ☐

If No, indicate which alternate review/investigation route is most appropriate. (see Guidance on making decisions about appropriate pathways for investigation/review **(IMF Guidance Section 2)**.

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

Information required for decision making

Is further information required to assist a decision to review?

Yes ☐   No ☐

If Yes please Indicate the type of information required

HealthCare Record Review ☐

Other: Specify:

Decision to Conduct a Review under the Incident Management Framework

Please indicate the decision in relation to the level of review to be conducted:

Comprehensive Review ☐

Concise Review ☐

No Review ☐

Comprehensive Review

If the decision is to commission a Comprehensive Review, indicate whether this will be by way of:

Review Team approach ☐

Review Panel approach ☐

The Final Report of the Comprehensive Review must be accepted by the Commissioner within 126 days of occurrence of the incident.

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Concise Review	
If the decision is to commission a Concise Review, indicate whether this will be by way of:	
Multi-disciplinary team review	☐
After Action Review	☐
Incident Specific Review Tool	☐
Desk-top Review	☐
The Final Report of the Concise Review must be accepted by the Commissioner within 126 days of the occurrence of the incident.	

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

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 here

No Review
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.
Decisions not to review must be: ■ *Communicated to person affected i.e. service user, family and staff* ■ *Submitted for review and ratification by the Quality & Safety Committee* ■ *Entered onto NIMS and this should include the reason and rationale for same.* **These incidents should be included in an Aggregate Review process.**

Level of Independence attaching to the review	Please Tick
1. Team internal to the team/department/NAS Operational Region	☐
2. Team internal to the service/hospital/NAS Operational Area	☐
3. Team external to the service/hospital but internal to the CHO/HG/NAS Operational Area	☐
4. Team involve persons external to the CHO/HG/NAS Operational Area	☐

Contacts in relation to the review process
Commissioner of the Review
Title
Email
Telephone
Service User Liaison Person
Title
Email
Telephone
Staff Liaison Person
Title
Email
Telephone

Category 1 Incidents
Signature of Senior Accountable Officer (SAO)
SAO Name [Block Capitals/Typed Text]
Title:
SAO Email:
Telephone No:
Date:

Appendix 3 Membership of the Incident Management Framework Co-Design Group

Cornelia Stuart
Assistant National Director Quality Safety Risk, Quality Assurance and Verification Division (Chair)

Margaret Brennan
Assistant National Director, Quality and Patient Safety Lead, Acute Hospitals Division

Celia Cronin
Quality Patient Safety Lead, South South West Hospital Group

Finola Cashman
Senior Administrative Officer, Quality Safety and Risk, Quality Assurance and Verification Division

Una Healy
Safety Manager, Quality & Safety Improvement Directorate, St. James's Hospital

Carol Hickey
Business and Performance Information Manager, Quality Assurance and Verification Division

Una McCarthy
Risk and Incident Compliance Officer, Primary Care Division

Cora McCaughan
Lead National Incident Management and Learning Team, Quality Assurance and Verification Division
(replaced by **Annette Macken** National Incident Management and Learning Team, Quality Assurance and Verification Division)

John McElhinney
Quality Patient Safety Lead, Saolta University Health Care Group

Pádraig McLoone
Risk and Incident Compliance Officer, National Social Care Division

JP Nolan
Head of Quality & Service User Safety, National Mental Health Division

Mary Rose O'Neill
Risk Manager, University College Hospital Galway

Brid-Ann O'Shea
Business Manager, Office of the National Director Quality Assurance and Verification

David Sutton
Programme Manager NIMS Phase 2

Angela Tysall
Lead in Open Disclosure, HSE Quality Improvement Division

Seirbhís Sláinte | Building a
Níos Fearr | Better Health
á Forbairt | Service

Incident Management Framework – Guidance

Care | Compassion | Trust | Learning

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Introduction

The following guidance has been developed to support services in applying the Incident Management Framework 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 Incident Management Framework.

Further guidance will be developed in response to service need. This guidance, along with any revisions of the guidance contained in this document will be made available on the HSE's internet page https://www.hse.ie/eng/about/QAVD/

Section 1 Terms and Definitions

Term	Definition
Accountability	Being answerable to another person or organisation for decisions, behaviour and any consequences.
Adverse Event	An incident which results in harm, that may or may not be the result of an error.
After Action Review	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.
Apology	"Apology", in relation to an open disclosure of a patient safety incident, means an expression of sympathy or regret *(Department of Justice and Equality's Civil Liability (Amendment) Act 2017)*
Audit	The assessment of performance against any standards and criteria (clinical and non-clinical) in a health, mental health or social care service.
Best Practices	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.
Case Officer	A case officer is a person, appointed by the SAO in advance of the SIMT meeting, to gather all available information relating to an incident. The case officer presents this information at the SIMT to allow a preliminary assessment of the incident to take place. This assessment is used to guide decision making in relation to review. Case officers are entirely independent and have no personal interest in the outcome of any cases.
Clinical audit	A quality improvement process that seeks to improve care and outcomes through systematic review of care against explicit criteria and the implementation of change.
Clinical Governance	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.
Commissioner	The role of the Commissioner is to establish the review, oversee its progress, sign off the final report and ensure that there are systems in place to monitor the implementation of recommendations made as a consequence of the review. In relation to Category 1 incidents and SREs this is generally the Senior Accountable Officer.
Competence	The knowledge, skills, abilities, behaviours, experience and expertise to be able to perform a particular task and activity.

Term	Definition
Complaint	The Health Act 2004 defines a complaint as: "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".
Complaint Manager	A person delegated by their organisation for the purpose of championing the feedback management process, including the routine monitoring and review of same.
Complaints Officer	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
Concerns and Enquiries	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.
Confidential Recipient	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 in good faith from patients, service users, families, other concerned individuals and staff members.
Contributory Factor	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.
Culture	The shared attitudes, beliefs and values that define a group or groups of people and shape and influence perceptions and behaviours.
Dangerous Occurrences	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)
Data	Data are numbers, symbols, words, images, graphics that have yet to be organised or analysed.
Effective	A measure of the extent to which a specific intervention, procedure, treatment or service, when delivered, does what is intended for a specific population.
Error	The failure of a planned action to be completed as intended or use of a wrong inappropriate or incorrect plan to achieve an aim.
Evaluation	A formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved.

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Term	Definition
Evidence	The consistent and systematic identification, analysis and selection of data and information to evaluate options and make decisions in relation to a specific question.
Fair Procedures and Natural Justice	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 and is known as *"nemo iudex in causa sua"*. It means that no person can judge a case in which they have an interest.
	The second rule *"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.
Family	An individual who is a parent, guardian, son, daughter, spouse or civil partner of the service user, is cohabiting with the service user, or has been expressly identified by the service user to the service provider as an individual to whom clinical information in relation to the service user may be disclosed. (Adapted from the definition of a connected person as per the *General Scheme on Open Disclosure-Periodic Payment Orders 2015*.) Family involvement is in line with the expressed wishes of the service user.
Harm	**Harm to a person:** 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 a patient safety incident. Degrees or levels of harm include:
	None – service-user outcome is not symptomatic or no symptoms have been detected and no treatment is required.
	Mild – service-user outcome 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.
	Moderate – service-user outcome 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.
	Severe – service-user outcome 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.
	Death – on balance of probabilities, death was caused or brought forward in the short-term by the incident.
	(As adapted from the World Health Organisation's Conceptual Framework for the International Classification of Patient Safety, 2009.)
	Harm to a thing: Damage to a thing may include damage to facilities or systems, for example environmental, financial, data protection breach etc.
Hazard	A circumstance, agent or action with the potential to cause harm.

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Term	Definition
Health Information	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.
Incident	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. Incidents can be clinical or non-clinical and include incidents associated with harm to: ■ patients, service users, staff and visitors ■ the attainment of HSE objectives ■ ICT systems ■ data security e.g. data protection breaches ■ the environment
Incident Review	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.
Incident type	A descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features.
Integrated Risk Management	A continuous proactive and systematic process to understand, manage and communicate risk from an organisation-wide perspective.
Just Culture	An environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action.
Key Causal Factor	Issues that arise in the process of delivering and managing health services which the review team considers had an effect on the eventual harm.
Look Back Review	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.
Monitoring	Systematic process of gathering information and tracking change over time. Monitoring provides a verification of progress towards achievement of objectives and goals.
National Incident Management System (NIMS)	The National Incident Management System, hosted by the Clinical Indemnity Scheme, 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.

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Term	Definition
National Incident Reporting Form	The National Incident Report Form (NIRF) 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 Circumstances)/Complaints.
Near Miss	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. *(National Standards for the Conduct of Reviews of Patient Safety Incidents)*
No Harm Incident	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.
Open Disclosure	Where a health services provider discloses, in accordance with Part 9 of the Department of Justice and Equality's Civil Liability (Amendment) Act 2017, at an open disclosure meeting, to: (a) a patient that a patient safety incident has occurred in the course of the provision of a health service to him or her, (b) a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient concerned, or (c) a patient and a relevant person that a patient safety incident has occurred in the course of the provision of a health service to the patient, that disclosure shall be treated as an open disclosure by the health services provider of that patient safety incident and *section 10* shall apply to: (i) the information, in respect of the patient safety incident, provided to the patient or relevant person (or both of them) at the open disclosure meeting, additional information provided at the additional information meeting and information provided in a clarification under *section 19*, (ii) an apology, in respect of the patient safety incident, where an apology is made at that meeting, or the additional information meeting. Open disclosure: information and apology not to invalidate insurance; constitute admission of liability or fault; or not to be admissible in proceedings *(Department of Justice and Equality's Civil Liability (Amendment) Act 2017)*
Patient Safety	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.

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Term	Definition

Patient safety incident	As defined in the Health Information and Patient Safety Bill Revised General Scheme (2015) a 'patient safety incident' means:
	
	(a) an incident which has caused an unintended or unanticipated injury, or harm, to the patient and which occurred in the course of the provision of a health service to that patient, or
	
	(b) an incident:
	
	  (i) which has occurred in the course of the provision of a health service to the patient and did not result in actual injury or harm, and
	
	  (ii) in respect of which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm, or
	
	(c) the prevention, whether by timely intervention or by chance, of an unintended or unanticipated injury, or harm, to the patient in the course of the provision, to him or her, of a health service, and in respect of which the health services provider has reasonable grounds for believing that, in the absence of such prevention, could have resulted in such injury, or harm, to the patient.

Patient safety data	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.
Person	This refers to individual people e.g. service users, patients, members of staff, carers, family members and visitors.
Person Affected	This refers to individual people e.g. service users, patients, employees, carers, families and visitors that may be affected as a consequence of an incident occurring.
Protected Disclosure	Protected Disclosure describes a procedure where employees, in good faith and where they 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 employees from penalisation as a result of making a protected disclosure in good faith in accordance with this procedure.
Pseudonymisation	The technical process of replacing service user labels (e.g. data items which identify service users, such as name, date of birth) in a dataset with other values (pseudonyms), from which the identities of individuals cannot be intrinsically inferred (adapted from Caldicott Guardian, NHS; 2009).
Reportable Circumstance	A situation in which there was significant potential for harm, but no incident occurred. (WHO Conceptual Framework for the International Classification for Patient Safety 2009).
Review Commissioner	The Commissioner of a review differs across the health system, but it is typically the Senior Accountable Officer in a service, division or care group that commissions an investigation of a clinical or non-clinical safety incident.

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Term	Definition
Reviewer	An individual who has training and experience in conducting reviews in accordance with HSE's Approaches to Reviews Guidelines
Risk	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. *(HSE Integrated Risk Management Policy 2017)* **Note:** in the context of incident management the objective is often service user and employee safety from harm.
Risk Management	One of a number of organisational systems or processes aimed at improving the quality of health care, but one that is primarily concerned with creating and maintaining safe systems of care
Risk Management Process	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.
Safety culture	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.
Safety Incident Management Team	A Safety Incident Management Team is convened by the Senior Accountable Officer in a service, division of care group, particularly for incidents of death and serious harm. The team is convened within 24 hours of the Senior Accountable Officer being informed of the incident. The Safety Incident Management Team may be an existing appropriate management team or a subgroup of an existing appropriate management team e.g. the Quality and Patient Safety Committee, Clinical Governance Committee or any other similar group provided that the team has a chair and appropriate membership.
Senior Accountable Officer	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. E.g. in a hospital group this could be the hospital manager or where services are organised on a cross hospital Directorate basis the directorate lead, in a CHO it could be the service manager and in the case of the NAS it could be the NAS corporate area manager.
Serious Harm	Harm that result in a rating of major or extreme as per the HSE's Risk Impact Table.
Serious Incident	An incident that results in a rating of major or extreme as per the HSE's Risk Impact Table.
Serious Reportable Event	Serious reportable events 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.
Service	Please note that the term "service" as used throughout these guidelines refers to all HSE health and social care services including services funded by the HSE.

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Term	Definition
Service Provider	(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 person social service on behalf of the Executive e.g. nursing homes, non-statutory Residential/Respite Homes/Centres etc.
	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 personnel social service by that person on behalf of the Executive.
	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;
	Contributing to the expenses incurred by the person or the body
	Permitting the use of 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.
	Providing premises (with all requisite furniture and fittings) for use by the body or the person.
Service User	The term "service user" used throughout this Framework includes patients and clients of the HSE and of services funded by the HSE.
Staff	(a) a person who:
	(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
	(ii) is (or was) placed for the purpose of vocational training with the health services provider, and
	(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;
	(In line with the definition of Employee as defined in the Department of Justice and Equality's Civil Liability (Amendment) Act 2017)
State Claims Agency	The National Treasury Management Agency 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.
Systems Analysis Review	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 the Key Causal Factors that the investigator(s) considered had an effect on the eventual adverse outcome, the Contributory Factors, and recommended control actions to address the Contributory Factors to prevent future harm arising as far as is reasonably practicable.

Section 2 Guidance on making decisions about appropriate pathways for investigation/review

This section of the guidance was developed by the Incident Management Co-Design Group in collaboration with the Human Resources Division and the Quality Assurance and Verification Division.

The HSE has a number of policies and procedures dealing with issues requiring investigation/review. In order to deal effectively and efficiently with issues requiring review it is critical that the correct investigation/review 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 care 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, would however be appropriately dealt with under the Incident Management Framework.
> - An isolated patient safety incident involving a staff member referred into HR that on examination 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 should 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 investigation/review, what is the most appropriate route for the investigation/review 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 investigation/review route as it might contain elements requiring differing investigation/review 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. Examples of this are provided in Box 2.

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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 care. In this case the complaints officer should, in line with governance arrangements, consult with the QPS manager and relevant service manager to propose an overall approach to management of the complaint. 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 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 Manager and based on the known facts and supported by use of the Incident Decision Tree, 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 with the potential to result in elder abuse opportunities, then a systems analysis may also be required. 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. 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[1]

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
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)	Relevant local policy developed in compliance with the requirements of the HSE Safety 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	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: ■ 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) ■ Safeguarding Vulnerable Persons at Risk Policy 2015 Where the allegation relates to non-staff refer to Manager of Older Persons Services to deal with complaint in line with: ■ Protecting Our Future (2002)
Concerns made to the Confidential Recipient (CR)	■ A preliminary written report is required within 15 working days from the relevant National Director from the date of receipt of the file from the CR. The preliminary report may indicate the need for a review/investigation under another policy/procedure.

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1   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.

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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	■ Safety Health and Welfare at Work Act 2005 ■ Grievance and Disciplinary Procedures for the Health Service (2014) ■ Dignity at Work Policy for Health Services (2014)
Complaints about bullying and harassment made against staff	Head of Discipline/HR to deal with complaint in line with some or all of the following: ■ Dignity at Work Policy for Health Services (2004) ■ Grievance and Disciplinary Procedures for the Health Services (2004)
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 to deal with the complaint in line with the Freedom of Information Act 1997 and 2003. Info@oic.ie
Complaints in relation to breaches of Data Protection Rights	Refer to Consumer Affairs Area Officer to deal with the complaint in line with the Data Protection Act 1988 and 2003. info@dataprotection.ie
Complaints in relation to Environmental Issues	Refer to local Environmental Health Office to deal with the complaint in line with some or all of the following: ■ Food Safety Authority of Ireland Act 1998 ■ European Communities (Hygiene of Foodstuffs) Regulations 2006 ■ Food Hygiene Regulations 1950-1989 Public Health (Tobacco) Acts 2002 & 2004
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
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.

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Details of Incident/Complaint/Allegation	Policy/Procedure, Guideline or legislation to be followed
Complaints about entitlements under Part 3, Chapter 9 of the Social Welfare (Consolidation) Act 2005	Refer to Health Service Executive Appeals Process/Social Welfare Appeals Office in relation to Basic Payments and Supplements
Disability Act (Part 2, Accessibility)	Refer to the HSE Disability Complaints Officer (Part 2) in line with the Disability Act 2005.
Disability Act (Part 3, Accessibility)	Refer to HSE Disability Complaints Officer (Part 3) in line with the Disability Act 2005.

Section 3 Incident Decision Tree – Guidance for Use

Introduction

The Incident Decision Tree (IDT) was developed by the National Patient Safety Agency (UK) to assist managers in making decisions around the actions required in the aftermath of an incident where there is uncertainty around the culpability of an individual staff member. Its use supports the promotion of a just culture.

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.

Use of the Incident Decision Tree

The Incident Decision Tree has been designed specifically for use following a patient safety incident rather than in situations such as breakdown in working relationships, poor general performance or absenteeism.

Individual accountability is in no way diminished by the use of the Incident Decision Tree, rather it helps organisations focus on the 'what' and 'why' rather than the 'who'.

The tool can be used for any employee involved in a patient safety incident, whatever his or her professional group. Ideally it should be applied as soon as possible after the incident while the facts are still fresh in people's minds. If new information subsequently comes to light, it can be worked through again and may or may not indicate a different outcome.

The Incident Decision Tree guides the user through a series of structured questions about an individual's actions, motives and behaviour at the time of the incident. These questions may need to be answered on the balance of probability i.e. determining the most likely explanation whilst taking into account the information available at the time, although the importance of pausing to gather data is emphasised. Each time you use the Incident Decision Tree, you need to work through each of four tests sequentially for each staff member involved in the situation under consideration.

The four sequential 'tests' are as follows:

- the Deliberate Harm Test
- the Physical/Mental Health Test
- the Foresight Test
- the Substitution Test

Possible reasons for the individual's action are reviewed against these four tests and the most likely explanation identified. Once you have worked your way through the tool you will be led to the appropriate **outcome box**. The outcome box will suggest a range of actions you might consider taking in the circumstances.

The tool does not seek to take away the manager's judgement by imposing firm answers or solutions. Rather, it emphasises that the outcome of a particular incident needs to be based on the review of individual circumstances. Indeed, the importance of the manager applying judgement rather than slavishly following the tool is emphasised.

The tool is best used at the time of preliminary assessment of the incident i.e. before an approach to review is decided. It is recommended that in cases where there is uncertainty about the management pathway to be followed that the tool be used as a focus of discussion between the line manager, the QPS Advisor and the Human Resources Manager.

Top Tips for use of the Incident Decision Tree

1. The tool is best applied by the line manager in conjunction with HR and QPS advice.

2. If the incident has just come to light and you are pausing to gather more information, check whether the individual is likely to present an immediate danger to patient safety and apply any protective measures that may be required.

3. Until preliminary information in relation to the facts relating to the incident are available, do not make assumptions about the incident, the individual's behaviour or motivation, the individual's ability to deal effectively with the situation, the effectiveness of protocols or procedures in place at the time the incident occurred.

4. Before you begin, gather as much evidence as you can but recognise that there could be situations where information proves sparse or inadequate. In these circumstances you may have to answer the question based on your best judgement.

5. The Incident Decision Tree can be worked through stage by stage. The questions do not have to be answered in one attempt. If you cannot answer a question it is important to pause and try to establish the facts.

6. Managers need to have reasonable information/evidence about a situation before taking action but do not need to establish proof beyond reasonable doubt.

7. Always record the facts you have gathered and the reasons used to arrive at your decision.

8. Work through the Incident Decision Tree separately for each employee and complete the full process i.e. apply all four tests to each case.

9. If you need further advice or support please contact your local risk advisor or Human Resources Manager.

INCIDENT DECISION TREE*

START HERE

Note: Work through the tree fully from left to right
and separately for each individual involved.

Yes
No

Deliberate Harm Test	Incapacity Test	Foresight Test	Substitution Test
Were the actions as intended?	Does there appear to be evidence of ill health or substance abuse?	Did the individual depart from agreed protocols or safe procedures?	Would another individual coming from the same professional group, possessing comparable qualifications and experience, behave in the same way in similar circumstances?
Were the adverse consequences intended?	Does the individual have a known medical condition?	Were the protocols and safe procedures available, workable, intelligible, correct and in routine use?	Were there any deficiencies in training experience or supervision?
		Is there evidence that the individual took an unacceptable risk?	Were there significant mitigating circumstances?

Deliberate Harm Test

Consult relevant regulatory/professional body

Advise individual to consult their staff representative body

Consider:

- Suspension
- Referral to Gardaí and disciplinary/ regulatory body
- Occupational Health referral

Highlight any System Failures identified

Incapacity Test

Consult relevant regulatory/professional body

Advise individual to consult staff representative body

Consider:

- Occupational Health referral
- Reasonable adjustment to duties
- Sick leave

Highlight any System Failures identified

Foresight Test

Advise individual to consult staff representative body

Consider:

- Corrective training
- Improved supervision
- Occupational Health referral
- Reasonable adjustment to duties

Highlight any System Failures identified

Substitution Test

Consult relevant regulatory/professional body

Advise individual to consult staff representative body

Consider:

- Referral to disciplinary/ regulatory body
- Occupational Health referral
- Reasonable adjustment to duties

Highlight any System Failures identified

Systems Failure
Review System

* Based on James Reason's Culpability Model.

Section 4 Writing a Personal Recollection of Events – Guidance for Staff[2]

Introduction

The main purpose of writing a personal recollection of events is for you to have a contemporaneous record of the event at a time when your recall of the event is fresh in your mind. This is useful in assisting you later particularly in the event of a decision being taken to conduct a review of the incident.

From the perspective of a review team, the availability of written Personal Recollection of Events from employees 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 also often allows the review team to limit the number of staff interviews that are required.

Written Personal Recollection of Events must be produced as soon as possible, but within 10 working days of the date of request. Ideally staff involved in a serious incident 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.

Personal recollections are records of fact so please ensure you are aware of the formal status of the document and read this guidance carefully before preparing and if required, submitting your recollection 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

You are responsible for ensuring that your Written Personal Recollection of Events is stored in line with good data protection principles i.e. securely and confidentiality. This is of particular importance if the recollection contains any information relating to individual service users which may be identifiable.

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 member of the review team.

In such circumstances, your recollection will be kept as part of the incident review file which will be stored by the organisation for 7 years and will be available to members of the review team.

You should be aware that the Personal Recollection of Events submitted by you as part of an incident review may be used to support further review of an event or other issue if this later becomes the subject of e.g. a complaint, an investigation under one of the HR procedures, or if a case is subject to a Coroner's Inquest, or a legal claim.

Incident information is within the remit of the Freedom of Information and Data Protection legislation and requests made under this legislation will be assessed balancing what is required to support the public interest versus the right to privacy of the individual.

The position in relation to information that must be released under Freedom of Information and Data Protection legislation is constantly evolving in line with decisions made by the Information Commissioner and all requests will be reviewed and considered on an individual basis.

Always ensure you retain a copy of your recollection of events.

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2   Adapted with kind permission of NHS Greater Glasgow and Clyde

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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, including dates of birth and any significant dates 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.
- 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 factual 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 leave it to them to say what they said or did. You must not express opinions or criticise colleagues.

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 medical 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) and what has been taken from the records.

Make reference to any policies, procedures and guidelines **relevant to the incident**, that you were aware of at the time of the incident. Where you deviated from these, provide an explanation for such deviations.

If you must 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 5 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.	The Standard Report Form available on the Tusla website should be used when reporting child protection and welfare concerns. http://www.tusla.ie/children-first/roles-and-responsibilities/organisations/report-a-concern. If a report is made by telephone, this form should be completed and forwarded subsequently to Tusla If a child is in danger outside office hours you can contact the Gardaí	All staff working with children and staff designated as mandatory reporters under the Children First Act 2015
Coroner's Office	There are a total of 32 instances in which death must be reported to the Coroner. These are listed on the Coroners Service Website http://www.coroners.ie/	Directly to the relevant Coroner Each County has a designated Coroner(s) and these are listed on the Coroners Service Website http://www.coroner.ie/en/CS/Pages/Coroner%20Contact%20Details	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 processor must be reported to the relevant data controller as soon as the data processor becomes aware of the incident. Certain breaches relating to the loss of personal data must be notified to the Data Protection Commissioner. https://www.dataprotection.ie/docs/Data-Security-Breach-Code-of-Practice/y/1082.htm	By completion of a Data Breach Incident Form submitted to the designated Data Controller in the area where the breach occurred	Designated Data Controller in the area where the breach occurred
Garda Síochána	Events of an allegedly criminal nature involving staff or child protection concerns.	Directly to the local garda station	Senior Site/Service Manager

Name of Body	What to report	How to report	Responsible Person
Health and Safety Authority	1. The death of an employee/other person if this is as a result of an accident at work or occurs within the workplace. 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. 3. The injury of a person involved in an incident/accident within the workplace who dies or sustains injuries requiring medical treatment. 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. 5. Designated incidents described as Dangerous Occurrences as listed by the HSA. For further information in relation to the above consult the HSA Website. http://www.hsa.ie/eng/Publications_and_Forms/Publications/Safety_and_Health_Management/Accident_and_Dangerous_Occurrences_Reporting.pdf	IR1 form for items 1-4 and IR3 form for item 5 Both forms available on-line from www.hsa.ie	Senior Site/Service Manager
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 https://www.hiqa.ie/guidance-providers/disability-services/notification-forms	By email using the appropriate notification form, or Via the on-line provider portal https://www.hiqa.ie/guidance-providers/disability-services/notification-forms	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 https://www.hiqa.ie/guidance-providers/older-persons-services/notification-forms	By email using the appropriate notification form, or Via the on-line provider portal https://www.hiqa.ie/guidance-providers/older-persons-services/notification-forms	The registered provider or person in charge of the designated centre

Name of Body	What to report	How to report	Responsible Person
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 https://www.hpra.ie/homepage/medical-devices/safety-information/reporting-safety-issues	Line Manager in whose area the incident occurred
Health Products Regulatory Agency	**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. Of particular importance to report are; ■ 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. ■ Serious suspected reactions to established medicines. ■ Any suspected increase in the frequency of minor reactions. ■ Any suspected teratogenic effects. ■ Any suspected reactions associated with the use of vaccines or medicines used in pregnancy.	Form and on-line reporting available at https://www.hpra.ie/homepage/about-us/report-an-issue	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 https://www.hpra.ie/homepage/about-us/report-an-issue	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.	Downloadable report form available at https://www.hpra.ie/homepage/about-us/report-an-issue This form should also be emailed to Organ Donation Transplant Ireland nops@hse.ie. For more information see http://www.hse.ie/eng/about/Who/organdonation/qualityandsafety/	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. http://www.hpsc.ie/NotifiableDiseases/ListofNotifiableDiseases/	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. http://www.hpsc.ie/NotifiableDiseases/NotifyingInfectiousDiseases/	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
Maternal Death Enquiry (MDE)	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" 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". 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". 4. Coincidental (Fortuitous) Maternal Deaths which are defined as: "Deaths from unrelated causes which happen to occur in pregnancy or the puerperium". 5. Late Maternal Deaths which are defined as: "Deaths occurring between 42 days and 1 year after abortion, miscarriage or delivery that are the result of Direct or Indirect maternal causes". * This term includes delivery, ectopic pregnancy, miscarriage or termination of pregnancy.	Maternal Death Notification form available from: Maternal Death Enquiry office: 5th floor, Cork University Maternity Hospital Wilton, Cork Tel: 021 4205042 E-mail: mdeireland@ucc.ie	Identified MDE hospital coordinators

Name of Body	What to report	How to report	Responsible Person
Medical Exposure Radiation Unit	Radiation incidents to patients. Incidents above a threshold level where the wrong patient received a radiation dose or received a dose much greater than intended. Guidance in relation to this can be accessed on this link. https://www.hse.ie/eng/about/Who/qualityandpatientsafety/safepatientcare/medexpradiatonunit/Incident%20reporting.html	Medical Exposure Radiation Unit at 01 6201624 Email meru@hse.ie	Radiologist in charge Radiation Protection Advisor Radiation Safety Committee
Mental Health Commission	Approved centres are required, under Article 14(4) of the Mental Health Act 2001 (Approved Centres) Regulations 2006 to notify the Commission of all deaths of any resident of an approved centre within 48 hours of the date of occurrence. All mental health services are required to notify the Commission of all sudden and unexplained deaths of any person availing of/in receipt of a mental health service or recently discharged (within four weeks of the date of occurrence) from a mental health service and not in receipt of a mental health service within 7 days of the date of occurrence.	Via the Mental Health Commission's Death Notification Form which is available online http://www.mhcirl.ie/for_H_Prof/Forms/ Forms should be submitted by email to mentalhealthdata@mhcirl.ie	Treating Consultant Psychiatrist
Mental Health Commission	Summary incident reports are required on a six-monthly basis.	Via the Mental Health Commission Summary Incident Report template which is available online http://www.mhcirl.ie/for_H_Prof/Forms/ or an extract from the NIMS system (MHC report template) Forms should be submitted by email to mentalhealthdata@mhcirl.ie	Registered Proprietor or person with delegated responsibility

Name of Body	What to report	How to report	Responsible Person
Mental Health Commission	Approved centres are required to notify the Commission of any Serious Reportable Event (SREs) involving any resident of an approved centre, within 48 hours of the date of occurrence/detection. SREs are as defined in the HSE's National SRE list.	SREs resulting in death via the Mental Health Commission's Death Notification Form All other SREs via the Mental Health Commission's Serious Report Event Notification template. Forms are available online http://www.mhcirl.ie/for_H_Prof/Forms/ Forms should be submitted by email to mentalhealthdata@mhcirl.ie	Registered Proprietor or person with delegated responsibility
National Haemovigilance Office	Incidents relating to severe adverse reactions and events relating to blood component administration.	Notifiable to the NHO as soon as possible using the Initial Report Form (IRF) (this is available on the NHO webpage accessed through www.giveblood.ie clicking on clinical services tab and choosing Haemovigilance. 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 blood components from a donor which may remain in stock. In this case notification is initially made by phone, followed by the completion of an IRF.	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	Form available from https://www.giveblood.ie/Clinical_Services/Haemovigilance/Reporting_to_the_NHO/Initial-Report-Form-V4-.pdf For guidance on completion contact 01 4322825/01 4322741 or haemovigilance@ibts.ie	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 Report Form V2 Hospital Blood Bank Near Miss Confirmation Report Form V2	Transfusion Surveillance Officer in conjunction with Consultant Haematologist/ Pathologist or patient's Primary Consultant
National Perinatal Epidemiology Centre (NPEC)	Perinatal Mortality – All stillbirths, early and late neonatal deaths arising from births within the calendar year. Still births are defined as: "Baby delivered without signs of life from 24 weeks gestation or with a birth weight ≥500g". Early Neonatal Deaths are defined as: "Death of a live born baby occurring within 7 completed days of birth". Late Neonatal Deaths are defined as "Death of a live born occurring after the 7th day and within 28 completed days of birth".	Electronic submission via the NPEC Perinatal Mortality online database or by paper format on the Perinatal Death Notification Form available on the NPEC website: http://www.ucc.ie/en/ npec/npec-clinical-audits/	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
National Perinatal Epidemiology Centre (NPEC)	Severe Maternal Morbidity – Any woman experiencing one of 16 reportable severe morbidities during pregnancy or within 42 days following the pregnancy end. Reportable morbidities are defined in the reference manual and include: major obstetric haemorrhage (≥ 2,500 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.	Electronic submission via the NPEC Maternal Morbidity online database or by paper format on the Maternal Morbidity Notification Form available on the NPEC website: http://www.ucc.ie/en/ npec/npec-clinical-audits/	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

Name of Body	What to report	How to report	Responsible Person
National Perinatal Epidemiology Centre (NPEC)	Mid-trimester prolonged rupture of membranes: and delayed interval delivery in premature multiple pregnancy 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. 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.	NPEC paper template – supplied by the NPEC.	Identified NPEC hospital co-ordinator within maternity units
Office of Radiation Protection and Environmental Monitoring, Environmental Protection Agency	Radiation incidents to staff or members of the public. ■ Any incident involving the unintended exposure of a person arising from a design flaw, incorrect calibration or malfunction of a licensed item. ■ 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. ■ 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.	Contact the EPA, www.epa.ie tel. (01) 268 0100	Radiologists in Charge, Radiation Safety Committee and/or relevant local processes
State Claims Agency	Personal injuries (including clinical adverse events) Property damage (including motor vehicle) http://stateclaims.ie/contact-us/reporting-events-or-incidents/	Via NIMS	Local QPS/Risk Manager in whose area the incident occurred

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Section 6 Serious Incident Management Team (SIMT) Guidance

Introduction

The SIMT has a key role in the overseeing the management of Category 1 incidents and SREs. In Community Healthcare Organisations a SIMT should be in place at each Head of Service level with the Head of Service delegated with responsibility for the role of the Senior Accountable Officer (SAO). In Hospital Groups, depending on the management arrangement in place, the SIMT can either sit at Hospital site level or at the Group Clinical Directorate level where this is the management arrangement across the Hospital Group.

Role of the SAO in relation to convening a SIMT Meeting

On notification of a Category 1 incident the SAO will directly assure themselves in relation to the immediate actions taken to manage the incident. They will then move to schedule a meeting of the SIMT. The scheduling of this meeting must enable decisions relating to the review of Category 1 incidents to be made in a timely manner. Ideally such decisions **should be** made within 72 hours of identification of the incident and at latest **must be** made within one working week following identification.

In order to assist decision making at the SIMT, the SAO on notification of the incident should assign a case officers, for example the Quality Patient Safety (QPS) Advisor or equivalent, who will engage with relevant staff to identify and gather preliminary information related to the incident.

The case officer(s), will use this to prepare a short case report outlining available factual information relating to the incident, for presentation at the SIMT meeting. (See Part A of the Preliminary Assessment Form on page 33)

For example in relation to a service user incident, the case report should at a minimum consist of the following presented using the SBAR communication framework:

Situation – to include detail of the current status of the person affected, assurance that all immediate actions required by Step 2 and Step 3 of the Incident Management Process have been addressed and detail of any meeting held with the service user/family, the outcome of this and the expectations expressed by them.

Background – background detail relating to the service user e.g. their age, pre-existing health status and reason for contact with/admission to the service. A brief chronology leading up to the incident should also be provided.

Assessment – a summary assessment of the above focusing on the adequacy of actions taken to date. This will assist the SIMT in identifying any outstanding actions required to ensure the appropriate management of the incident.

Recommendation – based on the above and the judgement of the case officer, provide a recommendation to the SIMT in relation to the further management of the incident.

Consideration may be given to inviting the nominated patient and staff liaison persons to SIMT meeting as though they will not necessarily be central to the decision making process, they will be central to the communication of the decision taken, to relevant stakeholder groups after the meeting.

Role of the Serious Incident Management Team

Whilst in many organisations the SIMT is a standing group that meets on a regular and scheduled basis to oversee and report on the management of serious incidents to the SAO, they will also need to meet on an unscheduled basis in the event of a Category 1 incident being notified to the SAO. Members of the SIMT must be impartial and sufficiently removed from the incident and in the rare event a member is conflicted they must declare this and absent themselves from the deliberative and decision making process of the Team.

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Their role therefore includes the following:

1. To meet within 72 hours – one working week of the notification of the incident to the SAO.
   Note: Depending on the nature of the incident the SAO may decide to convene this meeting earlier than 72 hours.

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 others. Where adequate assurance is not provided, they should agree and communicate the need for any further actions that may be required.

3. To receive and consider the report of the case officer e.g. Quality and Safety Advisor.

4. To make recommendations to the SAO in relation to the further management of the incident in line with the requirements of the HSE's Incident Management Framework.

5. Once a review is commissioned, to receive monitoring reports on the progress of the review to ensure it is completed within the prescribed timeframe.

6. Where delays to the review process are identified, to recommend remedial action and where required to advise the SAO of issues requiring his/her attention.

7. To receive the final draft report of the review and consider in the context of the **Governance Approval Process for Finalising the Review Report (IMF Guidance Section 13)** and to recommend (or not) acceptance of the report to the SAO.

8. In the case of multi-incident reviews or where there are other review/investigation processes running concurrently to an 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.

Membership of SIMT

At a minimum, membership of the SIMT should involve the participation of the following:

- SAO or their nominee.
- Nominated members of the executive management team e.g. Clinical Director, Director of Nursing.
- HR manager.

The QPS Advisor is in attendance at the SIMT to present the case report and to provide technical advice in relation to the on-going process.

Depending on the nature of the incident it may be decided to involve others e.g. clinical expertise relating to the incident, health and safety manager/officer etc.

Timeframe for Decision Making in relation to Review

The SIMT must take a majority decision in relation to whether or not a review is required and where it is identified that a review is required, to decide on the level and approach to review. The decision regarding the plan for review (or not), **should ideally be made** within 72 hours and at latest **must be made** within one working week, of the notification being made to the SAO.

In the period between the service user and/or family and staff becoming aware of the incident and the decision being made around the plan for review, the importance of on-going communication and support is critical as this is often the time when it may be perceived that they have been left isolated by the service and are not aware of what is going on.

Note: the SAO may decide to convene the SIMT earlier depending on:

- The seriousness of the incident,
- Whether the nature of the incident indicates that this would enhance the effective management of the incident, or
- Whether there was a low level of assurance provided in relation to the robustness of actions taken in relation to the immediate management of the incident.

At the SIMT Meeting

The case officer(s) will present the case report to the SIMT members present Part A of the Preliminary Assessment Form (see page 33).

The first consideration for the SIMT is to identify whether the incident should be primarily 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 pathways** guidance **(IMF Guidance Section 2)** may support decision making in this regard. If there are concerns in relation to individual culpability that might indicate that the incident may not be suitable for review in the context of the Incident Management Framework, the SIMT should use of the **Incident Decision Tree (IMF Guidance Section 3)** to support decision making in this regard.

Options for decision making

1. In the event that a decision is taken that **it is appropriate** to review the incident using the Incident Management Framework, the SIMT should then move to consider the following:

   - Level of Review (including methodology).
   - Level of independence of the Review.
   - Commissioner of the Review (except in exceptional circumstances, for Category 1 incidents this should be the SAO).
   - Scope of the review.
   - Who will be assigned to undertaken the review (named roles but not named individuals).
   - Support requirements for persons affected and the review process.

   The decision to recommend a review and the supporting information i.e. the rationale, the recommendation and detail of the review process recommended is documented on Part B of the Preliminary Assessment Form (see page 33) and forwarded to the SAO for endorsement. If the SAO is part of the SIMT this endorsement can be provided at the time of the meeting.

2. The recommendation of the SIMT may be, **not to commission a review** and refer it back for continued management to the service within which it occurred or recommend that it be reviewed using an alternate management pathway or process.

   This decision must be formally documented along with detail of the reason/rationale upon which the decision was made. The documented decision along with any supporting documentation must be forwarded to the relevant Quality and Safety Committee (or an equivalent). The relevant Quality and Safety Committee (or equivalent) will review and ratify or reject the recommendation at their next meeting. In circumstances where the decision is rejected by the Quality and Safety Committee, this should be endorsed by the SAO with both a reason for this and a recommendation for further management.

3. In the event that it is recommended that it is appropriate to **both manage the incident** using the Incident Management Framework **and via** one or more other pathways the SIMT should also make a recommendation in relation to the scheduling of these processes. **(IMG Guidance Section 2)**. This should be documented and endorsed by the SAO for implementation.

4. In exceptional circumstances a decision in relation to review may not be reached at the SIMT meeting and it may be decided to defer the decision for review pending receipt of further information e.g. a **Healthcare Record Review (IMF Guidance Section 7)**. Arrangements must be made to obtain any information required 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.

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Following the SIMT meeting

Making the Decision in relation to the Review

Where the SAO accepts the recommendation of the SIMT, he/she should move to commission and establish the review by developing the Terms of Reference and appointing the review team. In cases where the SAO does not accept the recommendation he/she must document this, the basis for rejection of the recommendation and identify what alternate plan is to be put in place.

Communicating the Decision

Persons affected should be advised of the decision of the SAO and where it has been decided to commission a review they should also be advised:

- Of the level and approach to the review.
- That their concerns or perspectives 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 **recollection of events (IMF Guidance Section 4)**.
- That any supports required to assist them will be put in place for the duration of the review process.

Monitoring Progress of Commissioned Reviews

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

To assist in achieving the relevant timeframe, SIMTs should have in place a system for monitoring the progress of all reviews that are commissioned within their area of responsibility. Where it is noted that the timeline for the completion of a review will not be achieved, the SIMT should take or recommend actions to bring it back on track or mitigate the risk of further delay. Issues of significance should be notified to the SAO who has ultimate accountability for the management of these reviews.

Review of Final Draft Reports

The SIMT has a role in recommending acceptance of the final report to the Commissioner and in so doing need to be assured in relation to the quality of the report and the integrity of the process applied to the review. The **Governance Approval Process for Finalising the Review Report** should be should be used to inform this **(IMF Guidance Section 13)**.

Preliminary Assessment to assist review decision making

(Guidance in Green Font should be deleted on completion)

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

Incident Details	
NIMS Ref No:	Date entered on NIMS:
Date of Incident:	Incident Category:
Date Notified to SAO/Local Manager:	
Date of SIMT/Review decision meeting:	

Situation	Include here 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 support needs of persons affected i.e. service users, families and staff. ■ That Open Disclosure has been initiated or if not that an explanation of why not, is provided. ■ Detail of any questions or issues raised by the family 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. ■ That named service user/family and staff liaison persons have been appointed. ■ Detail of any meetings with the service user/family.
Background	Include here detail of; ■ The background to the service user e.g. their health status and reason for admission/attendance. ■ A brief chronology of the events leading up to the incident.
Assessment	Include here a summary assessment of the above focusing on the adequacy of the actions taken to date. The purpose of this is to identify any areas where action is outstanding or required to provide assurance that the incident is being adequately managed.
Recommendation	Based on an assessment of the information above provide here a recommendation to the SIMT/review decision making meeting in relation to further action required, the level and approach to the review and the level of independence attaching to the proposed review process.
Name of Person completing Part A	

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

Management of incident to date

Based on the report of the Case Manager and discussions at the meeting include here an assessment of the adequacy of actions taken or planned in relation to the incident. Include also detail of any further actions required.

Appropriate Pathway for Review of Incident Reported

Having considered the case report is the SIMT/review decision making meeting satisfied that the incident is appropriately reviewed under the Incident Management Framework?

Yes ☐　　No ☐

If No, indicate which alternate review/investigation route is most appropriate. (see Making decisions about appropriate investigation pathways guidance).

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

Information required for decision making

Is further information required to assist a decision to review?　　Yes ☐　　No ☐

If Yes please Indicate the type of information required

HealthCare Record Review　☐

Other: Specify:

Decision to Conduct a Review under the Incident Management Framework

Please indicate the decision in relation to the level of review to be conducted:

Comprehensive Review　☐

Concise Review　☐

No Review　☐

Comprehensive Review

If the decision is to commission a Comprehensive Review, indicate whether this will be by way of:

Review Team approach　☐

Review Panel approach　☐

The Final Report of the Comprehensive Review must be accepted by the Commissioner within 126 days of occurrence of the incident.

Concise Review

If the decision is to commission a Concise Review, indicate whether this will be by way of:

Multi-disciplinary team review	☐
After Action Review	☐
Incident Specific Review Tool	☐
Desk-top Review	☐

The Final Report of the Concise Review must be accepted by the Commissioner within 126 days of the occurrence of the incident.

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

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 here

No Review

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.

Decisions not to review must be:
- *Communicated to person affected i.e. service user, family and staff.*
- *Submitted for review and ratification by the Quality & Safety Committee.*
- *Entered onto NIMS and this should include the reason and rationale for same.*

These incidents should be included in an Aggregate Review process.

Level of Independence attaching to the review	Please Tick
1. Team internal to the team/department/NAS Operational Region	☐
2. Team internal to the service/hospital/NAS Operational Area	☐
3. Team external to the service/hospital but internal to the CHO/HG/NAS Operational Area	☐
4. Team involve persons external to the CHO/HG/NAS Operational Area	☐

Contacts in relation to the review process
Commissioner of the Review
Title
Email
Telephone
Service User Liaison Person
Title
Email
Telephone
Staff Liaison Person
Title
Email
Telephone

Category 1 Incidents
Signature of Senior Accountable Officer (SAO)
SAO Name [Block Capitals/Typed Text]
Title:
SAO Email:
Telephone No:
Date:

Section 7 Healthcare Record Review Guidance

In the context of the incident management process it may be necessary to seek an independent 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 to the service user. This may be done either:

- To support decision making as to whether a review is required e.g. where 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 which had been identified as required.

The decision to make a request for Healthcare Record Reviews should be approved by the Senior Accountable Officer or his/her designate. 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.

It is therefore essential that in requesting the report, the reviewer is clear about the purpose for which the report is being requested e.g. that it is to support the decision making in relation to whether an incident has occurred or to support the conduct of an incident review under the Incident Management Framework. This is important as whilst Healthcare Record Reviews for use to support the Incident Management Framework focus on the episode of care provided from a service user safety perspective, independent reports can also be requested 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.

The following template is provided to assist services in framing such a request in order to assist the person to whom the request is made.

7.1 Template request for an independent healthcare record review

Request for the provision of a Healthcare Record Review in relation to the care provided to
Name of service user
Requestor details
Background to Request Brief description of the case and the concerns raised which prompted this request.

Terms of Reference

1. To receive and consider the following documentation relating to the **care of xx** from her/his admission on **XX/XX/XX** to her/his death/discharge on **XX/XX/XX** (list the documentation provided below)
   - *Yy*
   - *Zz*

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/family with the hospital/service 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 writer.
   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 writer (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:

Section 8 Approaches to Incident Review Guidance

Introduction

Key to the development of safe services is the creation of a culture where safety is seen as a priority to staff at all levels of the organisation. The manner in which an organisation responds in the aftermath of an incident provides an insight into the extent to which such a culture exists.

This is of particular importance when it comes to the review of incidents and services therefore need to align their response to incidents to the HSE values of Care, Compassion, Trust and Learning. Core to this is, rather than viewing the review process as negative or even adversarial, 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.

This guidance seeks to set out 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.

A number of 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. Such an approach seeks 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;

Table 1.

Level of Review	Approaches to Review
Comprehensive	1. Systems Analysis (Review Team approach) 2. Systems Analysis (Review Panel approach)
Concise	1. Systems Analysis (Facilitated Multidisciplinary Team approach) 2. Systems Analysis (Desktop approach) 3. Incident Specific Review Tool e.g. Falls and Pressure Ulcers 4. After Action Review (AAR)
Aggregate	1. Systems Analysis (Aggregate approach)

With the exception of AAR all approaches utilise a systems analysis methodology. The application 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.

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Regardless of the approach adopted Systems Analysis focuses 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 any actions required to reduce the risk of a similar incident recurring. Such an approach has been shown as most effective in improving safety. The application of systems analysis using a variety of levels and approaches is consistent with international practice.

The purpose of this guidance is to provide services with an overview of each approach.

Locating Reviews

Regardless of the approach to review adopted, all reviews must have clear governance arrangements in place. This is essential both 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.

What is the difference between a Comprehensive and a Concise Approach to Systems Analysis?

Table 2 below sets out the key differences between the Comprehensive and Concise[3] approaches in terms of the people involved, the time taken, the process used and the outcome. It is important also to note that though the process for the conduct of the review varies between Comprehensive and Concise they should both result in a standard style of report.

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3   Adapted from the WHO Patient Safety Programme, Concise Incident Analysis Draft Methodology, October 25, 2012

Table 2.

Action	Concise	Comprehensive
Should include person(s) with knowledge of incident analysis, human factors and effective solutions development	✔	✔
Often conducted by an individual (such as a QPS Advisor) with input gathered from staff and clinicians local to the event.	✔	
Conducted by an interdisciplinary medium to large ad hoc group (includes staff and clinicians local to the event as well as recognised independent internal or external experts*/consultants not involved in the incident). The group is facilitated by a person(s) with knowledge of incident analysis, human factors and effective solutions development. * *External experts – experts that are external to the incident but not necessarily external to the participating hospital/hospital group*		✔
Time taken for analysis	Short timeframe (2-6 weeks)	Long timeframe (120 days)[4]
Identifies causal and contributing factors as well as remedial actions(s) taken (if any) and recommendations for improvement	✔	✔
Principles of incident analysis	Reflects the intent, but may not address all	Incorporates all principles
Is cognisant of the principles of natural justice and fair procedures	✔	✔

Steps in the Systems Analysis Review Process

Irrespective of the approach used, the process consists of six steps.

Step 1: Organise the review and gather the data

Step 2: Determine the incident chronology

Step 3: Identify the key causal factors and incidental findings

Step 4: Identify the contributory factors

Step 5: Make recommendations

Step 6: Prepare a report and submit to the person requesting the review[5]. All reports are pseudo-anonymised in relation to the names of persons and the locations of services.

Concise approaches to systems analysis

Concise approaches to incident review are most commonly used for **Category 2 incidents** and some SREs (particularly service user Falls and Pressure Ulcers not resulting in death.)

There are four approaches designated by the HSE for the conduct of concise reviews. Unlike Comprehensive Reviews which require commissioning by the SAO, the decision to conduct a Concise Review is most often taken by the manager of the service.

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4   Whilst 120 days is the timeframe for completion of all commissioned reviews it is accepted that due to the nature of some reviews this timeframe may be breached. The HSE will therefore set an annual target for completion of reviews within 120 days.

5   In the case of a serious incident the person requesting the review will be the SAO (the Commissioner) in other instances it may be relevant service manager.

The relevant manager must agree the scope of the review and the methodology to be used with the person leading or facilitating the conduct of the review. It is recommended that this be documented.

1. Systems Analysis: 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 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 pre-meeting preparation by the facilitator (a person possessing both, knowledge of systems analysis and skills in group facilitation) to:

- Engage with the service user/family to gain their input into the process and if required to gain their consent for access to clinical records,
- Engage with the service where the incident occurred to gain their support for participating in the process. This may include having informal discussions with individual staff about the circumstances relating to the incident.

The person facilitating the review should be sufficiently independent from the matter under review.

Conducting a Facilitated Multidisciplinary Team Approach

Assuming there is agreement to proceed with the process the following steps are taken.

Prior to the meeting

1. If indicated, request and receive an independent review of the healthcare record.
2. In partnership with the service, identify the scope of the review and the staff to be invited to participate.
3. Agree a date, time and suitable venue for the meeting.
4. Advise relevant staff of the plan for review, the scope of the review and invite them to attend. Ensure that they are facilitated by the service to attend.
5. Draw up a high level chronology of events from available documentation along with any other relevant information e.g. the discussions held with the service user/family and staff.
6. Provide staff attending the meeting with a copy of the draft chronology.

At the meeting

The facilitator should open the meeting by setting 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.

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The aim is, through open discussion and using a systems analysis approach:

- to agree the chronology of events that led up to the incident.
- to identify and agree any key causal factor(s) that led to the incident occurring.
- using the Yorkshire Contributory Factors Framework to identify the factors that contributed to the key causal factors.
- to identify any incidental findings.
- to identify any areas of good/commendable practice.
- to address any questions/queries raised by the family that were not already considered in the review process.
- to identify and agree any recommendations that are required to improve safety and reduce the risk of an incident from similar causes occurring in the future.

Following the meeting

- The facilitator writes up a draft report (see page 52 for Review Report Template).
- The draft report is circulated back to the manager of the service for review by staff participating in the process for factual accuracy checking and comment.
- Following consideration of any feedback received from staff a final draft report is prepared.
- A meeting is held with the family to discuss the report and ensure that any issues raised by them have been considered and the outcome of this is reflected in the report.
- The report is finalised and presented to the person who requested the review e.g. the Commissioner.
- The service develops an action plan to implement the recommendations and this is reflected in their overall quality improvement plan for monitoring.

Strengths

- It applies the principles of systems analysis in a way that is proportionate and responsive.
- It supports patient safety by identifying the key causal factors of incidents and the factors that contributed to these.
- It engages with the team in a way which is inclusive, participative and solution focused.
- It assists in developing a culture where safety management is a priority of the team, as it requires them to reflect on the issue in a manner which takes account of the incident from multiple perspectives.
- As the analysis and any improvements identified are 'owned' by the team it will assist in supporting their implementation.
- It is practical and results in a concise report which can be provided to relevant stakeholders.

Weaknesses

- Whilst focusing on a timely and proportionate response, the compromises involved may mean that more subtle causes of the incident or issue aren't detected and therefore aren't corrected.
- It may not be perceived by service users/families as sufficiently independent.

2. Systems Analysis: Desktop approach

Application of systems analysis using this approach is most commonly used for incidents which have occurred in the significant past. A desktop approach is used in this instance as it is unlikely to be able to utilise staff testimony either by way of available written recollections or by interview owing to the passage of time or staff availability e.g. staff may have retired or left the service. Where staff are still available they should be advised of the plan to conduct the review and invited to submit a written recollection of events if they wish.

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The review will be conducted 'at the desktop' by a single reviewer experienced in systems analysis who has been provided with a terms of reference (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/family involvement can be included through the reviewer meeting with the service user/family 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 and the likely timeframe for completion of the review.

Having considers the available information the reviewer will:

- Develop a high level chronology of events that led up to the incident.
- Consider the report arising from the independent Healthcare Record Review or other expert report requested.
- Identify any key causal factor(s) that led to the incident occurring.
- Using the Yorkshire Contributory Factors Framework will consider the factors that contributed to the key causal factors occurring.
- Identify any incidental findings.
- Identify any areas of good/commendable practice.
- Address any questions/queries raised by the family 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.
- Develop a draft concise report using the Review Report Template (see page 52).
- Circulate the draft report in the first instance to any person who provided an independent Healthcare Record Review or other expert report to ensure that their opinion has been accurately reflected in the report.
- In the instance where negative criticism or an adverse finding may be made in respect of a staff member (current or former) and in line with the principles of natural justice and fair procedures, the draft report must be provided to them at this point for their review and opportunity to comment.
- Following this the draft report is circulated for factual accuracy review 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/family 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 Commissioner to provide a copy of the report to the service user/family.
- The service develops an action plan to implement the recommendations and this is reflected in their overall quality improvement plan for monitoring.

Strengths

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

Weaknesses

- 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 review to known risks and that the more subtle causes of the incident or issue aren't detected and therefore aren't corrected.

3. Systems Analysis: Incident Specific Review Tool

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.

These tools include a preliminary assessment and decision making process to identify which incidents require review and then provide a standardised concise review process. The tools are designed so that the preliminary assessment carried out by a line manager feeds forward into the review process which is carried out with the support of the local QPS advisor. The review focuses on identifying factors which contributed to the key cause in order to identify recommendations to reduce the risk of recurrence.

Each tool contains guidance on its use including the involvement of service users/families. The incident specific review tool can be applied using a multidisciplinary team or desktop approach.

Strengths

- It supports patient safety by identifying the key causal factors of incidents and the factors that contributed to these.
- 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.

Weaknesses

- 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.

4. After Action Review

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. AAR is an intervention that is undertaken soon after the incident occurs that seeks to understand the expectations and perspectives of all those staff involved. It generates insight from the various perspectives of the multidisciplinary team, enables lessons learned to be identified and leads to greater safety awareness, changes to team behaviours and assists in identifying actions required to support safety improvement.

AAR exists to create both individual and team opportunities to improve personal, team and organisational performance.

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AAR is a flexible tool which can be applied in a number of situations e.g.

- As a briefing tool when planning for a specific event or more generally at the start of the team's work day. In this case the team will use AAR to gain a common understanding of the plan, critical steps to be taken and expected results. They will ask 'what if' questions, agree actions, confirm the team's understanding of these and plan for a de-brief after the event or shift.

- For use as a process for teams to debrief/learn in the immediate aftermath of an incident. **Note:** Where AAR is used by the team to de-brief in the aftermath of a serious incident and where a comprehensive review is also required, the AAR meeting and its outcome should not be used as a primary source of evidence for the comprehensive review process.

- For use as a review methodology for incidents which do not reach the threshold of rating as 'serious' or for serious incidents which, following an initial assessment, a decision has been taken that a comprehensive review is not indicated i.e. where it has been determined that a concise review is more appropriate.

- To review and debrief on situations where there was a positive outcome i.e. to better understand what were the key factors/actions that led to the positive outcome so there is an opportunity for the team to reflect the learning this event offers.

AAR works best in situations where there is a positive, psychologically safe, multidisciplinary team dynamic and an openness to discuss the event. It differs from a multidisciplinary team review in that it is not structured using a systems analysis approach. It is structured around four key questions that are asked of staff attending the event. These are:

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

Detailed guidance for managers and facilitators on the application of AAR are available and a training course for facilitators has been developed.

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 & 3 hours.

The report (usually 2-3 pages) will generally take a further day or two to draft and circulate (see AAR Report Template). Two weeks is provided for feedback and the report is then finalised and provided back to the service. A meeting should be arranged with the service user/family to present the report and discuss its findings.

Strengths

- It is a responsive and timely approach to review.
- There is a high level of team involvement in the process which results in a high level of ownership in the outcome.
- If it is facilitated by a person independent of the service it can be seen as more objective.

Weaknesses

- If it is not facilitated by someone sufficiently removed from the incident it can be seen as lacking independence.
- It does not result in a detailed analysis of the factors which caused or contributed to the event.
- It may not be suitable for use in services if there is not a positive multidisciplinary team dynamic and an openness to discuss incidents.

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Comprehensive approaches to systems analysis

Comprehensive approaches are most commonly used for the review of **Category 1 incidents**. They therefore require commissioning by the SAO i.e. development of a TOR and the appointment of a review team/panel.

There are two approaches designated by the HSE for the conduct of comprehensive reviews. Details of these are set out below.

1. Systems Analysis: Review Team Approach

The review team consists of at least two people, one of whom is trained in systems analysis. Depending on the nature of the incident the review team may also require nomination of an external clinical expert to answer a specific clinical or technical question and/or validate a final draft report to ensure clinical/technical accuracy and that it addresses the clinical/technical issues identified. In exceptional circumstances they may be requested to participate as a member of the review team.

This approach follows the **HSE's Systems Analysis: Review Team Approach Guideline 2017** which should be used when conducting a review using this approach. A copy of this guideline is available on the HSE Internet – www.hse.ie

Strengths

- It is comprehensive and thorough and incorporates all the principles of systems analysis.
- It supports patient safety by identifying the key causal factors of incidents and the factors that contributed to these.
- It makes recommendations which when implemented will improve safety.
- It adopts a high level of impartiality and rigor.

Weaknesses

- Reviews using this approach can take considerable time and resources and as such may not provide a timely response to those affected.
- The formality of the approach can be perceived as adversarial by some if applied without due consideration of the support requirements of persons affected.
- The reports can be technical and persons affected may not perceive them as accessible or personal.
- It does not routinely require the involvement of a subject expert as a member of the review team e.g. a clinician experienced in the area to which the subject matter of the review relates.

2. Systems Analysis: Review Panel Approach

This approach involves the establishment of a review panel made up of senior staff relevant to the incident under review e.g. an obstetric incident may involve an obstetrician, neo-natal paediatrician, anaesthetist, senior midwife etc. The role of the review panel is to consider the case report (see below) and to conduct the analysis and agree any recommendations required. The Review Panel approach requires commissioning by the SAO i.e. development of a TOR and the appointment of the chair and other members of the review panel. Oversight of the process is carried out by the Serious Incident Management Team (SIMT).

Following the establishment of the Review Panel

- A meeting of the panel is scheduled for 6-8 weeks and members of the panel are asked to reserve this date.
- A person is appointed as a case officer to the incident. The case officer should have knowledge of incident analysis, human factors, systems approach and effective solutions development. The role of the case officer is to liaise with the chair and to gather all relevant information required to prepare a case report. The case report will be circulated to members of the panel a week in advance of their scheduled meeting. The information gathered should include:

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- A copy of the clinical/care record.
- A copy of the incident report.
- The written recollection of events from staff.
- The notes relating to any meetings held with any staff to clarify aspects of their written recollection of events (if required).
- An account of the output of a meeting with the service user/family. The purpose of this meeting is to advise them of the plan for review, to ascertain their perspective on the incident and any key questions they would wish to see the review answer.
- Copies of any PPGs relevant to the incident.
- Any other information that may be relevant to the incident e.g. staff rosters, equipment maintenance records, phone logs etc.

The case officer then prepares a case report which outlines the background relating to the service user and their interaction with the service i.e. a summary of their clinical/care history, the chronology of events leading up to the incident (derived from available information), detail of the immediate steps taken in relation to the management of the incident and the outcome of the incident.

As soon as it is ready and at least one week prior to the review panel meeting, each member of the panel receives a file consisting of the information gathered and the case report prepared by the case officer. They are required to read and consider this information in advance of attending the review panel meeting.

At the panel meeting, the case is presented by the case officer. The review panel, supported by the case officer, discuss the case and the evidence provided. They reach a consensus on the identification of key causal factor(s) and using the Yorkshire Contributory Factors Framework, identify the factors that contributed to these. They then consider the specific queries that arose at the meeting with the service user/family and agree the response to these if they have not been covered in the analysis. The review panel then move to consider any recommendations required to improve safety and reduce the risk of recurrence.

Following the meeting the case officer drafts the review report to include the analysis, the recommendations and the response to family questions agreed at the panel meeting. The draft review report is provided to members of the review panel for consideration and feedback.

In the event that the draft review report makes negative criticism of or an adverse finding against an individual staff member, in keeping with the principles of natural justice and fair procedures that staff member must be provided with the draft report and have an opportunity to comment/defend themselves against the criticism/finding. Following this the draft report (amended if required) is circulated for factual accuracy review and comment to the staff who participated in the review process or who may have been impacted by the process.

Following consideration of any feedback received from staff, a final draft report is prepared and a meeting is held with the service user/family to discuss the report and ensure that any issues raised by them have been considered and the outcome of this reflected in the report.

Following receipt of the feedback the case officer meets with the Chair of the review panel to finalise and sign off the final draft report for consideration by the SIMT as per the **governance approval process for finalising review reports (IMF Guidance Section 13).**

Arrangements are made for the Commissioner to provide a copy of the report to the service user/family and to the service. The service is required to prepare an action plan to enable the monitoring of implementation of recommendations.

Note: the review panel should where possible be constituted from within the Hospital Group/CHO or NAS Area.

Though the review panel is commonly made up of a number of senior clinical/care staff, the time commitment required from them is not onerous i.e. they are required to read the case file in advance of the review panel meeting, to participate in the review panel meeting and to review the draft report developed following the review panel meeting.

Strengths

- It is comprehensive and thorough and incorporates all the principles of systems analysis.
- It allows for the efficient use of independent expert time.
- It supports patient safety by identifying the key causal factors of incidents and the factors that contributed to these.
- It adopts a high level of independence.
- It involves the perspectives of a multidisciplinary panel of subject matter experts independent of the incident.

Weaknesses

- It requires the establishment of a review panel of appropriate subject matter experts which could be challenging for some services.

Aggregate Review of Incidents: Systems Analysis Approach[6]

In addition to individual incident analyses (comprehensive and concise), consideration should be given to the aggregate analysis or meta-analysis of multiple incidents that are identified by a particular theme. For example:

- A group of individual patient safety incidents, similar in composition and/or origin that caused no harm or lesser degrees of harm i.e. **Category 3 incidents**.
- A group of individual patient safety 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 experience 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 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.

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

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/families, 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 patient safety 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, patient diagnosis, etc.
- 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 (causal 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.

Guidance on 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 you need to pick and choose your words carefully, and present your points in a style, manner and sequence that best suits the message you are sending. 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/family 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/family, 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 and the findings.

3. Tone

Tone refers to the style or manner of expression you use in your speech or writing. Just like in a conversation, the tone you use in your writing affects the way a reader interprets and responds to your 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 you from alienating the reader** – If you use a tone that's too casual, you 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 your reader. This makes it more likely you'll get the desired response to your message.

- **help the reader connect with your message** – By using the right tone and choosing your words carefully, you can help readers "hear your voice." You can make them feel more connected to what you are writing about.

See page 52 for the draft template for a systems analysis report and page 60 for the After Action Review report template.

8.1 Systems Analysis Report Template

Systems Analysis Review Report

CONFIDENTIAL

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

Note: Guidance is provided throughout the template in **green font** – please ensure that this is deleted before finalising the report.

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1.0	Executive Summary

To include: Detail of the incident type and the impact on the service user/person affected, (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

Key findings to include key causal factors, and recommendations made and the learning points

Consider writing this summary so that it can be easily adapted as the basis for sharing learning with other services.

2.0	Apology/Acknowledgement

Detail of apology

Acknowledgement – to the persons affected e.g. service user, family, 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 and/family 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 family here.

Document the approach used and what information/material was considered e.g. documentation 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 any key causal factors and that the Yorkshire Contributory Factors Framework was used to identify any factors that contributed to the causal factors.

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

3.0	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. He was admitted 5 days prior to the incident for … and outline what happened.

	Chronology of Events

Refer to the process for developing a chronology of events and if required mention the structure of this i.e. key events leading up to the incident, the incident itself and the nature of actions taken to mitigate the effect of the incident – As many chronologies are lengthy rather than interrupt the flow of the report, consider referring the reader to an appendix for full detail of this.

	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/family/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.

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6.0	**Analysis and Findings of the Review Team**
	To include:
	Key Causal Factors and the Factors that contributed to each of these (see Yorkshire Contributory Factors Framework Section 11 IMF Guidance)
	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
7.0	**Review Outcome**
	Indicate which ONE of the following outcomes best applies and delete ALL others
	1. Appropriate care and/or service – well planned and delivered, unavoidable outcome and no key causal factors identified.
	2. Indirect system of care/service issues – no key causal factors identified but Incidental Findings were identified i.e. improvement lessons can be learned but these were unlikely to have affected the outcome.
	3. 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.
	4. 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.
8.0	**Other issues raised by the service user/family not addressed by the systems analysis**
	Cross check to see the extent to which the questions posed by the family 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.
9.0	**Recommendations**
	What is recommended to address each causal factor? These may be for Local, Service or National action. See Guidance on Developing Recommendations (**IMF Guidance Section 12**) 1. 2. 3.
10.0	**Communication of the outcome of the review**
10.1	To complete Section 10 the review team will need to engage with the Commissioner of the review or a person designated by them.
	Service Users/Family
	Describe how feedback on the outcome of the review was provided to the family or if this has not happened how it is planned to feedback to them.
	If the service user was not involved, document any reasons for this and how the outcome is to be shared with them
10.2	Staff
	State how staff (those involved and wider organisation) were involved and supported both following the incident and for the duration of the review process, State also how it is planned to make staff aware of the review outcome and lessons learned)
10.3	Sharing Learning
	State how the service will deal with this e.g.
	Amongst staff in the area where the incident occurred
	With the relevant Hospital/Service QPS Committee e.g. Case Presentation at meeting, etc)
	Whether it is planned to share the report more widely

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Appendix 1 Terms of Reference

<Include a copy of the terms of reference here>

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Appendix 2 Definitions and Abbreviations used in the report

xxx

Appendix 3 Chronology

List dates and times of key events or actions taken in chronological order (For a concise review the detail required is that which relates to key events and actions only)

Date	Time	Source	What happened	Comments

Review Report

Pseudoanonymisation Codes

Note: Whilst it is important to maintain the confidentiality of the names of staff participating in the review process, it is also important to maintain a record of staff involved in the care of the service user to which the report relates.

Please complete the table below but do not attach to the final report. This page should be provided only to the Commissioner and should not be filed with the report.

NIMS Number relating to the Review	
CODE	**Name of Staff Member to which the code relates**

8.2 AAR Summary Report Template

After Action Review (NIMS Number)
Learning Report
Date of meeting: <insert date here>

Background to AAR

Provide a brief summary of the issue to which the AAR relates i.e. key chronological points here

▼

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

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Section 9 Fair Procedures and Natural Justice

Background

The HSE's Incident Management Framework requires managers to consider on receipt of an incident report whether the issue reported is appropriate to the Framework 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 2)** should be referred to if clarification is required. Use of the **Incident Decision Tree (IMF Guidance Section 3)** may also assist managers in making such decisions.

The purpose of an incident review conducted under the Incident Management Framework is to examine the effectiveness of systems 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 Incident Management Framework comply with these principles?

Adherence to these principles is ensured by the review:

1. Having a clear **terms of reference (IMF Guidance Section 10)** 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 for interview, the right to be accompanied if required to attend an interview.
3. Advising persons harmed e.g. service users and/or their families 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.
5. That staff members participating in or affected by the outcome of the review process are requested to provide feedback on issues of factual inaccuracy.
6. That any report arising from the review will be pseudo-anonymised to protect the identity of service users and staff.
7. That the person affected and or their family will have an opportunity to consider the draft report and to provide feedback particularly in relation to matters of factual accuracy.

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8. 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 entire report in the following order:

1. That where issues of criticism or implied criticism or where the findings of the review might be seen to adversely affect an individual employee are identified, that the employee:

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

2. The report when amended should go in full to all participants and the process repeated i.e. they are asked to provide feedback on matters of factual accuracy. Issues relating to factual inaccuracy, for which there is evidence, must be changed and where observations or comments are received the review/ investigation team may make changes or decide to leave as is. It is recommended that individual staff should receive feedback on all items of feedback provided to them along with reasons for the basis why these are accepted or rejected.

3. Service users and/or their families are met with to review the draft report and to ensure that it is factually accurate and addresses in so far as is possible the issues that they wished to see considered by the process. Matters of factual inaccuracy, for which there is evidence, are corrected and where possible any outstanding issues not reflected in the report are addressed.

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 employee 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 especially where their employment rights may be adversely affected by a review.*

- *The review team must allow the employee an opportunity to prepare 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 bias.*

Evidence

- *Any decision 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 recommendation or decision is based.*

- *All the evidence must be provided to the person who may be adversely affected or criticised.*

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Section 10 Guidelines on the development of terms of reference 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 issues and 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 terms of reference for an adequate and appropriate review should not be underestimated.

The ToR should also seek to include any key issues or questions raised by the service user/family in the aftermath of the incident.

Benefits of a ToR

As well as establishing an understanding of what is required and by when, ToR can prevent such pitfalls as misunderstandings, unintended breaches of privacy and negative effects on relationships. Sound ToR provide the means by which emotive 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 ToR 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 ToR 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 ToR in relation to <an incident> which occurred **in XX location on XXXX date**. It also identifies who is the Commissioner of the review.

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 <the incident>, to identify any factors which caused and contributed to <the incident> and to make recommendations which when implemented would reduce the risk of a similar incident occurring in the future."

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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 should also include detail of any experts or other persons to whom the team may access for advice.

Objectives

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

- The policy under which the review is being carried out.
- The process and methodology to be applied.
- 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 Commissioner providing details of the incident, findings and recommendations.

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 Commissioner of any issues that might result in a delay to achieving completion within the stated timeframe.

Communications during the conduct of the review

Staff and service user/family liaison persons will be appointed for the purpose of communicating information pertaining to the review to the patient/family/staff member(s) (delete as appropriate) affected by and/or involved in the incident.

Communications queries made by any external party will be directed to the Commissioner of the review 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 Commissioner and that all parties will be informed of the change.

Section 11 Yorkshire Contributory Factors Framework

The Yorkshire Contributory Factors Framework 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 identify contributory factors of Patient Safety Incidents.

This Framework, illustrated below, depicts the contributory factors domains as a series of concentric circles, with active failures (mistakes, slips/lapses and violations) at the centre and the external policy context as the outer circle. 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.
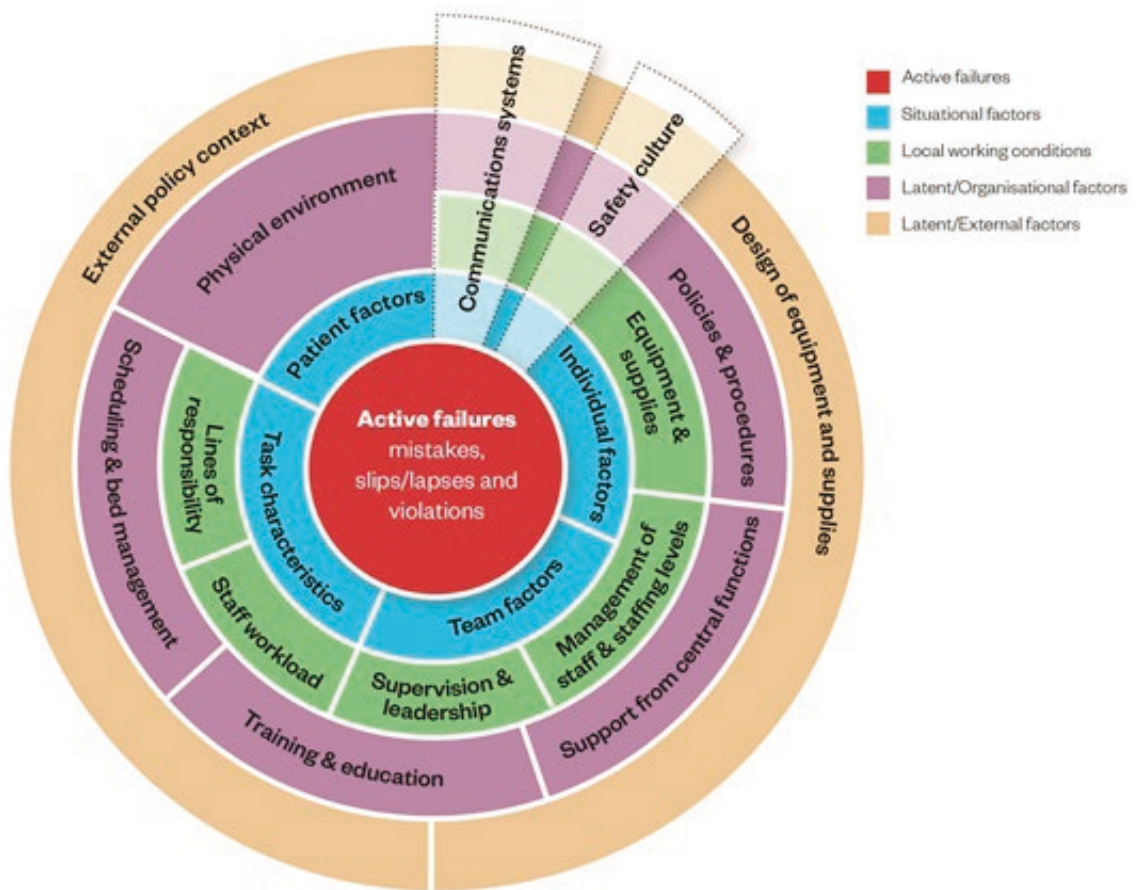
Copyright Bradford Teaching Hospitals NHS Trust.

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 all 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 2 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 overleaf.

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.

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

Improvement
Academy

Prompting Question	Relevant to Incident?	CONTRIBUTORY FACTOR DOMAIN
		Situational Factors
Did the staff involved function as a team?	☐ Yes ☐ Maybe ☐ No	Team Factors – For example: ■ Conflicting team goals ■ Lack of respect for colleagues ■ Poor delegation ■ Absence of feedback
On the day of the incident, how did you feel?	☐ Yes ☐ Maybe ☐ No	Individual Staff Factors – For example: ■ Fatigue ■ Stress ■ Rushed ■ Distraction ■ Inexperience
Did the task features make this incident more likely?	☐ Yes ☐ Maybe ☐ No	Task Characteristics – For example: ■ Unfamiliar task ■ Difficult task ■ Monotonous task
Were there any reasons this incident was more likely to occur to this particular service user?	☐ Yes ☐ Maybe ☐ No	Service User Factors – for example: ■ Language barrier ■ Uncooperative ■ Complex medical history ■ Unusual physiology ■ Intoxicated
Prompting Question	**Relevant to Incident?**	**CONTRIBUTORY FACTOR DOMAIN**
		Local Working Conditions
Did staff provision match the expected workload around the time of the incident?	☐ Yes ☐ Maybe ☐ No	Workload & Staffing issues – For example: ■ High unit workload ■ Insufficient staff ■ Unable to contact staff ■ Staff sickness
Did everyone understand their role?	☐ Yes ☐ Maybe ☐ No	Leadership, Supervision & Roles – example: ■ Inappropriate delegation ■ Unclear responsibilities ■ Remote supervision

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| Were the correct drugs, equipment and supplies available and working properly? | ☐ Yes
☐ Maybe
☐ No | Drugs, Equipment & Supplies – e.g.
■ Unavailable Drugs
■ Equipment not working
■ Inadequate maintenance
■ No supplies delivery |

Prompting Question	Relevant to Incident?	CONTRIBUTORY FACTOR DOMAIN
		Latent/Organisational Factors
Did the ward environment hinder your work in any way?	☐ Yes ☐ Maybe ☐ No	Physical Environment – e.g. ■ Poor layout ■ Lack of space ■ Excessive noise/heat/cold ■ Poor visibility (e.g. position of nurses' station) ■ Poor lighting ■ Poor access to service user
Were there any problems from other departments?	☐ Yes ☐ Maybe ☐ 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?	☐ Yes ☐ Maybe ☐ No	Scheduling and Bed Management – e.g. ■ Delay in the provision of care ■ Transfer to inappropriate ward ■ Difficulties finding a bed ■ Lack of out-of-hours support
Were there any issues with staff skill or knowledge?	☐ Yes ☐ Maybe ☐ No	Staff Training and Education – e.g. ■ Inadequate training ■ No protected time for teaching ■ Training not standardised ■ No regular/yearly updates
Did local policies, protocols and Procedures help or hinder?	☐ Yes ☐ Maybe ☐ No	Local Policies, Protocols or Procedures – e.g. ■ No protocol exists ■ Protocol too complicated ■ Lack of standardisation ■ Contradictory policies exist
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?	☐ Yes ☐ Maybe ☐ No	Design of Equipment, Supplies & Drugs – e.g. ■ Confusing equipment design ■ Equipment not fit for purpose ■ Similar drug names ■ Ambiguous labelling and packaging

Have any national policies influenced this incident?	☐ Yes ☐ Maybe ☐ No	national policies – e.g. ■ Commissioned resources ■ National Screening Policy ■ Interference by government organisations ■ National medical/nursing standards ■ National Performance Targets

Prompting Question	Relevant to Incident?	**CONTRIBUTORY FACTOR DOMAIN**
		General Factors
How would you describe the culture of you clinical/care areas in relation to service user safety?	☐ Yes ☐ Maybe ☐ No	Safety Culture – e.g. ■ Service User Safety awareness ■ Fear of documenting errors ■ Attitude to Risk Management
Were the notes available, accurate and readable? Did poor or absent verbal communication worsen the situation?	☐ Yes ☐ Maybe ☐ No	Communication – written and verbal – e.g. ■ Poor communication between staff ■ Handover problems ■ Lack of communication/notes ■ Unable to read notes ■ Inappropriate abbreviations used ■ Unable to contact correct staff ■ Notes availability

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Section 12 Developing Recommendations – Guidance

If the purpose of conducting the review of an incident is to find out what happened and why it happened so that lessons can be learned, then it is essential that the recommendations of the review are presented in a manner that is clear and relate to the findings identified in the analysis. Attention to recommendations will assist in ensuring that any consequent action plan developed, targets the areas where improvement is identified as required. Clear recommendations are therefore critical in the development of a robust and relevant action plan. 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 where service improvement may be required i.e. incidental findings.

Quality of Recommendations Made

A retrospective analysis of review reports will often indicate a wide variance in both the style and the clarity of recommendations. In some reports they are very specific and the reader can find a clear linkage between these and the findings made following analysis of the event. In other reports the recommendations can be non-specific and there is a less obvious linkage between them and the analysis and findings relating to the event.

Recommendations which are non-specific 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.

Good Recommendations should:

- Be clearly linked to identified causes and the factors that contributed to the occurrence of the incident. This is to ensure that they address the underlying problems rather than symptoms.
- Address all of the causes and key learning points identified.
- Be designed to significantly reduce the likelihood of recurrence and/or severity of impact if there is a recurrence.
- Be clear and concise.
- Be Specific, Measurable, Achievable, Realistic and Time-bound (SMART) so that changes and improvements can be evaluated.
- Be prioritised wherever possible.
- Not conflict with best practice or the agreed strategic direction of the service.

Recommendations should be categorised as:

- Those **specific** to the area where the incident happened i.e. local level.
- Those that are **common** only to the organisation involved i.e. service level.
- Those that are **universal** to all and, as such, have national significance i.e. national level.

Recommendations might also include issues:

- Which were not directly linked to the event but were identified in the course of the review as areas where service improvement may be required i.e. incidental findings.
- Relating to the aftermath of the incident e.g. provision of on-going support of patients and staff affected by the incident.

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Top Tips for making recommendations

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

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

What does a SMART recommendation mean?

SMART is an acronym used to describe the key elements/features that a recommendation should have to support successful implementation.

Specific

Measurable

Achievable

Reasonable/realistic

Time-bound

A recommendation that follows SMART is more likely to succeed because it is:

- **Specific** – targets a specific area for improvement.
- **Measurable** – quantifies the outcome e.g. a deliverable.
- **Achievable –** attainable and aligned with the objectives of the service.
- **Realistic –** it identifies an outcome that can realistically be achieved, given available resources.
- **Time-bound** – specifies the time by which it will be completed.

How do you ensure that a recommendation is SMART?

Though the primary responsibility for the development of recommendations lies with the review team they alone are often not in a position to develop recommendations in a manner that conforms to SMART principles. This is because whilst being able to specify from their analysis of the incident the areas requiring improvement, they may not have the ability to state the extent that they are aligned to the strategic direction of the service, the resources available to support implementation, both human and financial or the timeframes required to achieve implementation.

From the perspective of the service user or family the recommendations represent the commitment to learn and change and from the outset they will have provided perspective of this. It is therefore vital that the service user or family have confidence that the service commits to implementation of recommendations and that can only happen when any recommendations made are achievable and pertinent.

This is also important to staff affected and their managers as they will want to make sure that the incident review and the recommendations made as a result of the process lead to tangible improvement.

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This means that in the case of reviews commissioned by the SAO, representatives of the SAO e.g. SIMT should be engaged with prior to finalisation of the report. The purpose of this engagement is to ensure that the recommendations are clear, relate to the analysis and are written in a way that facilitates implementation. In order to preserve procedural fairness and the role of the Commissioner as the decision maker in the final acceptance of the report, this engagement should not include the Commissioner of the review.

Examples of recommendations

CASE 1

Case involved the failure of a service user to return to a mental health residential service following a planned absence. A recommendation was required to ensure that there was a system in place to govern planned absences.

Example 1 (not SMART)

Breakdown in communication within the Mental Health Service Team contributed to the outcome for the service user. Managers to ensure communication is effective.

Example 1 (reworked using a SMART approach)

Review and amend the 'time out of ward' proforma and include prompts for

    a)   time leaving ward,

    b)   time due to return,

    c)   time by which action to be taken if patient fails to return, and

    d)   actions to be taken if patient fails to return.

Develop and implement a service user pass information card, which outlines items a) to d) above, ward contact details and instruction for the patient to contact if return is delayed. Remind staff of importance of establishing and recording extent to which next of kin/families/carers are involved in and informed of decisions around pass. Conduct a minimum of two monthly audits of a representative sample of cases where the performa was used.

Timeframe for implementation and initial audits: 6 months

CASE 2

This case related to the failure to recognise and respond to clinical deterioriation of a patient in a timely manner.

Example 2 (not SMART)

Nursing staff need to record early warning scores effectively.

Example 2 (reworked using a SMART approach)

- All nursing staff in Ward 4 to have a refresher training of calculating and escalating early warning scores.
- Monthly audit of early warning scores documentation to commence in **October 20XX** to monitor if documentation has improved.
- Ward nursing focus group to establish if there are any currently unknown factors influencing the poor documentation of early warning scores.
- Output of focus groups and audits to be reviewed by lead nurse and used to inform improvement.

Timeframe for implementation: 4 months

The importance of monitoring implementation of recommendations

The ultimate goal of making recommendations is to develop an action plan, which when implemented, will provide assurance that the quality and safety of care has been improved. The monitoring process that pertains to action plans must therefore go beyond simply ensuring that each action has been implemented but also consider the extent to which this change has improved safety in the longer term. For example if one of the recommendations related to prevention of a certain type of incident, the question must be asked as to whether this has resulted in the event not recurring or where 100% prevention is not possible that a lower incidence or lesser impact relating to this event has resulted e.g. falls.

Linking recommendations into your services Quality and Safety Improvement Plan

If recommendations have been structured in a manner that is SMART the development of an action plan for implementation will be more straightforward. To assist with effective monitoring of actions it is recommended that the action plan when developed should be integrated into the service's Quality and Safety Improvement Plan (QSIP).

The adoption of such an approach means that rather than monitoring the action plans of multiple reports, many of which may have similar recommendations, a service has one master improvement plan against which recommendations from all reports will be cross checked.

To assist with reporting on progress of implementation of actions from individual reports, a record should be kept, on a per report basis, which maps recommendations against actions in the QSIP. Monitoring reports can then be pulled from the QSIP by selecting the actions from it that relate back to individual review reports.

Consideration should also be given to aligning the structure of a service's QSIP to the themes in the relevant National Standards/Judgement Framework. Such a mapping exercise will assist services in demonstrating to inspectors how the service links reactive processes such as incident management with their proactive safety and quality improvement process.

References

1. Greater Glasgow and Clyde NHS Trust Developing Recommendations Guidance
2. Healthcare Improvement Scotland, Learning from Adverse Events May 2016
3. National Patient Safety Agency Root Cause Analysis Investigation Tools
4. Practical Support for Accident Investigators, Investigation Guide, British Rail. P 24: 2014

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Section 13 Governance approval process for finalising 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[7].
- That the process applied was consistent with the requirements of the approach taken for the review[8].
- 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 sign off process occurs with the Commissioner it is essential that the above points are considered throughout the review process. 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 review 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. Members of the SIMT must be aware of this in conducting the sign off process. Risk of perceived bias can be further addressed by the 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 Commissioner is part of the SIMT and there is a decision taken by them to absent themselves from this part of the review 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 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.
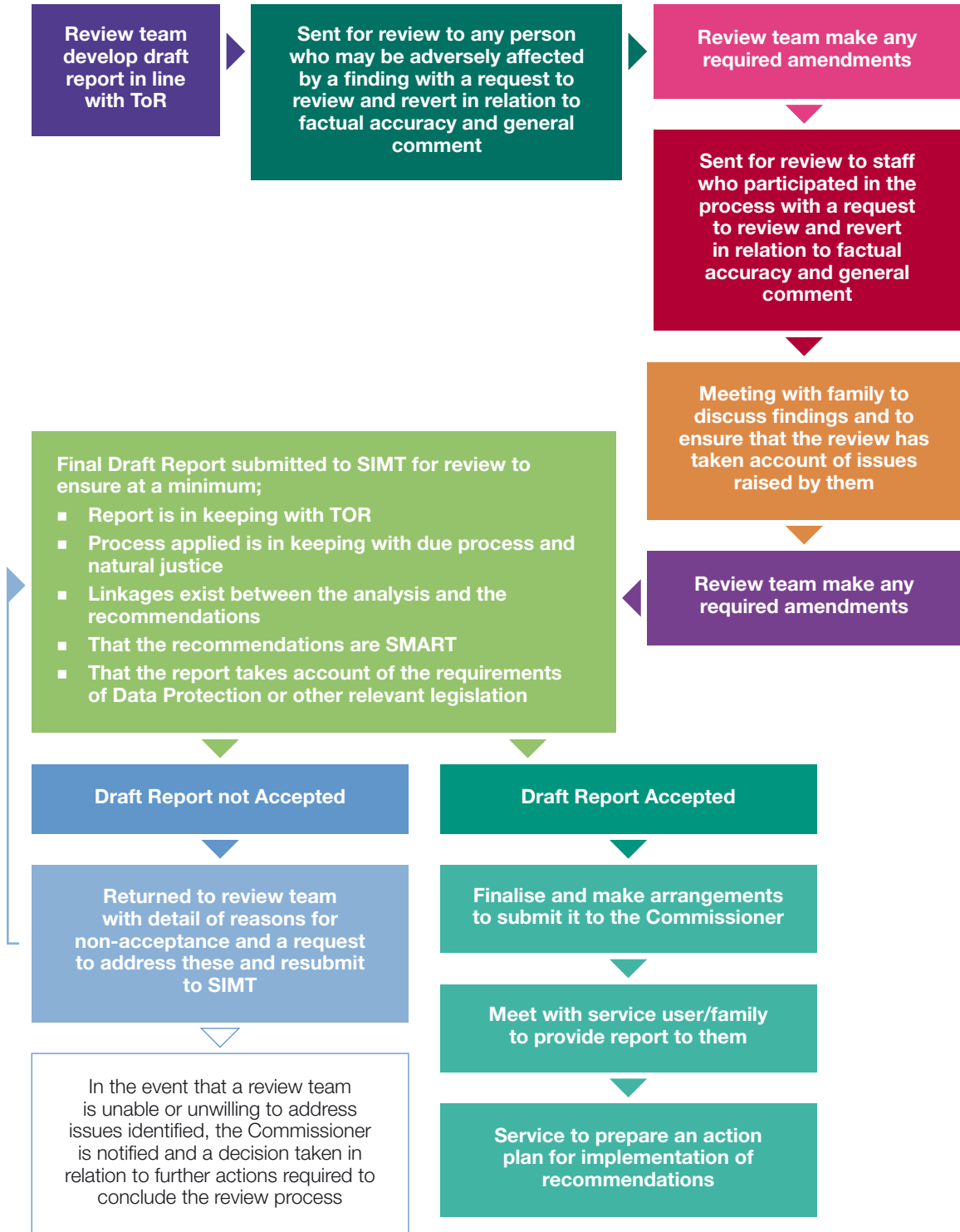
In the rare circumstance that a review team is unable or unwilling to address issues identified, the Commissioner is notified and a decision taken in relation to further actions required to conclude the review process, up to and including stepping down the review team.

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 76 of this section.

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7   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.

8   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 approaches.

Figure 1. Governance Approval Process for Final Report

Review team develop draft report in line with ToR	Sent for review to any person who may be adversely affected by a finding with a request to review and revert in relation to factual accuracy and general comment	Review team make any required amendments

Sent for review to staff who participated in the process with a request to review and revert in relation to factual accuracy and general comment

Meeting with family to discuss findings and to ensure that the review has taken account of issues raised by them

Review team make any required amendments

Final Draft Report submitted to SIMT for review to ensure at a minimum;

- Report is in keeping with TOR
- Process applied is in keeping with due process and natural justice
- Linkages exist between the analysis and the recommendations
- That the recommendations are SMART
- That the report takes account of the requirements of Data Protection or other relevant legislation

Draft Report not Accepted

Draft Report Accepted

Returned to review team with detail of reasons for non-acceptance and a request to address these and resubmit to SIMT

Finalise and make arrangements to submit it to the Commissioner

In the event that a review team is unable or unwilling to address issues identified, the Commissioner is notified and a decision taken in relation to further actions required to conclude the review process

Meet with service user/family to provide report to them

Service to prepare an action plan for implementation of recommendations

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[9].
- 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

1	NIMS Number
2	Date Reviewed
3	Reviewed By

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-anoymisation codes form completed? **Note:** this is to be returned separately to the 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?		
Is full text rather than abbreviations of terms used?		
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?		

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9   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.

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		
Name of Commissioner		
Chair of Review		
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 manage the service within which the incident occurred.		
Does the executive summary summarise the key findings of the report and include the Key Causal Factors and recommendations to address these?		

Apology/Acknowledgement	Y/N/Partial/n/a	Comment
If appropriate, is an apology included or referred to in the report? (note an apology that is referred to in the report should state that the apology has already been made or will be made by the relevant body)		
Is an acknowledgement included in the report		

Overview of the Review Process	Y/N/Partial/n/a	
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/family (as appropriate) were involved and supported in the review?		
Is there detail in relation to how staff were involved and supported in the review?		
Is there detail in relation to how the principles of natural justice and fair procedures were observed? E.g. ■ 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? ■ Does the report state if feedback from persons participating in the review was incorporated into the final report? ■ Does this review report include details of a legal review? **Note:** 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.		
Persons involved in the conduct of the review		
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?		

Chronology of Events	Y/N/Partial/n/a	Comment
Note: Unless this is brief it may be preferable to include this as an appendix rather than in the body of the report and if so reference should be made to it at this stage.		
Is the exact date and time of each event specified?		
Where an exact time and date is not known is the approximate time noted?		
Where an exact time and date is not known is the event placed in chronological order?		
Are the individuals involved or that witnessed each event specified?		
Does the chronology section detail the source of the information used to inform the chronology e.g. healthcare records, timesheets etc?		
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 **a) Key Causal Factors**	**Y/N/Partial/n/a**	**Comment**
Are Key Causal Factors (KCFs) identified or does the report state that none were identified following the analysis of the chronology?		
If the report states that no KCF(s) were identified is there evidence to support this?		
If the report identified KCF(s), is the context in which the KCF(s) occurred explained and is each KCF adequately supported by evidence within the report?		
b) Contributory Factors	**Y/N/Partial/n/a**	**Comment**
Does the report show that the reviewers used the Yorkshire Contributory Factors Framework to identify the Contributory Factor(s) for **each** key causal factor?		
Is each identified Contributory Factor clearly linked to the relevant Key Causal Factor?		
If no Contributory Factors are identified does the report state a reason for this?		

c) Incidental Findings	Y/N/Partial/n/a	Comment
Does the report identify issues that while not impacting on this incident highlight an area for service improvement?		

d) Notable Practice	Y/N/Partial/n/a	Comment
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 4 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?		
Is there evidence that a hierarchy of controls was used to determine the weakest to the strongest recommendations?		
Is the SMART principle (i.e. Specific, Measurable, Achievable, Realistic and Time-bound) applied to each recommendation?		
Does the report state who has responsibility for implementation of the recommendations? (This may already have been covered in the terms of reference.)		
Does the report state that nationally applicable recommendations were identified and communicated as appropriate?		

Action Plans	Y/N/Partial/n/a	Comment
Does the report refer to a requirement for the report Commissioner/person responsible for implementing the report recommendations to oversee the development of an action plan?		

Appendices (whilst a review may require the addition of a number of appendices the two most commonly included are referred to in this checklist).		
a) Terms of Reference	**Y/N/Partial/n/a**	**Comment**
Are terms of reference included in the review report?		
Does the timeframe for this review appear to be appropriate for the incident under review? **Please note:** The *"time frame"* in question here is the *"scope in time"* that was reviewed in the review (e.g. from the time of admission to the time surgery commenced).		
Is it clear who commissioned/requested this review?		
Is it clear who is responsible for implementing the recommendations of the report?		
b) Chronology	**Y/N/Partial/n/a**	**Comment**
Note: If the chronology was brief it may have been included in the main body of the report and in such instances this appendix will not be required.		
Is the exact date and time of each event specified?		
Where an exact time and date is not known is the approximate time noted?		
Where an exact time and date is not known is the event placed in chronological order?		
Are the individuals involved or that witnessed each event specified?		
Does the chronology - detail the source of the information used to inform the chronology e.g. healthcare records, timesheets etc?		
Communication of the outcome of the review	**Y/N/Partial/n/a**	**Comment**
Does the report identify how the outcome of the review is to be communicated to: a) The service user/family b) Staff c) Other services?		

Notes:

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Níos Fearr | Better Health
á Forbairt | Service

Incident Management Framework – Patient and Staff Stories

Care | Compassion | Trust | Learning

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Patient Stories – "The First Victim"

Patients for Patient Safety is a World Health Organisation initiative inaugurated in 2004 which acknowledged patients and families as an untapped resource and also recognised the patient's experience of their care as a learning tool. In the intervening years PFPS networks have been formed around the world, including Ireland.

Patients for Patient Safety Ireland (PFPSI) is a group of 16 volunteers whose aim is to promote patient safety in our health care system. They are a collaboration of patients and family members who have experienced preventable harm in our health care system, as well as patient advocates, policy makers and health care workers who are committed to improving patient safety. Each of the group's members has a story to tell. Some have witnessed preventable harm occur to their loved ones, including death, in our hospitals. Others are dealing each day with the challenge of managing life-threatening and taxing illnesses caused by unsafe practice.

They are committed to using their unique experiences to inform healthcare improvement and the prevention of adverse events. They do this in a collaborative and partnership engagement with healthcare at all levels – education, research, regulation, policy making and especially through presentations at conferences, workshops and in-service days.

The following stories, written from the perspective of members of Patients for Patient Safety Ireland in their words, have been kindly shared to support staff in the application of the principles outlined in the HSE's Incident Management Framework.

Eve's Story

During 2010, twelve-year-old Eve had recurring ear infections. A few days before Christmas that year, her mother, Paula, brought her to A&E at the local hospital. The doctor she saw diagnosed an ear infection and prescribed antibiotics. Over Christmas, Eve was very nauseous and experienced dizziness. On New Years Eve, she was very unwell. She was unable to dress herself or do anything, and had double vision, so Paula took her back to A&E in the same hospital.

They arrived mid-morning, when A&E had only 4-5 patients, but had a very unsatisfactory and distressing experience with the registrar. Initially he refused to see them at all. Paula and Eve were in a curtained-off cubicle and could hear the doctor talking to the nurse outside, saying aloud, and in front of everyone, *'she was already seen, I don't want to see her, why should I see her. She has been diagnosed with an ear infection, hasn't even finished the antibiotics, why should I be doing this.'*

They heard the nurse trying to cajole him, again in front of everybody. *'Ah, do it for my sake, do it as a favour to me, she has a little bit of double vision'*. Eventually, as a favour to the nurse, he came in to see them, but it seemed that he couldn't be bothered, had made his mind up before he saw them and that they were wasting his time.

He looked in Eve's ear and said there was still infection there, and to finish the antibiotics. Paula asked about the nausea and double vision, and felt it should be obvious that Eve was very ill as she had to help her from the chair to the bed. The doctor dismissed this, saying, *'I think a little bit too much television, looking at her phone, and getting a lot of attention from her mum.'*

Although Paula believed that the doctor was negligent in his manner and diagnosis, she didn't say anything at the time. This was for fear of antagonising him and the ramifications this might have for Eve's care. But it was awful to have a doctor saying *'no, I'm just not dealing with it.'*

As it was New Year's, Paula then had to wait until January 2 to get an appointment for Eve with her GP. *'I was so scared, because I thought maybe she had a tumour. And you feel completely isolated, totally on your own, just kind of pushed away…no one to go to.'*

The GP was appalled when she saw Eve and heard of their experiences. Paula *'felt like a paranoid Mum'* but the GP said *'no, you know your daughter, keep going'* and that they would just have to skip that hospital (even though it had the ENT speciality), go to another hospital and get a different team to work for them. So they went to A&E at this second hospital, hoping they would get somewhere there.

Eve's Story (continued)

Luckily, they did. The young registrar said *'kids don't make up stuff about headaches and double vision, so there is something causing it…an ear infection won't cause that'*. He phoned a consultant and they admitted Eve. The next morning she had an MRI scan and it showed a 3 to 4 inch transverse sinus thrombosis (clot in her head, in the sinuses) which was putting pressure on the optic nerve. Eve was very ill…a 12 year-old at risk of a stroke that could do damage to the brain. She was transferred back to the first hospital (as an ENT case), where she had a mastoidectomy (removal of the mastoid bone behind the middle ear). This had completely rotted, probably from infection that had been there for about three months (the doctors thought that Eve must have a high tolerance for pain or that the nerve endings had been affected because of so much pus). After the mastoidectomy, Eve had to have treatment for the clot and she was transferred back to the second hospital where she remained for a month. She also was seeing an ophthalmologist from a third hospital (a university hospital).

Overall, with the exception of the registrar who wouldn't listen, Paula and Eve feel they experienced excellent care and dealings with healthcare personnel. Paula remembers one day during Eve's stay at the first hospital, when she had been particularly upset and crying. A doctor who had been on the rounds earlier that day came back to the ward when he was finished duty. He had taken off his scrubs to go home, but came back just to try to cheer her up. This was a registrar, just like the first doctor in the same hospital's A&E who had originally dismissed Eve and Paula – such a difference!

Eve eventually recovered well. She says herself *'all that happens now is that I get recurring ear infections, luckily none of the bad things happened'.* But Paula knows they could have, easily. *'In the time from New Year's Eve, us not being able to get a doctor until Jan 2. During that time, she could have had a stroke. When she got admitted to hospital, she was woken up every hour on the hour, asking her little tricks to make sure she understood where she was, what her name was…light shone in her eyes.'*

Paula didn't raise the incident at the time – she was only concerned for Eve's wellbeing and didn't want to antagonise anyone providing care for her. She has not raised the matter formally since then either, something which she often feels she should have done…especially if it would have reduced the possibility that the doctor in question might continue with this attitude with other patients.

The first hospital (the one that they had been sent away from by the registrar) never mentioned or acknowledged the incident either, despite the fact that the second hospital had to call over their ENT team to help treat Eve. The doctors at the second hospital did indicate that they thought Eve was inappropriately sent home by the registrar in the first hospital, without proper examination. Paula says, *'they were very careful, as of course they would have to be.'*

At the time, Paula did wonder about not being asked by the first hospital why they had ended up in the second hospital. *'When they got the phone-call from the other hospital…you saw a girl a couple of days ago…she's now presented here…she's got a thrombosis. Surely someone, whichever doctor, be it the consultant or medical registrar or whatever, would open Eve's file and say 'oh, she was here, we had her here and we sent her home…why did we send her home?"*

While they were in the second hospital, a Patient Liaison Officer asked about their experience in that hospital. They told her it was fantastic, but also explained their initial problems in the first hospital. Although not able to officially comment on this, the Liaison Officer said that they were certainly going to learn from it.

And Paula says that's all she wants, that lessons are learned from their awful experience. *'It would be great if something good can come out of it. To change the mind-set of even one person, then you are changing the experience of all the patients that they come into contact with afterwards.'*

For the past five years Eve has had recurring ear infections, and she attends the ENT consultant's clinic at the first hospital about every 6 months for this. Recently, an administration system mix-up led to Eve being inappropriately discharged from the clinic and a difficult battle to get re-instated…but that's another story…

Mark's Story

About fifteen years ago, 15-year-old Mark was brought to an A&E department with a range of psychological symptoms. After some time he was diagnosed as having schizophrenia, and that this was brought on by drug abuse. For his mother, communications were very traumatic. She was told that *'he had paranoid schizophrenia',* there was a *'75% chance of him committing suicide'* and there was *'nothing that she could do for me'.* Medication was also problematic: *'the first time I brought him out he was so doped up that he was drooling and he couldn't speak. … I thought that if this was the quality of life he was going to have for the rest of his life, he would be better off dead'.*

Mark sometimes needed A&E services in the last 15 years. Problems occurred: *'Attitudes from some registrars are poor in relation to getting a separate room away from the main area to help in maintaining the dignity of the patient. They could cause disruption while waiting as they are very unwell'.* The *'refusal to admit patients leaves the responsibility for coping with patients behaviour with the carer, often when they have little or no knowledge of medications, for example. This is a danger to all'.*

GP services were also problematic: *'the GP did not know enough about mental health as he said he only had 6 weeks training in psychiatry'.* When she rang the hospital to get him assessed for the first time she was told that *'she was an over-reacting mother'* over the phone. Eventually she got an appointment which ended up as an involuntary admission and Mark was subsequently hospitalised as an in-patient for 6 months.

Psychiatric services provided further difficulties. One issue was the inconsistency between psychiatrists in terms of emphasis on medication. When Mark decided to change his psychiatrist, there were different approaches to him. Every time he became incompliant it was known as a *'blip'* and no emphasis on finding out the cause of why he was not taking his medication. Psychiatrists *'were more concerned about drug levels than psychiatric symptoms or behaviour'.* On three occasions, Mark went missing from a semi-secure unit. Once he turned up again only through his own initiative. He was not missed by staff for 5 hours, even though he could be a suicide risk.

Gaining access to services during relapses was often a challenge, sometimes needing dramatic measures. Once, Mark had to be made homeless before he could receive appropriate treatment – *'I had to put him into a homeless shelter to get service … They gave him many life skills – they were the life saver'.*

Care plans were also an issue. *'Families should be present with the patients consent, but this was not always the case'.* Care plans were often deficient. Continuity of care was also a problem. *'A lot of team doctors do not read up on notes prior to interviewing the patient. Discontinuous treatment, poor handover between doctors (registrars)'.*

There is a lack of involvement of the family or the carer in the care plans: *'If the person is living within the family, they should be involved in the care plan. If they are living independently, that is a different care plan altogether'.* However, *'If the person refuses to let the family into the care plan while living with the family, now you have a huge problem, and how to get over this is another problem'.*

The carer can have a key role in supporting people, but often they have no formal role: *'Patients should be made aware that they can have a carer with them in the early stages as this would facilitate communication and treatment. We live with this all of the time and we are not educated in how to recognise problems and how to deal with them'.*

Families and carers should be involved in care plans and treatment from the beginning of treatment… *'Education, support and knowledge of how to cope with a crisis – this should be part of a care plan, even where the patient has reached the age of 18…'* *'The patient is the primary service user, but the family unit is the 'secondary service user'.*

Families need to be assessed following the diagnosis of mental illness. They have both needs and potential resources to bring to bear: *'the family could have been assessed, what are their needs and resources in the context of the diagnosis?' … 'If every carer who has a person with a mental health problem refused to take them back into their house, what would the HSE do?'*

Much of the treatment that Mark has received has been medication oriented. There is a reluctance to reduce medication to a minimum, especially where there is perceived stability in the patient's condition: *'at one stage he was on 7 drugs. Eventually he was being kicked out of the housing services he was receiving until his medication was changed. This took extraordinary efforts'.*

Mark's Story (continued)

Mark has wanted to reduce the drug dosage, but there can be little support for this from psychiatric services: *"your levels are great, and you are doing well so you are better off staying with this dosage, why rock the boat"*. *'Mark wants to get down to the least amount of drugs possible. He knew he was prepared for it … but dosages have to be discussed first with the team and then they decide to reduce the dosage or not. This should be Mark's choice as who else knows his body better than him – he should be encouraged to do so at safe levels'… 'Reductions are possible… although complete reduction of drugs in some cases is not an option, a review system on the diagnosis should be put in place every few years'*.

Caroline's Story

In 2005, Caroline (a 39 year-old-nurse) was diagnosed with an 8cm ovarian cyst and scheduled for admission to hospital for routine surgery to have it removed. She is married with one daughter who was aged 5 years at the time. Caroline and her husband were both working full time then. Her daughter was in her first year of national school. Everything seemed to be going well for Caroline and her family – life was good with no major worries or concerns.

In March that year, she went into hospital for the surgery. This was expected to be conducted laparoscopically, with a view to open surgery if any complications arose. It is usually a fairly routine procedure and it was expected that Caroline's hospital stay would be no longer than 5 or 6 days at the most. However, after the surgery on Friday morning she experienced severe pain when she awoke in the recovery room. After review by the consultant and anaesthetist, more analgesia and sedation were administered and Caroline was transferred back to the ward. It wasn't until late afternoon on Monday that the cause was diagnosed – a life-threatening perforation of the bowel.

Over the weekend Caroline's condition deteriorated – she continued to have severe pain as well as difficulty passing urine, difficulty eating and drinking, and felt she could not have a bowel movement. She had spiking temperature and a rapid pulse rate. A doctor who reviewed her thought she might have a urinary tract infection. Nothing abnormal was detected when a urine specimen was tested, but the doctor anyway started her on oral antibiotics for a urinary tract infection.

She felt herself that there was something seriously wrong, but the nursing staff thought she was just anxious. When the doctor came to see her again on Sunday morning Caroline says '*…[he] wrote on the chart "feeling better"(god!), but I wasn't feeling better…*' Her mother and other visitors that afternoon could see how unwell she was '*…but still the staff seemed to think there was not anything wrong with me…it was like nobody listened, no matter what…*' Sunday evening and night Caroline continued to get worse. She was seen by the Registrar, who suspected it could be a pulmonary embolism, and a portable x-ray was taken during the night.

On Monday morning Caroline had a very upsetting experience while her husband was visiting. She recalls '*…one of the nurses came into the room and clapped her hands and said ''out of bed, up out of bed''* and persisted with this even when Caroline refused because of the pain '*…She went out, came back in with a colleague, and they proceeded to drag me out of the bed, to sit me in the chair…to make the bed…when the bed was made, she told me I could get back into it…!*'

The consultant who had conducted the surgery came to see her that morning and said an ultrasound needed to be done to see what was going on, but it was 3.30 that afternoon before Caroline was brought down for the scan. After about 2 hours she was brought back to the ward where, as she says, '*…there seemed to be doctors coming out of the woodwork, I was surrounded – at last they were noticing…trying to find veins in my arms, putting cannulaes in, intravenous fluids, pain relief, various doses of IV antibiotics…told me then that I had a perforated bowel and needed to go for surgery…*'

An emergency operation found a perforation of the sigmoid colon with associated peritonitis. She developed septicemia and from theatre went straight to intensive care, where she remained on life support. Her husband was told she had a 50:50 chance of survival, if she made it through the first night, but she was getting progressively worse and her chances went down to 30:70 at one stage. Thankfully Caroline survived and came off the ventilator after about 10 days. But she remained seriously ill '*…developed everything you could possibly…multi-organ failure, acute respiratory distress syndrome…had to have a colostomy…had problems with my blood clotting mechanism, required several blood transfusions…sinus tachycardia…absolutely everything you could possibly think of…*' She also needed a lot of intravenous anti-fungal treatment and developed a deep rooted wound infection, which was compounded by an MRSA infection. '*…had that everywhere as well…*'

Eventually she was moved from ICU to the ward and was in hospital for a number of weeks. Around the end of April Caroline went home in a wheelchair, with a vac therapy unit for the wound. She needed a lot of care at home and was very weak, requiring a daily nurse visit for getting the dressings done, colostomy bags sorted out, and so on. Over time, Caroline was gradually getting better in some ways, but she then developed a large incisional hernia, and the colostomy was still there and giving a lot of problems. Around October she went back to hospital for colostomy reversal surgery and repair of the incisional hernia.

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Caroline's Story (continued)

Because of Caroline's medical problems her husband had to take time out of work to look after their daughter, and ended up working part-time. Caroline herself tried to go back to work, but even part-time she wasn't really able for this and was then off sick for the best part of four years. This had a major impact on the household income. She was in and out of hospital regularly (and still is) – had a lot of sub-acute small bowel obstructions and then had to have her gall bladder removed.

When she was recovering Caroline started to wonder how something could go so awfully wrong, when she went in for a relatively simple procedure. She had received no explanation or apology for what had happened, so she lodged an official complaint to the HSE. HSE conducted a full root cause analysis by their Risk Management team and a final report was issued in April 2008. The report acknowledged that there was a care management issue in the delay in the diagnosis of Caroline's presenting clinical condition, and recommended a care management review of how this would be preventable in future.

One element of Caroline's complaint was that, when she got a copy of her records from the hospital, she found information about her emergency surgery that had not been given to her before. During the emergency surgery for the perforated bowel it was discovered that she had another cyst (on the same ovary), but nobody had ever mentioned this to her before. The surgical team had not been aware of this and it was inadvertently perforated during the surgery. The HSE review report recommended that full disclosure and explanation of events (including unplanned events) should be part of the post operative consultation with the patient.

But there was no admission of error in the report and Caroline was left without answers. She says there *'…was never going to be an admission of any error on his [the consultant's] behalf…they said that I had a weak bowel – but I had never had a problem with my bowel prior to that… I was left with a lot of questions, like, do I have an underlying bowel condition or not?' I needed to know!'* So Caroline had to resort to litigation in order to try to get to the truth. This was a long, expensive and stressful process. Caroline's case was lodged with the court system in March 2007 and was eventually set to go to trial in January 2013. But it was settled at the last minute at a meeting in December 2012, with an admission of liability by the HSE. And Caroline says *'…that's all I ever wanted…for somebody to say, we did wrong here, we caused you harm.'* Even without ever going to court, there were 200,000 euro legal costs just from Caroline's side. She says *'…this is money that could be much better spent on improving patient care…there's got to be an easier way for people to get the truth…not to be putting up a full defense for something that's really indefensible…'*

The recommendations in the HSE's risk management review report on her case address some aspects of care, but Caroline feels there is need for mechanisms to ensure fuller learning from adverse incidents such as hers. Doctors and nurses should listen more to the patient and observe, not rely only on machines. More attention should be given to patient consent (highlighted by the episode where a nurse forced her to get out of bed). It would be good to capture both sides of the story (ideally for herself and the consultant to work together on the story) and the lessons that can be taken from it. Patients should be supported during the review process after an incident (e.g. by Patient Liaison Officer).

Kevin's Story

Kevin's mum, Margaret, recounts the beginnings of the tragedy in 1997, a year and ten months before Kevin died. During that year, 19-year-old Kevin presented on a number of occasions with persistent back pain. Without any improvement, he was referred to an orthopaedic consultant in the autumn. Blood tests revealed high levels of calcium (3.51m.mol/l). This level of calcium causes serious damage to health and is most commonly an indication of primary hyperparathyroidism or a malignancy. Other parameters were also raised. All of these abnormal results were underlined in the laboratory report. When the consultant wrote to Kevin's GP he noted his intention to see him again early in the New Year, but underplayed the high calcium levels and ignored a plasma creatinine level indicative of more than 50% loss of overall renal function. That letter is not on the GP's file and the consultant's intention to see him again was never conveyed to Kevin.

Kevin's file contains a notation by the Consultant's secretary following subsequent contact by Kevin's Mum. *"Telephone call from patient's mother. She is extremely worried about her son. She wishes you to know that she thinks he may be depressed also. Failed his first year exams, repeating and not doing well either, finding it hard to study. He is now remaining in bed a lot. She has arranged an appointment with Dr X (a psychiatrist) tomorrow and would like to have results of bloods, bone scan, etc for the consultation. She wonders if he really has a back problem. What can I tell the mother? She wished to speak to you. Results in file"*. The doctor's response was "fax results to Dr. X"…and there was no direct contact with the mother or the patient.

After this, Kevin had repeated consultations with his GP, physiotherapist and other services, but nobody diagnosed his condition. He spent the summer of 1999 in the US, and on his return attended his GP complaining of lethargy, occasional vomiting and continuing bone pain. Blood and urine samples were taken, with test results being telephoned to the surgery the next day and written on a Post-It note by the practice nurse, who drew attention to the high calcium level (now at 5.73m.mol/l). However, the GP did not mention this in his letter of referral to the hospital, focusing only on those elements of the blood test results which supported his own diagnosis of Leptospirosis, but he did send the Post-It with the letter.

When compiling the file in the hospital, the Post-It note containing those vital calcium results was stuck to the back of the letter and was not seen until six weeks after Kevin's death. The standard blood test in that particular hospital did not include testing for calcium levels. So, throughout his time there they remained unaware of Kevin's dangerously high calcium levels, and a diagnosis of nephritis was made.

At this time, even as his condition deteriorated rapidly, no medical personnel seemed to appreciate how ill Kevin was. He became dehydrated and described muscle pain and neurological problems – his medical notes quote him as saying *"I have crazy thoughts coming into my head".* These notes also show advancing renal failure. Margaret says '…*Two crucial days were lost during his stay in that hospital – further missed opportunities as yet another point of contact failed Kevin…'*

Finally, Kevin was transferred to a tertiary hospital and it was there that the family first heard concern over calcium levels of 6.1m.mol/l. Kevin's care was left to be managed at Registrar level – senior personnel were not alerted and more aggressive treatments were not available at the weekend. Margaret cannot say if that would have resulted in a better outcome…*' but it would be nice for me, his mother, to know that he was given every chance'.*

Margaret tells how Kevin tragically passed away at the hospital '…*during Sunday, Kevin was lucid but very sleepy, giving a thumbs-up to his father before he left his bedside. At 3.30 p.m, just as the young SHO came to check on him, Kevin suffered a heart attack as his sister and I sat at the bedside. Sadly, attempts at resuscitation failed… Kevin had died right before my eyes.'*

Margaret says '…*Kevin's death certificate lists multi-organ failure, hypercalcaemia, parathyroid tumour… but adverse events happen to real people. Kevin was more than a statistic, he was more than a medical condition. He was a real person, a young man, full of life. But above all, he was my beautiful boy – handsome, strong and carefree…'* And that was the end of Kevin's patient journey, a journey which could and should have been much less prolonged, and with a happy ending…if only the obvious had been properly flagged and appropriate interventions made during his various contacts with GPs and Consultants over the two years before he ended up in hospital.

Kevin's Story (continued)

Even worse was the apparent lack of learning from the tragic events. Margaret recalls a chance meeting with the SHO, six weeks after Kevin's death. *'He said "Kevin was very unlucky" – that was all he brought away from the tragedy. What a waste of an opportunity for learning and self-growth for that young man. The organisation took the easy way out and left him with a superficial perception of what had happened.'*

This is despite the fact that the family have a special memory of that young SHO on the afternoon of Kevin's death. As Margaret recounts *'…Kevin's friends started to arrive at the hospital – they were confused, bewildered and in a state of shock, many of them sitting on the hospital corridor floor with their backs to the wall, heads in hands. That SHO passed by, stopped, took off his white coat (the barrier), rolled it up, placed it on the ground and, saying nothing, he just sat with them – a most wonderful spontaneous demonstration of solidarity. He showed himself to be a decent, empathic and insightful young man. He deserved better than a superficial explanation.'*

Margaret and her family were in shock and left with so many unanswered questions. *'Nothing or no one had prepared us for this – we had no warning, we never considered his life to be in danger and no one had intimated that this was the case. We had questions and we needed answers. How can a twenty-one year old young man be admitted to hospital on Thursday and die on Sunday? What went wrong? What we encountered was closing ranks, lame excuses, muddying the waters and protestations of loyalty to colleagues.'* In the immediate aftermath of Kevin's death Margaret says *'…there were initial honest and humane reactions from individuals, especially the nurse, for which I will always be grateful.'* But this was soon replaced by a process of damage limitation. One doctor described his dilemma as an issue of *"loyalty to colleagues"*.

Because their confidence in being able to find the truth through honest dialogue was shattered, Margaret and her husband were forced to go the litigation route. *'For ordinary people, like ourselves, it is a David and Goliath experience. Until the 11th hour every effort was made by the defendants to settle without admission of liability – a wearing-down strategy that lacks compassion and consideration for heart-broken people.'* Still, Margaret and her family stuck with it. Almost five years later, they were vindicated in the High Court where medical experts stated (and the judge agreed) that Kevin's condition should have been clearly evident and, properly treated, *'…Kevin would have had surgery to remove the over-active parathyroid gland. He would have been cured and would still have been alive today."*

There was a financial provision, but Margaret says *'…monetary compensation was never an issue for us as a family… we donated the settlement figure to two charities.'* Two GPs, a private consultant, a hospital consultant and a hospital all admitted liability. They expressed their regret at Kevin's death and sympathised with the family. Sadly, this was done through legal representatives and not in person, something that would have provided credibility and acceptance of individual and corporate responsibility for the tragic outcome.

Margaret's call for open disclosure, her call for reporting and learning are all grounded in the fact that: *'I was present at Kevin's birth. I know every detail of that birth. I was also present when he died. As his mother, I needed and deserved to know everything relating to how that came about. Over and above that, it is essential that I be assured that lessons will be learned, that those lessons will be disseminated – all in the hope of preventing recurrence.'*

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Melissa's Story

In 2009, Melissa was five or six weeks pregnant. She had a history of early miscarriages and was worried about this latest pregnancy. *'I went to the doctor even though I was showing no signs of miscarrying and she said to go to the early pregnancy unit at the hospital. I had a scan the following day where they said that they couldn't see anything but they asked me to come in again in 2 weeks' time.'*

In the intervening time Melissa had been on holiday in the West of Ireland and had felt many of the signs of early pregnancy, including sickness. She didn't have that feeling on the 4 pregnancies that she had lost, but she did on the pregnancies of her 2 children, so she thought this was going to be OK. When she returned from holiday, Melissa attended the early pregnancy clinic at the hospital for the scheduled follow-up scan.

She could see on the scan that the foetal sac had gotten bigger, but the doctor looked at the midwife and just shook her head. The doctor said: *'Sorry, but this pregnancy is not going to progress'.* Because she was still only 8 weeks pregnant and had not displayed any of the signs of a miscarriage, Melissa asked again were they sure. But they said that there was no heartbeat there, and that they needed to discuss the options. *'It was pretty devastating. Our options were that we could let nature take its course, they could give me tablets, or I could have a D&C… we said that we would go for the D&C, because it was quick and it was clean and I had had it before.* There wasn't a slot available until 2 days later and Melissa says '*…they told me to go home and gave me a drug…to be taken on the morning of the D&C, to open the neck of my womb and help it contract.'*

The following day Melissa still felt pregnant. On a friend's advice, she went to a local GP for a second scan, and what a surprise when she got this scan! *'She [the GP] put the probe on my stomach and I could see a heartbeat, I could see it. My initial reaction was pure joy. And I said to her 'is that my baby's heartbeat?'* The GP wanted to check with another doctor *'… He came in and flipped a switch on the machine, and all you could hear was' bump, bump, bump', of my baby's heartbeat, and he said 'I'm afraid the hospital are very wrong".* They were so fortunate to have got the second opinion when they did. *'Luckily they [the hospital] didn't have a slot on the Wednesday or Thursday or I would have had the D&C and I would never have known.'*

Melissa's husband rang the hospital to tell them that she would not be coming in for a D&C. *'They wanted to see me again so that they could clarify what had happened, and it was at that point then that I began to feel very nervous.'* Melissa and her husband went to the hospital and she was seen by the doctor in charge of at-risk pregnancies. It did take her a while, but eventually she said that she had found a good strong heartbeat. Melissa was given medication to help the pregnancy along and she was told to book herself in for her next appointment.

But Melissa wasn't really satisfied. *'I said 'is that it? I need to know what happened and why this happened.'* The doctor asked would Melissa like to speak to the Head of the Department, which she agreed to do. *'They brought us into someone else's office and apologised for what happened, and said that this had happened once before. I said that, given that I had a history of miscarrying, should they not have given me another scan the following week instead of writing the baby off? They didn't listen to me'.* Melissa also asked who would be looking after her for the remainder of her pregnancy and they asked a senior consultant to take over her care. *'I was assured that the original doctor would not be any part of my care'.*

Melissa continued the pregnancy and was hospitalised twice before giving birth. But there was no further mention of the incident by the hospital; its seriousness seemed not to have registered with the system. *'Nobody else spoke to me about what had happened. Nobody else came near me. At one point during the pregnancy the doctor who had done the initial scan came along to do another scan! I didn't believe that they would let her near me…we had to tell the senior staff what had happened and what we had been assured of. They had no knowledge of the incident and, incredibly, had to read through my notes!'*

Melissa's Story (continued)

During that period, Melissa's husband had been in touch with their solicitor and had informed him of the situation. In October 2009, they found out from the solicitor that the hospital were conducting an internal investigation. But they had never discussed the case with Melissa. *'All throughout my pregnancy and my three hospital stays, not one member of management or staff spoke to me about my experience, which I found upsetting. I felt that if I hadn't gone to my solicitor I would never know why I was misdiagnosed and what the hospital planned to do about it'. In January 2010 the hospital reported on my case.* The hospital had found that the heart rate monitor was old and subjected to a heavy workload and that this had been known before Melissa's misdiagnosis. In addition, the couch that was used in the examination was the wrong kind of couch, and the person who did the scan wasn't qualified to do so. Despite these findings, nothing had been done as a result of the investigation. *'They were still using that scanning machine 6 months after my case.'*

Melissa was left feeling very unhappy and unsatisfied. *'When I found out all of this, I just felt that it was my duty to go public with it. I needed to go public with it and to let women know to trust their instincts in these matters. I didn't believe that I was the only one that this had happened to. I needed changes put in place to prevent it happening again.'*

The story was covered in the press and on TV, and the publicity eventually led to the establishment of an independent enquiry covering all HSE maternity hospitals. This found 24 similar cases in the previous 5 years, with similar problems of faulty and outdated equipment, lack of training, lack of appropriate couches and a lack of appropriate services. The National Miscarriage Misdiagnosis Review was published and the HSE has been implementing its recommendations since through the Clinical Care Programme in Obstetrics and Gynaecology.

Publicising her story has helped to reduce the likelihood of similar incidents occurring again. Melissa also emphasises that it would have been both more proper and more effective for the hospital to have involved Melissa in its investigation in the first place, and to have communicated its results to her. She also feels that one of the root causes of the problems she encountered was that she wasn't listened to during the initial scan. She feels that if she had been listened to, none of the subsequent problems would have occurred, and that women need to be enabled to trust their own feelings in situations like the one she encountered.

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Sinead's Story

Anna tells the story of her sister Sinead who developed kidney problems which needed dialysis for all of her life. Anna became Sinead's primary carer. Eventually, Sinead's health had deteriorated to the extent that she was reaching the end of her life. Bute some problems with occurred – *'One day she did a dialysis exchange after which she got MRSA – she was in hospital for nearly 5 months'.* After this, Anna feels that some of the health care team could not face up to the issues. *'Sinead died steadily between 2003 and 2008. And she died hard. By 2007 I could see she was failing. They could not talk to us about end of life. I think that they just did not want to lose her because some of the team had worked with her since she was a child'.* This failure continued – Sinead moved to a high dependency unit in 2008 where Anna had a confrontation with a consultant *'I said to the consultant she's dying… The consultant asked "Well you tell me what she is dying of [because it didn't show up on the tests]". But I said "I'm her sister not a doctor. You tell me what she is dying of…"*

Anna says there were other distressing incidents *'for instance one night a confused old man climbed into her bed – she was terrified because she couldn't move physically… we refused to leave her alone in the hospital then, and I think that maybe we were regarded as being the 'bad (*awkward) *family.'*

The attitude of some staff left a lot to be desired. Once, Anna was publicly criticised for gaining entrance to the ITU – *'When I went in, the nurse saw me and came across the ward…and she raised her voice to me and was quite aggressive about coming in without permission,* [even though a doctor had invited her in].*'* There were other examples. *'One evening Sinead was actually bending over in pain. The nurse was trying to support her to cope with another half hour of dialysis.'* Sinead said to Anna *'I can't do this anymore'.* Anna said *'It was too late – we were saying she can't take it – we are saying no – what part of no don't you get?'* Anna was very concerned at this lack of listening and the failure to recognise the gravity of her condition – *'I was looking at a potential suicide. Sinead did not want to end her days hooked up to machines, but this is what happened. Nobody could talk to me about palliative care. She is facing end of life and no one is talking to her (or me) about it.'*

The end was coming close – *'She was getting sicker and sicker and then she plateaued for a while. I had to go to abroad but then I was told to get home fast. She had slipped onto a coma by the time I arrived, and we never saw her again. I then had to make the decision about withdrawing treatment and this happened without her own consultant being there. He would not talk about Sinead dying.'*

Anna felt that interaction with her at the very end was insensitive. *'When they were turning down the noradrenalin the nurse who was doing it was chewing gum as she spoke across Sinead… then they asked me to step outside to discuss a post-mortem while she was still alive. When I was outside with the consultant, one nurse was discussing what she was doing that night. Also while my sister was still alive they were talking about a post-mortem in the middle of this busy ward. The discussion about a post-mortem should have been done after her death and not in an open hospital ward.'*

When Sinead eventually died, there was little sensitivity around family needs. *'It was very, very hard. Lucky it was a Saturday, because there was a 2 day delay in doing the post-mortem and that was the only time we had to come to terms with what happened. Sinead was at the heart of the family and, quite apart from direct family, we had a load of foster kids who had seen Sinead as a key part of their lives. They didn't get to say goodbye.'*

Anna feels that end of life treatment was not handled professionally. *'This is their bread and butter every day, but to us it is one of the most traumatic experiences of our lives. I had to pick up the pieces for my family afterwards and no one ever came to ask us how we were.'*

Sinead's Story (continued)

Lessons to be learned …

- Some parts of the system and some people were very helpful – '*Not all of it was awful. For example, the dialysis nurses that came down to our home for the funeral were wonderful.* Anna also feels that MRSA is a complex issue and she doesn't harbour blame for it. '*The MRSA that Sinead got, I'd say that it was waiting to happen and that it is a global issue. The MRSA just finished her off.'*

- End of life care was slow to happen and was handled badly. '*When she died there were brochures for ocean cruises with dialysis services! She was a … woman who loved life and it seems that, no one actually thought that she might die. What did they think, that someone with an illness like Sinead's was going to live forever?* There is a failure to deal with issues relating to dying. '*There needs to be a more open attitude about terminally ill patients …, and not have a fear of failure, or whatever it was.'*

- Anna feels strongly that palliative care should have been made available. She says '*First of all it should have been in a palliative care setting. The difficult conversation had to be had and no one recognised it except me that she was dying. We missed the last few weeks of her life as a result.*'

- For Anna, insensitivity was at the heart of the negative experiences that she had. '*They need to have awareness all the time of the patient and family. And death has to be handled more sensitively. After Sinead died I got her stuff back in a yellow bag. I know that this has changed since then.'*

- Anna also notes the failure of services to listen to her about the severity and nature of Sinead's illness. '*I wasn't listened to, I think because they are so busy. I don't think they are unkind people, I think they would have sat down if they had the time to do it. But if you have 10 people doing 20 people's work this is what you are going to get.'*

- Another point Anna raises is that many clinicians do not face up to the issues of death and dying. '*The consultant did not want to see that she was dying. He thought that he should do everything to keep her alive, that this was his role, but now it was time to let go.'* More generally, Anna thinks that '*every hospital should have a hospice ward for a start. Politeness and courtesy are not an add-on. It is a part of the culture that we are supposed to care.'*

- Structural problems need to be addressed. '*In ICU, we have to be very careful of burnout. We have high octane situations with high octane workers. I see this with some of my own students. Some of them have to be in on the drama. We do need people like that, dynamic people who will not collapse under the pressure and we need those workers.'*

- There is a need to have a pastoral role and perspective in the care team: '*We need to have someone else on the team, but someone who is involved all of the time who can stand back and soften the situation. We need someone to oversee the pastoral care.'* She goes on '*There is a disjointed system – maybe we need a patient advocate, or someone who has been through it, or we need a new role. It is an issue of the balance of the clinical team. It needs someone who is being human about it.'*

- Anna also feels there is a need to improve how the system deals with mistakes. '*The system doesn't learn from its mistakes, because they are afraid. There is a fear of negative consequences if they admit mistakes.'*

- Another issue for Anna is the almost exclusive emphasis on the patient. She feels that a more holistic approach is needed – '*the treatment is focused mainly on the person who is ill, not on the family or carers or significant others. However, the person who is ill is relying on the family or the carer to take them where they need to go, whether it is out of hospital or to let go.'*

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Staff Stories –
"The Second Victim"

What is meant by the term 'Second Victim'?

The term Second Victim was first coined by Albert Wu, MD, MPH, Professor of Health Policy and Management at the Johns Hopkins School of Public Health in a 2000 British Medical Journal article. He is a leading expert on disclosure and the psychological impact of medical errors on both patients and caregivers. In this article he recognised that when a patient is seriously injured by health care, there are almost always two victims and one of those victims is obviously the patient. A second victim is the health care professional involved in the incident that feels in some way responsible and is emotionally traumatised by what happened.

A May 2011 study[1] identified that one of the most striking findings was how every second victim participating in the project described their respective unanticipated clinical event as a life-altering experience that left a lasting impression on them. One healthcare professional described his second victim experience as an "emotional tsunami," unlike anything he had ever experienced before in his professional career.

Numerous variables contribute to the severity of the second victim response. A patient that 'connected' the healthcare professional to his/her own family (such as a service user with the same name, age, or physical characteristics as a loved one), the relationship between the service user and caregiver, length of professional relationships, cases that involved paediatric service users, and the healthcare professional's past clinical experiences influenced the severity of the second victim's response to the safety event.

Although each case was unique and the healthcare professionals involved developed individual coping skills they in common described a similar recovery path. The study identified six stages that described the second victim recovery process: (i) chaos and accident response, (ii) intrusive reflections, (iii) restoring personal integrity, (iv) enduring the inquisition, (v) obtaining emotional first aid, and (vi) moving on. The sixth stage was unique in that it led to one of three potential outcomes: dropping out, surviving, or thriving.

Though the six stages were common, the research found that similar to the stages associated with grieving, each individual, though not necessarily following the six stages in a linear sequence, does have a unique support requirement i.e. that no one intervention will meet everyone's support needs.

Supporting the 'Second Victim'

The first and most important source of support to staff who are involved in an incident is the person's line manager and their colleagues. They need not to feel isolated and alone, rather they need to feel a sense of empathy and support. This response in many instances, especially in the immediate aftermath of an incident, does not need to be complex, it can be as simple as acknowledging the event and the impact on them and enquiring about how they are feeling, whether they would like to take a break or to go home early. The impact of such an immediate response cannot be overestimated and can greatly assist in framing the next steps. We need to see the offering and acceptance of assistance and support as a positive human response to what can be an emotionally distressing experience rather than a sign of professional/personal weakness and vulnerability. In addition to providing an appropriate support response at the time of the incident and following this up with an offer of more formal support options to staff (such as employee assistance programs [EAPs], social workers, clinical psychologists, or counselors), the next relevant support of or when available relates to ensuring that they have a positive experience in contributing to the incident review process and a chance to participate in any identified system redesign to reduce the risk of a similar incident recurring in the future.

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1   The Second Victim Phenomenon: A Harsh Reality of Health Care Professions https://psnet.ahrq.gov/perspectives/perspective/102

Without such support the impact of incidents on staff can be so devastating that it can have a bearing on their future practice and often in their personal lives. In some cases this can lead to those staff not feeling able to continue to the extent that they leave practice. In the same way as the Incident Management Framework places emphasis on the need to support service users and their families it must also seek to support staff. Our objective is to ensure that health care services have comprehensive systems and support structures, including training programmes, in place to

(i) assist staff in preparing for and quickly responding to an incident including engaging in open disclosure discussions with service users and their families,

(ii) aid staff who are experiencing normal stress after experiencing abnormal/highly abnormal events/ incidents and

(iii) to help staff to manage this stress so that they can better care for their patients, so healing can occur, and so that staff can comfortably return to the work environment with normal productivity.

The following stories illustrate the phenomenon of the "Second Victim" and have been kindly and courageously shared with us by staff. They both relate to nurses but there is a desire to broaden the repository to include other healthcare professional groups.

Caroline's Story

On 21st May 2013 I was sent on relief to a 31 bedded surgical ward. The ward was very short staffed and it was a busy theatre day as well. I was working with a Nurse Manager, a Pre-Reg nurse, an agency staff nurse and an attendant. The student and I took handover on 3 six-bay rooms and 2 side rooms while the manager organised the rest of the ward.

I allocated the student to look after the patients who needed breakfast while I quickly ran around checking the observation sheets. I checked that the patients for theatre were ready and then turned my attention to my post-op patients.

Mary was Day 1 post abdominal surgery. She was on intravenous fluids, patient controlled analgesia and oxygen. She said she was comfortable at rest but did have shoulder pain on coughing. I encouraged her to use the PCA and after checking her vitals I moved along to see the other post – ops. The Consultant reviewed Mary while I was attending to another patient. Mary informed me that he reassured her that her shoulder pain was to be expected, he encouraged her to mobilise and advised her that she could commence sips.

She mobilised to the bathroom with assistance for a wash and on return to her bedside sat in an armchair. Her Early Warning Score was 3 at that time but I was not alarmed as she had mobilised and was on 2L oxygen.

Late morning she had routine bloods taken and after physiotherapy she returned to bed for a rest. When I checked on Mary she looked uncomfortable and she felt she may have overdone it. I checked her pulse noting she had a slight tachycardia so I encouraged her to use more analgesia.

Just after lunch, the Physiotherapist informed me that Mary was light headed so she didn't take her out for a walk. She had used a lot of analgesia and had pin point pupils. We got her back to bed as she felt unwell. At this point she was hypotensive and had a tachycardia. I contacted the surgical team, did an ECG and increased her fluids.

I continued to keep her under observation while I managed 2 other patients who had returned from theatre as well as giving 2pm medications. About an hour later the student called me to say Mary was nauseated. When I went to give her an anti-emetic I noticed she was very clammy. She said she was dying and asked me to get her husband in. I reassured her that it was probably the analgesia that was making her feel poorly and that she'd be fine.

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Caroline's Story (continued)

The Intern arrived after 4pm. He reviewed Mary and said the Registrar was on the way. It was about 5pm when the Registrar and Consultant came to the ward. I went to get her blood results while they reviewed her. I was alarmed to see that her urea and creatinine were extremely raised. Mary told the Consultant that her shoulder pain had gotten steadily worse throughout the day. He asked for an urgent x-ray and increased her intravenous fluids.

The nurse manager arrived and questioned why I had not documented more frequent observations in the Early Warning Score sheet. This was done in front of the consultant and patient who looked even more apprehensive. I was told to write up my notes and another nurse would take over from me. I completed my nursing notes on all the patients, and left the ward after 6.30pm.

I returned to work in my own ward the next day and was called into the manager's office. She said that Mary had died at 11pm that evening and that there was criticism of my records and the care I had given. My manager was sympathetic but advised me to jot down what happened as the risk manager wanted to interview me.

I was devastated for Mary and her husband who had joked with me that afternoon about Mary liking her morphine. I remembered telling her she'd be fine when she said she felt something bad was going to happen. I also remembered the nurse manager telling the consultant that I hadn't recorded the observations enough and was distraught that perhaps I was somehow to blame. It was so unfair as I hadn't stopped running all day and stayed back after my shift had finished because it was the right thing to do and I couldn't just walk away when it was so busy.

Later that day I met the risk manager who asked if I was ok. I burst into tears when she tried to be nice to me – it was as if she had opened the flood gates – a patient I had cared for died, I couldn't cope with someone being nice to me!

She asked me why I was so hard on myself and I told her about the conversation I had overheard and how I had left the ward that evening totally deflated but this was nothing now that the patient had died. She explained that she would carry out a review of Mary's care but not to worry. How could I not worry; a patient died and I was being asked to account for my actions.

I was so angry, I had never had any training on the Early Warning Score but I was a bloody good nurse and I may not have recorded every single thing I did with Mary that day but I did the best I could when the ward was short staffed and the manager never came near me.

The risk manager was soothing but I knew someone would be held to account and it would be me. She offered me support but I just wanted to get away from her, she asked if I wanted Employee Assistance and I felt my world was falling apart.

We arranged to meet the next day to finalise my statement. I phoned my partner and he told me that I shouldn't have given a statement without getting advice. I didn't sleep that night with worry. The next day when I was on duty the consultant was on my ward and he approached me. He asked me what had gone wrong the day I looked after Mary and why hadn't I called his team sooner. He was told that not completing the Early Warning Score sheet was a fitness to practice issue but this was something he wouldn't share with Mary's husband who wanted answers.

I felt sick; I didn't know who to turn to. I contacted my friend and she tried to reassure me but I couldn't even listen to her. I felt I was going to be physically sick and couldn't concentrate on anything. Eventually my manager told me to go home but to let the risk manager know as we were to meet up in the afternoon. I called her and she said she'd come to see me. When she arrived she didn't say a word she just hugged me and I felt my heart burst. I vividly remember that moment thinking I had never felt so crushed before – this is what devastated sadness feels like.

The risk manager took me to her office. I told her about the conversation with the consultant. She could see I was destroyed and kept telling me that it wasn't my fault, that I was good at my job and my line manager totally trusted me. It didn't help, Mary had died on my watch!

I gave my statement and was told to keep my chin up. She gave me her number and told me to call her anytime. She couldn't see that meeting her would be painful and so I kept it all inside and returned to work on my ward half the person I had been.

Caroline's Story (continued)

I had been planning my wedding but I felt my light had gone out and felt it was wrong to be planning my wedding in the aftermath of this awful event. Some weeks later I met the Intern who had reviewed Mary and he asked me how come I hadn't noticed the patient had deteriorated. I couldn't even answer him – I knew then I had to move to another hospital. That evening as I was leaving the ward the manager called me aside saying she was worried about me. I had lost weight and was drawn – Did she think I was made of stone!

The next day the risk manager came to the ward and I felt sick with worry. She took me for coffee and asked me to tell my story again as if it was for the first time. She jotted down some notes. She read out the statement I had given her 5 weeks earlier and then read out the notes she had just written. I was shocked at just how different they were. My statement was an account of my care and observations and the notes she wrote were ones of self-doubt and self-criticism.

She reminded me that Mary's death was subject to a Coroner's Case and we didn't know the cause of death and I was doing a disservice to every other patient in my care. She asked me what exactly I was taking the blame for. Did I order the bloods? Did I neglect to call the doctor? Did I falsely reassure Mary knowing her fate was to die!

She made me promise to phone the Employee Assistance Programme and I did.

The risk manager phoned me when the Coroner's Case was scheduled as I was called to give a statement and she came with me. It brought it all back, that sick feeling in my stomach that I'd have to meet Mary's husband again and see the anger in his eyes.

I answered the questions asked of me by the Coroner, he was very formal but his questions were very clear and there were no catches. He noted that my care was exemplary. Mary had sustained a perforation during surgery. She needed antibiotics and surgery to save her life.

That was over three years ago, a time in my life I will never forget. I did get married but it was a very different person who walked up the aisle. I did leave my job and went to work for an agency while I sorted my life out.

I am strong now and I care for my patients zealously, perhaps too intensely at times. I can never let go of the feeling that Mary might be alive if I had done more.

Sean's Story

I was a nurse manager in an Accident and Emergency Department in another country.

The department was experiencing one of its busiest ever days for emergency admissions. An inter-hospital/ambulance service overflow emergency plan had been instigated but the neighbouring departments were also full and the ambulance service continued to bring patients to my department. Having got in early at 7.30 that morning I decided to stay on after my shift finished as there were several ambulances "stacked" outside, all cubicles were full and the floor area was full of patients on trolleys. I took over the triaging of ambulance patients to try and get these people into the department from the ambulances waiting outside. I triaged one patient who had fallen and sustained a limb injury. The patient was conscious, alert and orientated. Having had the handover from the ambulance crew I allocated this person a "yellow" category (to be seen by a doctor within one hour) I asked a nurse to do a baseline set of observations. I moved another patient out of a cubicle and this patient was taken in and transferred to a hospital trolley. I did not see this person alive again. I left the department later that night – it was still extremely busy. I returned the following morning at 07.30. I was immediately informed that a patient had been "found dead" in a cubicle. It later transpired that this was the individual I had triaged and this person had not (to our knowledge) been checked subsequent to having had initial observations on arrival.

All of us who worked that evening and night were shocked and upset at this death. The fact that this person died alone behind a curtain, without being checked for several hours, was particularly distressing.

An external review was commissioned and all those involved were assured it would be a systematic review looking at all the operational aspects of that evening, night and morning. In the event it felt like an exercise in apportioning blame. In the immediate aftermath and during the review there was little or no support for those involved. None of us was asked if we were needed help or support – we were expected to get on and cope. There was significant media and political interest; it felt that there was a clamour to have the report completed and fingers pointed at the nursing staff in the department. Staff were kept in the dark about the outcomes of the review; we were informed that the report would be anonymised and focus on the issues of overcrowding, understaffing, medical and managerial support and bed management. In the event all these significant factors were given little if no credence and on the morning of publication we were told that the report would not be fully anonymised before release to the media by press conference.

This felt like a second blow to those involved. Each of us wanted a full but fair disclosure of events on that night but this was not to be. To those involved it felt like we had been hung out to dry. We acknowledged and fully accepted certain failures but the absence of support following the event and then during and after the review have had lasting effects on me and several of my former colleagues. The feelings of distress, failure, anger and something akin to grief never leave. They are suppressed but can resurface at any time, triggered sometimes by the most innocuous event or recollection.

It is a cliché but none of us came to work that day to give anything less than our best. An individual died alone in noisy A&E Department having been left for several hours without anyone checking their wellbeing. That tragedy can never be reversed nor erased.

The Health System, particularly Emergency Departments, is under incredible stress and strain. An event like this could happen again. I hope it doesn't but if it should I would ask that if you are a Senior Manager you remember that the concept of the "second victim" is a real phenomenon. A cursory "are you OK?" is not enough. There are at least three former colleagues who, following traumatic events, have left nursing and are scarred by the experience of the event and the lack of support in the aftermath. Supporting staff and caring for their welfare is a tenet of basic humanity let alone a managerial function. Not everyone wants to be cuddled, counselled or comforted but if you don't ask, how can you know?

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