Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Guideline Title: Guideline for the Implementation a Look-back Review Process in the HSE

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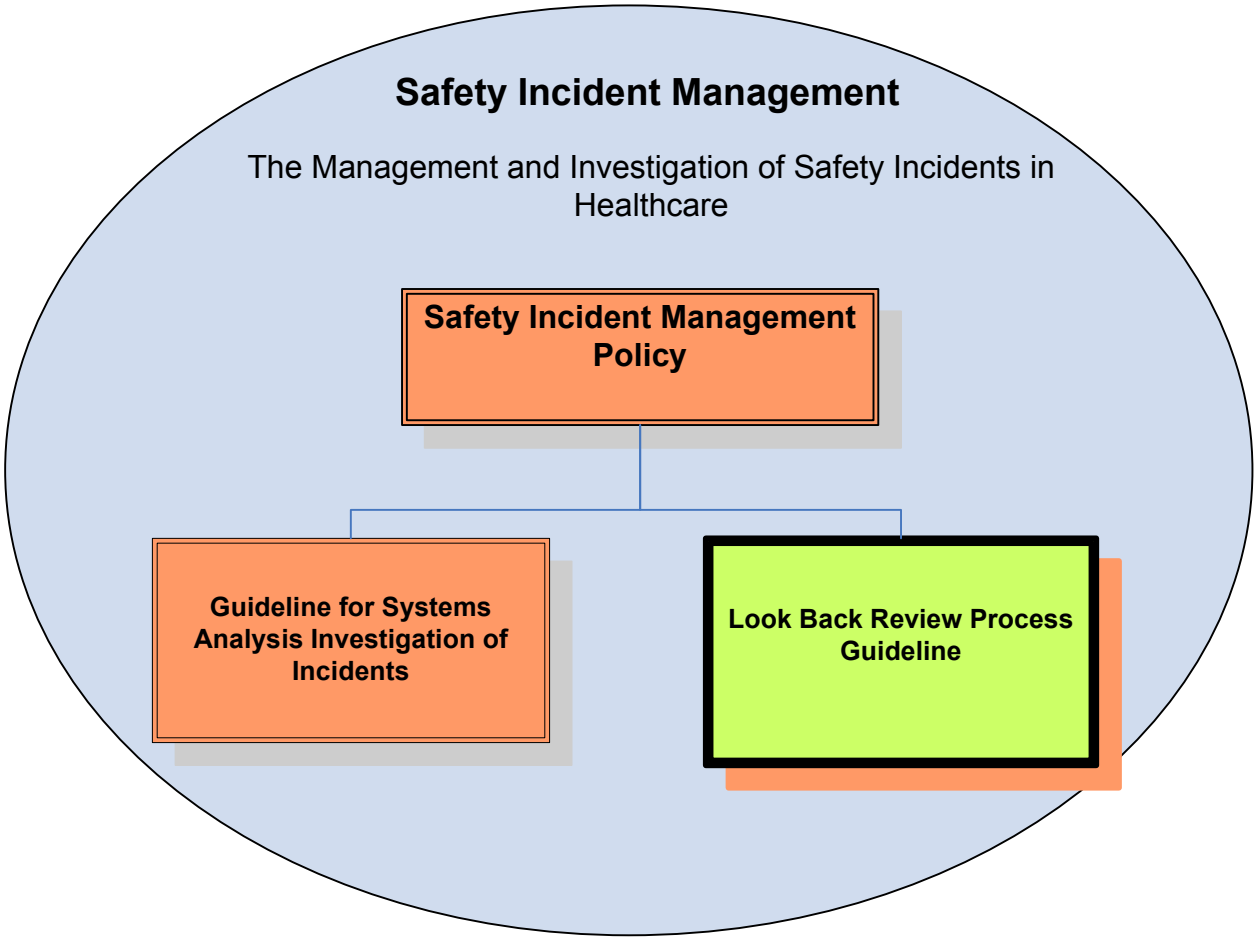
Management and Investigation of Incidents in the Health Service Executive

Framework Documents

The following is the framework of guiding documents that provides HSE staff with the required policies, procedures and guidelines to manage and investigate incidents within the HSE.
The Guideline for Systems Analysis Investigation of Incidents must be used in conjunction with the other documents within this framework to ensure that there is proper and considered communication, management and investigation of incidents throughout the HSE.



The Look-back Review Process Guideline falls within the context of the HSE Safety Incident Management Policy (2014, and subsequent revisions) which was not in place for the previous version of this guideline. The Look-back Review Process is implemented within the HSE in conjunction with the principles of Open Disclosure.

Please find all current versions of the above documents in the Quality Assurance and Verification section of the HSE website at http://hsenet.hse.ie/qav/

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1.0 Policy Statement

A Look-back Review Process is implemented as a matter of urgency where a number of people have potentially been exposed to a specific hazard in order to identify if any of those exposed have been harmed and to identify the necessary steps to ameliorate the harm.
Reasons for considering a Look-back Review Process may include but are not limited to the following:

- Audits showing that the results delivered by either a service or an individual was not in line with best practice standards and there is a concern that there was potential harm caused to a cohort of service users as a result;
- Identification of a faulty batch of vaccines;
- Equipment found to be faulty or contaminated in a manner that may put people at risk of harm;
- Concern about missed, delayed or incorrect diagnoses related to diagnostic services such as radiology/pathology services etc;
- Identification of a staff member who has been involved in exposure-prone procedures when there are indications that the staff member should not have done so e.g. Hepatitis B infected;
- Concerns raised due to competence of practitioner or outdated practices;
- As a result of findings of a Systems Analysis Investigation.

The existence of a hazard exposing a number of people to a risk of harm is not always immediately apparent. A systems analysis investigation of a specific incident of harm may unearth such a hazard and trigger the initiation of a Look-back Review Process. Conversely, it may be immediately apparent that a number of people have been exposed to a hazard and so a Look-back Review Process is immediately triggered. In these cases a systems analysis investigation of individual cases may still be required to identify the Key Causal Factors and related Contributory Factors that must be addressed. Systems Analysis Investigations must be undertaken in line with the HSE Guideline for the Systems Analysis Investigation of Incidents (2015).

In addition to these Look-back Review Process guidelines, there are specific national policies and guidelines in place that define actions to be taken and individual roles and responsibilities in relation to incidents of blood-borne diseases in the healthcare setting[1] which must be referred to in conjunction with this guideline (please refer to scope below).

2.0 Purpose

The purpose of this guideline is to provide a standardised methodology for the implementation of Look-back Review Processes undertaken by the HSE (and by HSE funded services) to ensure that they are valid, reliable and carried out in line with principles of open disclosure and a just culture.

3.0 Scope

This guideline applies to all employees of the health service and all agencies funded by the HSE including Section 38 and Section 39 service arrangements.
Note: Any reference to HSE services in this guideline includes agencies funded by the HSE.

Many Look-back Review processes involve infectious diseases. In such instances, the Medical Officer of Health has a statutory function in relation to the surveillance and control of notifiable infectious diseases and outbreaks. In addition, the Department of Health and Children has

[1] *The Prevention of Transmission of Blood-Borne Diseases (BBD) in the Health-Care Setting" Department of Health and Children 2005*

developed specific guidance in relation to the prevention and management of infections and blood-borne diseases. This guideline is not intended to supersede any regulatory or statutory obligations and is to be used as guidance for a Look-back Review process in the broader healthcare settings while being cognisant of any regulatory or statutory requirements.

4. 0 Policy and legislative context

4. 1. Legislation

Including but not limited to:

- Safety, Health and Welfare at Work Act 2005 and 2010
- The Health Act 1947- 2014.
- Data Protection Acts 1998 and 2003.
- Freedom of Information (Amendment) Act 2014.

4. 2. Guidelines that are being replaced by the HSE 2015 Guidelines for Look-back Reviews

Serious Incident Management Team Guidelines for Conducting Look-backs (Part 7) (2008).

4. 3. Related policies and guidelines

Related Policies, Procedures and Guidelines include the following and any subsequent revisions of same.

- QPSD-D-060-1.1: HSE Safety Incident Management Policy (2014).
- NIMLT 0010: HSE Guideline for Systems Analysis Investigation of Incidents (2015)
- Open Disclosure: National Guidelines (2013)
- Supporting Staff Following an Adverse Event: The Assist Me Model (HSE/SCA, 2013).
- Integrated Risk Management Policy (2011).
- Developing and Populating a Risk Register Best Practice Guidance (2009).
- Criteria for the Communication or Escalation of Incidents to the National Incident Management and Learning Team (2015)

5.0 Glossary of terms and definitions

Term	Definition
Accident	An unplanned, unexpected, and undesired event, usually with an adverse consequence.
Adverse Event	An incident which resulted in harm.
Audit	In the context of the Look-back Review process, audit involves the review of care/ processes against explicit standards and criteria to identify those who may not have received the required standard of care or where the procedure used did not adhere to explicit standards and criteria.
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.
Harm	**1. Harm to a person:** Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury **2. 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.
Safety Incident/ Incident	An event or circumstance which could have, or did lead to unintended 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 • Financial
Integrated Risk Management	A continuous, proactive and systematic process to understand, manage and communicate risk from an organisation-wide perspective.
Investigation Commissioner	The Commissioner of an investigation 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.
Investigator	An individual who has training and experience in conducting investigations in accordance with HSE guidelines i.e. Systems Analysis Investigations of Incidents and Complaints and / or Look-back Review Guidelines.
Just Culture	A just culture seeks to balance the need to learn from incidents and the need to take disciplinary action.
Key Causal Factor	Issues that arise in the process of delivering and managing health services which the Investigation Team considered had an effect on the eventual harm.
Look-back Review Process	A Process consisting of three key stages: Preliminary Risk Assessment, Audit and Recall. This process is initiated where a number of people have been exposed to a specific hazard in order to identify if any of those exposed have been harmed and what needs to be done to take care of them.
Near-miss	An incident which could have resulted in harm, but did not either by chance or timely intervention.
Open Disclosure	An open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.
Person(s) Affected	Patients/ Service Users/ Staff members potentially affected by the hazard which is the focus of the Look-back Review Process.
PPPG	Policies, Procedures, Protocols and Guidelines
Preliminary Risk Assessment	A thorough assessment of potentially affected areas of the health service to determine the chance of harm and the seriousness of that potential harm following notification that a Look-back Review may be indicated. The Preliminary Risk Assessment will be used to determine if the Look-back Review Process should proceed to the Audit and Review Stages.
Recall	An act or instance of officially recalling someone or something. In the context of the Look-back Review Process, the Recall will involve the examination of the patient/ service user and/ or the review all relevant records in line with the Terms of Reference and will identify any deviations from required standards of care. Appropriate corrective actions will be identified as appropriate.
Risk	The chance of something happening that will have an impact on objectives.

Term	Definition
Risk Management Process	The systematic application of management policies, procedures and practices to the activities of communicating, consulting, establishing the context, and identifying, analysing, evaluating, treating, monitoring and reviewing risk.
Safety Incident Management Team	A Safety Incident Management Team is convened by the senior accountable officer in a service, division or 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, 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	The senior accountable officer is the person who has ultimate accountability and responsibility for the services under his/her governance (e.g. in the case of a hospital or hospital group, it is the hospital or hospital group chief executive officer and in the Community Health Office it is the Chief Officer).
Serious Harm	Serious injury to a person, or serious damage done to a thing. • An injury which creates a substantial risk of death or which causes serious disfigurement or substantial loss or impairment of the mobility of the body as a whole or of the function of any particular bodily member or organ. • See HSE Impact table (appendix 1of Safety Incident Management Policy) for specific description of serious harm for both clinical and non-clinical incidents.
Serious Incident	An incident that results in death or serious harm.
Service User	Members of the public who use, or potentially use, health and social care services as patients, carers, parents and guardians. This also includes organisations and communities that represent the interests of people who use health and social care services.
Systems analysis investigation of an incident	A methodical investigation 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), interviews with those involved where the incident occurred and analysis of this data to establish the chronology of events that lead up to the incident, identifying the key causal factors that 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.

6.0 Roles and responsibilities

6.1 Role of Senior Accountable Officer

- It is the role of senior accountable officers in the HSE (and senior accountable officers in HSE funded services) to ensure that effective Look-back Review Processes are carried out, when required, in line with HSE policies, procedures and guidelines and that adequate resources are allocated to facilitate effective Look-back Review Processes.
- Upon identification that a Look-back Review Process is required, it is the role of the senior accountable officer to commission the Look-back Review Process and to establish a Safety Incident Management Team. The senior accountable officer (i.e. the Commissioner of the Look-back Review Process) will also chair the Safety Incident Management Team.
- The senior accountable officer will communicate findings of the Look-back Review Process to the National Director and the HSE as appropriate and as per the agreed communications strategy

6.2 Role of Safety Incident Management Team

In relation to Look-back Reviews, it is the role of the Safety Incident Management Team to:

- Commission a preliminary risk assessment to identify the requirement to undertake the Audit and Recall stages of the Look-back Review Process;
- Decide on the requirement for progression to the Audit and Recall stages of the Look-back Review Process;
- Communicate the need for the Audit and Recall stages of the Look-back Review Process to the National Director;
- Clarify the Scope and Terms of Reference for each element of the Look-back Review Process;
- Oversee the management of all aspects of the Look-back Review Process;
- Develop a Look-back Review Action/ Work Plan which outlines the methodologies to be implemented in relation to the Audit and the Recall stages of the Look-back Review Process;
- Ensure that service managers implement contingency plans for service continuity where necessary, including providing for additional health care demands which may arise as a consequence of the Look-back Review Process, for instance; agree referral pathways, rapid access clinics, diagnostic or pathology services, etc;
- Ensure that service managers allocate the necessary resources to implement the Look-back Review Process;
- Ensure timely communication and implementation of recommended actions arising from the Look-back Review Process;
- Communicate nationally applicable recommendations to the National Director for national implementation.

6.3 Role of Audit Team

An audit team will be established by relevant Service Providers to undertake an audit to identify those to be included in the Recall stage of the Look-back Review Process. It is their role to:

- Apply the audit methodology developed as part of the Look-back Review Action/Work Plan by the Safety Incident Management Team to the cohort identified through the preliminary Risk Assessment stage.
- Inform the Safety Incident Management Team of those identified by the audit as requiring inclusion in the Recall stage of the Look-back Review Process.

6.4 Role of the Recall Team

- Upon completion of the Audit stage of the Look-back Review Process, it is the role of the Recall Team to undertake an examination of the persons affected and/or review relevant patient/service user information/ results etc. in line with the Look-back Review Action/Work Plan and the requirements of this guideline.
- A number of Recall Teams may be required if the Look-back Review Process is required in multiple locations throughout the HSE. The number of Recall Teams required will be determined by the Safety Incident Management Team on a case by case basis.

- The Recall Team will identify actions to be taken as a result of the findings of the Recall stage of the Look-back Review Process.
- The Recall Team will implement any corrective actions as appropriate and will communicate any additional actions to be taken to the Safety Incident Management Team for further action.

6.5 Role of National Director

It is the Role of the National Director to:

- Ensure that the Look-back Review Process is being undertaken in line with the requirements of this guideline.
- Provide required management advice/guidance and support to the Look-back Review Commissioner, the Safety Incident Management Team and the Recall Team as required.
- Ensure that required actions identified by the Look-back Review Process are implemented.

6.6 Role of National Incident Management and Learning Team

- To provide procedural support and advice through the relevant Divisional Quality and Patient Safety Lead and/or the Look-back Review Commissioner as required in relation to the implementation of the processes outlined in this guideline.

Section 7.0: Look-back Review Process

7.1 Introduction

Section 7.2.5.6 of the HSE Incident Management Policy (2014) states that Look-back Review Processes are indicated in circumstances where a number of people have been exposed/ potentially to a specific hazard in order to identify if any of those exposed have been harmed, and to identify the necessary steps to ameliorate the harm (e.g. repeat investigation/ referral to relevant clinical service etc.). Included among the circumstances under which Look-back Review Processes would be considered are:

- Audits showing that the care delivered by either a service or an individual was not in line with best practice standards and there is a concern that there was potential harm caused to a cohort of service users as a result;
- Concern about missed, delayed or incorrect diagnoses related to diagnostic services such as radiology/pathology services, etc.;
- Identification of a faulty batch of vaccines;
- Equipment found to be faulty or contaminated in a manner that may put people at risk of harm;
- Identification of a staff member who has been involved in exposure-prone procedures when there are indications that the staff member should not have done so e.g. Hepatitis B infected;
- Concerns raised due to outdated/incorrect practices;
- As a result of findings of a Systems Analysis Investigation.

Current guidance outlines a three phase approach to the conduct of a Look-back Review Process i.e. risk assessment; audit of records to identified those potentially affected; and patient recall

Decision to undertake a Look-back Review Process

The decision to undertake a Look-back Review Process is a difficult and complex one and should not be taken lightly. A Look-back Review Process should only be considered in circumstances where it is indicated following careful risk assessment which may necessitate external peer review and advice from senior management and/or others with knowledge and experience in Look-back Review Processes and in the subject area in which a Look-back Review Process is being considered.

All processes are subject to variation in performance over time (common cause variation). Sometimes variation is greater than expected, suggesting a specific cause for performance falling outside the usual range (special cause variation). Causes for special cause variation need to be sought in particular, once it is identified (Nolan *et al.,* 1990).

A level of risk and uncertainty pervades all medical practice, and some areas of practice more than others e.g. radiology. Evidence from the literature would suggest that Look-back Review Processes in areas such as Radiology require particularly careful consideration as they are labour and resource intensive and are usually high cost which can result in resources being diverted away from current patient care (Brady *et al.,* 2012).

Nonetheless there is a requirement to determine if the level and nature of the risk is above the expected norms and to take the necessary action to identify patients who have been exposed to a hazard and ameliorate any harm.

The decision to undertake a look-back should be based on a rigorous risk assessment process that identifies that patients were (a) exposed to a hazard and (b) that a means of amelioration exists. In circumstances where these criteria are not met but there is a requirement to conduct an investigation, other methodologies e.g. audits or case reviews should be employed; for instance when there is a demand for retrospective reviews for the purpose of detecting and disclosing

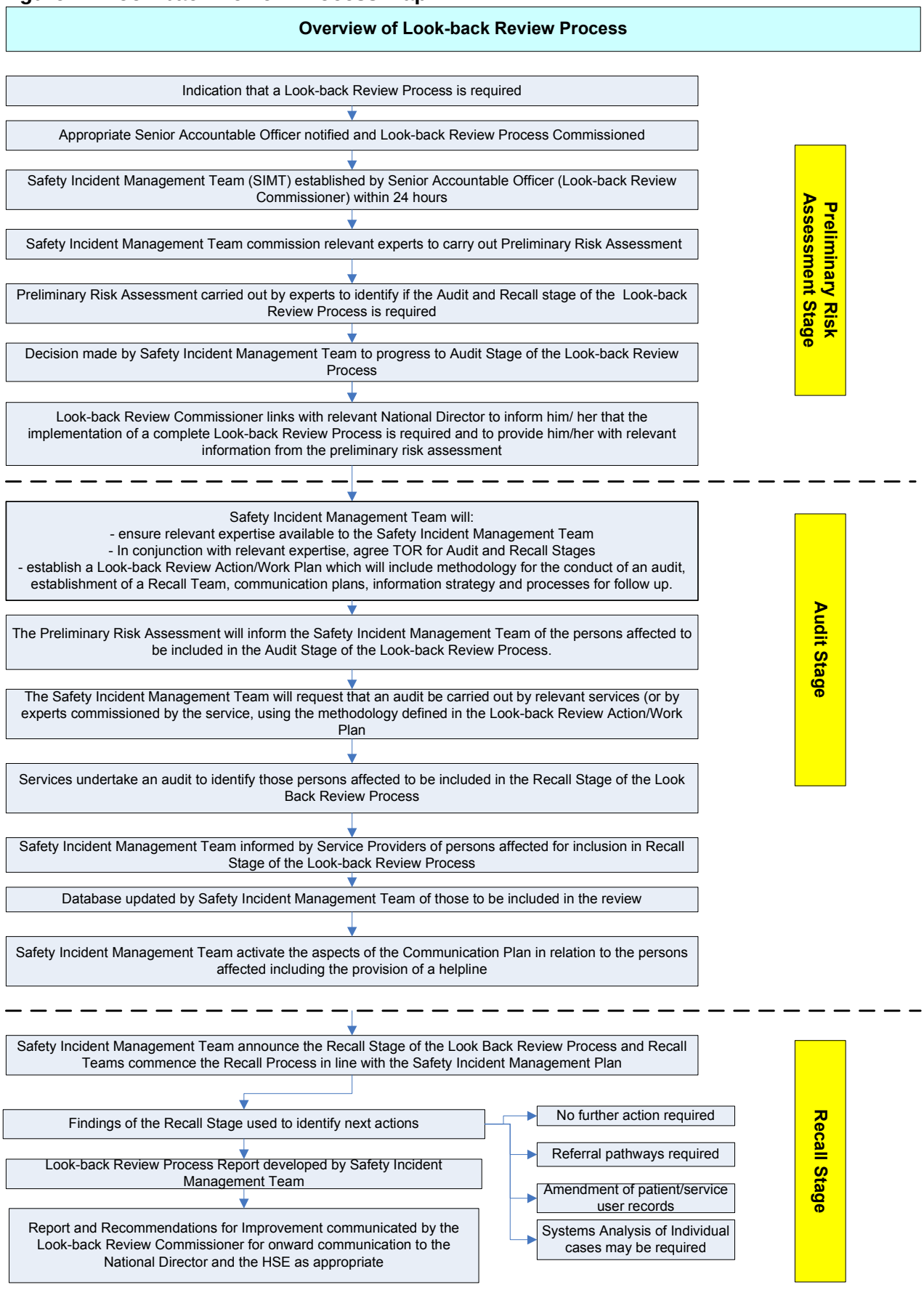
historic adverse events for which clinical remediation/intervention is not available, often in response to or anticipation of public/political demand.
Look-back Review Processes by their nature are high volume, high-complexity and high cost (including opportunity cost which diverts time and resources from ongoing care). As described they involve multiple stages, logistical challenges and cumulative delays. Once a decision has been reached to undertake a Look-back Review the process should be resourced and expedited along with parallel investigations linked to but not part of the Look-back Review Process.

Other Investigation Processes
As stated previously look-back reviews are carried out to in order to identify if any of those exposed to a hazard has been harmed, and to identify the necessary steps to take care of those harmed. Parallel systems analysis investigation(s) may be required to identify Key Causal and Contributory Factors related to the event in the first place; as this may lie outside the scope or not be evident from the Look-back Review Process. In some circumstances a Look-back Review Process may be prompted by a preceding systems analysis investigation

Look-backs may raise issues of professional competence/conduct, or a competence review may prompt a look-back in the first place. Competence assurance is a matter for regulatory and professional training /accreditation bodies and performance is managed through executive and clinical governance structures in accordance with contractual conditions.

Finally, external agencies such as the Health Information and Quality Authority are empowered to undertake independent external review of patient safety issues in the public health system and have done so since their establishment in 2007. This does not negate the service responsibility to conduct its own internal investigation or to conduct look-back exercises when merited in the interest of patient care and safety.

Figure: 1: Look-back Review Process Map



7.2 Senior Accountable Officer Notified

7.2.1 The senior accountable officer for the service within which the adverse event/ hazard has been identified must be immediately notified that such an event/ hazard has been identified.

7.2.2 The senior accountable officer will identify if a Look-back Review Process is required and, if it is deemed to be required, he/she will commission the Look-back Review Process.

7.2.3 The senior accountable officer may also require that a Systems Analysis Investigations of the adverse event/hazard is carried out and this will be initiated in line with the HSE Guideline on the Systems Analysis Investigation of Incidents (2015).

7.3 Safety Incident Management Team Established

7.3.1 Within 24 hours after the senior accountable officer becomes aware that a Look-back Review Process is required, he/she will commission a Look-back Review Process and will establish a Safety Incident Management Team (SIMT) in accordance with the HSE Serious Incident Policy (2014 (and any subsequent revisions of the Policy)). The senior accountable officer who commissioned the Look-back Review Process will chair the Safety Incident Management Team. The Safety Incident Management Team will develop and agree the Terms of Reference for the Look-back Review Process (see **Appendix 6A**).

7.3.2 Where the Look-back Review Process stems from a systems analysis investigation of an incident, a Safety Incident Management Team will already be in place, in this case the role of the Team is extended to include the management of the Look-back Review Process, the composition of the team should be reviewed to ensure that the Team consists of the appropriate personnel and expertise to manage the Look-back Review Process.

7.4 Composition of the Safety Incident Management Team

The Safety Incident Management Team should include but is not limited to:

- Look-back Review Commissioner (Chair)
- Service Managers
- People with expertise (including clinical) in the services/ processes which are the subject of the Look-back Review Process
- Quality/Risk Manager
- Communications Manager
- HR Manager
- IT Support
- Medical Records Manager

Non-HSE members of patient representative groups may be included as members of the Safety Incident Management Team. In these instances, a confidentiality agreement must be signed by the patient representative.

Sub teams may be established within the Safety Incident Management Team to support the Look-back Review Process e.g.

- Clinical Expert Team
- Communications Team
- ICT Team etc.

The composition of the Safety Incident Management Team will be dependent on the service involved and the nature and extent of the Look-back Review Process but must not involve personnel who may have been directly involved in the event/hazard that triggered the Look-back Review Process.

Note: In general, expertise already available from within the HSE should be sufficient to undertake Look-back reviews. *If, in exceptional circumstance, experts external to the HSE are required to support any stage of this process, as per the HSE Guidelines for the Systems Analysis Investigation of Incidents and Complaints (2015), the Chair of the Safety Incident Management Team must complete the form to request a nomination for external expert support to a HSE investigation which is available on the*

*NIMLT section of the Quality Assurance and Verification Division website (**http://hsenet.hse.ie/qav/**).*
This form should be forwarded via the Incident Information Management System (IIMS) (where available), to the relevant National Divisional Lead for Quality and Patient Safety. The completed request form should be accompanied by the Terms of Reference for the Look-back Review and a completed "Safety Incident Management Communication / Escalation Form" (as per Appendix 8 of the Safety Incident Management Policy (2014)).
The National Divisional Lead for Quality and Patient Safety will contact the National Incident Management and Learning Team (NIMLT), who will, in turn, contact the nominating body to seek the nomination and will arrange indemnity for the nominee.

7.5 Stages of the Look-back Review Process

The Look-back Review Process is divided in to three distinct stages:

1. **Preliminary Risk Assessment Stage (section 7.6)**
2. **Audit Stage (section 7.7)**
3. **Recall Stage (section 7.8)**

In all cases, if a Look-back Review Process is indicated, the Preliminary Risk Assessment is undertaken to identify if there is a requirement to progress to the Audit Stage and the Recall Stage of the Look-back Review Process. Each of these stages is described in detail in the next sections of this guideline.

7.6 Preliminary Risk Assessment

7.6.1 The first phase in the process is to undertake a preliminary risk assessment to determine whether the Look-back Review Process should progress. In order to do this, the Safety Incident Management Team will commission relevant experts to undertake this preliminary risk assessment. Relevant experts will be from within the HSE and may include but are not exclusive to people with expertise in the services/ processes which are the subject of the Look-back Review Process, Risk Managers, and Public Health Specialist etc. This will be determined by the Safety Incident Management Team on a case by case basis.

7.6.2 A decision to undertake the completed Look-back Review Process has major consequences for service users, providers and resources. The risk assessment, therefore, should provide a thorough assessment of the chance of harm and the seriousness of that potential harm. It must be conducted in a manner that balances the need to identify and address all cases where there might be safety concerns on the one hand, with the need not to cause any unnecessary concern to patients or to the public on the other.

7.6.3 Where expert, specialist opinion, external to the HSE, is required the HSE Guidelines for the Systems Analysis Investigation of Incidents and Complaints, and the HSE Safety Incident Management Policy provide guidance for accessing external independent experts for HSE Safety Incident Investigations.

7.6.4 The Preliminary Risk Assessment will look at:

- **The potential extent of the issue and the level of exposure to the hazard;**
- **Evidence of harm that has occurred;**
- **The likelihood of future harm occurring;**
- **The potential and actual (if relevant) outcomes of the issue e.g. missed diagnosis/ missed return appointments for follow up etc;**
- **The potential impact of the issue;**
- **The potential cohort of service users affected;**
- **The manner in which harm would be ameliorated (e.g. repeat investigation / onward referral for treatment)**
- **If the Look-back Review Process is limited to one HSE site or if the process will involve a number of HSE sites.**

A template Preliminary Risk Assessment proforma is included in **Appendix 1** of this document

7.6.5 Using the information obtained from the Preliminary Risk Assessment, the Look-back Review Commissioner and the Safety Incident Management Team must decide if the Look-back Review Process should proceed to the Audit and Recall stages. If a decision is made not to proceed to the Audit and Recall stages, this decision must be communicated by the Look-back Review Commissioner through the appropriate management structures to the relevant National Director, outlining clear reasons for the decision.

7.6.6 If the preliminary risk assessment identifies that the Look-back Review Process should progress to the Audit and Recall stages, this should be communicated immediately by the Look-back Review Commissioner, through the appropriate management structures, to the relevant National Director. The requirement for progressing to a full Look-back Review Process meets the escalation criteria as set out in the HSE Safety Incident Management Policy (2014) and the Criteria for the Communication or Escalation of Incidents to the National Incident Management and Learning Team (2015) and so the incident should be escalated in line with these documents.

7.6.7 The relevant National Director will, in turn, inform the Director General of the HSE and the Department of Health of the requirement for the implementation of all stages of the Look-back Review Process.

7.6.8 During all stages of the Look-back Review Process, the Safety Incident Management Team must ensure the following:

- Any immediate safety concerns that arise at any stage of the Look-back Review Process are addressed promptly. These would include but are not limited to:
  - Taking preventative action such as the removal of the hazard;

- HR management of staff member(s)/service whose caseload is under review as part of the Look-back Review Process;
- Notification of relevant authorities/regulatory bodies as required, including bodies outside Ireland;
- Clinical management of patients/service users/ staff identified by the Preliminary Risk Assessment and suspected of being adversely affected;
- Providing support to staff involved.

- The fact that a full Look-back Review Process is being considered can often become publicly known at the planning stage. Even if this does not occur, the Safety Incident Management Team needs to consider communications as a critical issue in managing the Look-back Review (See section 7.11).

7.6.9 At all stages of the Look-back Review Process, the Look-back Review Commissioner will ensure that contingency plans for service continuity are implemented, where necessary, including providing for additional health care demands which may arise as a consequence of the Look-back Review Process, for instance; agree referral pathways, rapid access clinics, diagnostic or pathology services etc.

7.6.10 The Look-back Review Commissioner is responsible for ensuring that the necessary resources are allocated to conduct the Look-back Review Process. If the resources required exceed what is available to the Look-back Review Commissioner then he/she must escalate this to the relevant National Director.

7.6.11 Systems Analysis Investigations

In general, a systems analysis investigation of an incident may be initiated before a Look-back Review Process and may prompt or inform the initiation of a Look-back Review Process.

However, it is also possible that systems analysis investigations may be prompted at any stage of the Look-back Review Process. If it is identified during the Look-back review process that it is appropriate to undertake a systems analysis investigation in line with the HSE Safety Incident Management Policy, this investigation may run in parallel with the Look-back Review Process and must be undertaken in line with the requirements of the HSE Guideline on the Systems Analysis Investigation of Incidents.

The initiation of a systems analysis investigation requires careful consideration with reference to the relevant policy and guidelines. This Look-back Review Process guideline cannot be prescriptive on the timing, nature and number of systems analysis investigations that may be required as this will be specific to each Look-back Review.

7.7 Audit Stage

In the context of the Look-back Review process, the Audit Stage involves the review of care/ processes against explicit standards and criteria to identify those who may not have received the required standard of care or where the procedure used did not adhere to explicit standards and criteria.

The objective of the Audit Stage is to identify the patients/ service users/ staff (persons affected) that must be included in the Recall Stage of the Look-back Review Process.

7.7.1 Terms of Reference

Immediately following the decision by the Safety Incident Management Team to proceed to the Audit and Recall stages of the Look-back Review Process, the Safety Incident Management Team will agree the Terms of Reference for the Audit stage of the Look-back Review Process (See **Appendix 6B** of this guideline).

7.7.2 Inclusions to the Audit Stage

The Safety Incident Management Team will identify from the information obtained by the Preliminary Risk Assessment (section 7.6) the cohort of patients/ service users/ staff/ services, etc. to be included in the Audit stage of the Look-back Review Process and the Look-back Review Commissioner will communicate this to the relevant service providers.

7.7.3 Look-back Review Action/Work Plan

The Safety Incident Management Team will establish a Look-back Review Action/Work Plan. As required, linkages may be also made with expert resources such as relevant Professional Bodies and Faculties (e.g. The Academy of Clinical Science and Laboratory Medicine, Faculty of Radiologists, Royal College of Physicians of Ireland, Royal College of Surgeons of Ireland, Irish Nursing Board etc.) to assist with the development of this plan and to ensure that the plan is in line with evidence based best practice.

The Look-back Review Action/Work Plan will include (but is not limited to):

- The management of immediate safety issues;
- Care for those harmed/affected including service users, the public and staff;
- Contingency planning for service continuity;
- Clear processes for the Audit stage (the function of which is to identify the patients/ service users/ staff (i.e. persons affected) to be included in the Recall Stage). This will include the development/ agreement of the:
    - Audit Criteria (e.g. criteria as to what will be considered within acceptable practice limits, minor or major discrepancy, the clinical significance of these discrepancies, and actions to be taken in each category and will be guided by national and international best practice, faculty requirements etc.);
    - Scope of Audit (including timeframes and definition of records to be reviewed);
    - Audit Methodology;
    - Audit Tool (may be developed by the Safety Incident Management Team in conjunction with relevant expertise or adopted from existing validated tools);
    - Instructions for analysis of audit data;
    - Process for the submission of audit outcomes to the Safety Incident Management Team.
- Procedures for ensuring the validity and reliability of the Audit stage to ensure that all auditors interpret and apply audit criteria in the same way;
- Recall Stage methodology;
- Communications Plan (see section 7.11);
- Information and Help Line Plan;
- Plans for patient/ service user follow up following both the Audit and Recall Stages;
- Quality and Safety Improvement Plan;

- Composition and expertise of the Recall Team(s) e.g. if the Look-back Review Process is being carried out in multiple HSE sites, a number of Recall Teams may be required and this should be considered as part of the Look-back Review Action/Work Plan.

Note: The audit of patient/service user's healthcare records should be undertaken by the healthcare team who would ordinarily have the right to access the patient/service user's healthcare records as part of the delivery of healthcare.
However, if the audit team is extended to include healthcare personnel who would not have a right to access the patient/service user's healthcare records, and consent has not been provided by the patient for these personnel to access their records, then these records must be sufficiently anonymised, such that an individual is not identifiable to those undertaking the audit.

7.7.4 Establishment of a Data Collation Tool

At the earliest stage following the Preliminary Risk Assessment, a data collation tool is created by the Safety Incident Management Team to collate the details patients/service users/ staff that have been identified by the Preliminary Risk Assessment (section 7.6) for inclusion in the Audit Stage of the Look-back Review Process.
The data collection tool will be used to document the patients/service users/ staff who are included and excluded following each stage of the Look-back Review Process. In general, it will be used to track persons affected and to record actions, interventions and outcomes,
This data collation tool will be held and maintained within the healthcare setting which is subject to the Look-back Review Process.

Note: The personal information for patients/service users must be treated in the strictest confidence. Patient personal information may be entered on to the data collation tool if access to the data collation tool is strictly limited to the healthcare team who would ordinarily have the right to access personal information belonging to the persons affected as part of the delivery of healthcare.
However, if the data collation tool may be accessed by healthcare personnel who would not have a right to access personal information belonging to the persons affected, and consent has not been provided by the patient for these personnel to view their personal information, then details for the persons affected must be sufficiently anonymised, such that an individual is not identifiable to those viewing the data collation tool. A coding system will be required for the data collation tool in order for the healthcare team(s) for the persons affected to identify the persons affected where required and where they have a right to do so.

Specific data variables will be determined by the nature of the incident, and the audit methodology being applied. An extract of this data collation tool may be exported to develop a more detailed data collation tool to facilitate the Look-back Review Process in later stages. A suggested core dataset for the Look-back Review Process data collation tool is outlined in **Appendix 2.** Ideally, the use of a data collation tool already developed by either a professional body (e.g. Faculty of Radiologists) or a previous Safety Incident Management Team is preferred.

Prior to commencing the Recall Stage of the Look-back Review Process, the data collation tool should be cross referenced with any available public records such as Dept of Social and Family Affairs records, Register of Deaths, www.RIP.ie etc. to help identify any people who may now be deceased. Hospital records and local knowledge (e.g. GPs, Public Health Nurse, Community Welfare Officers, etc.) are also relevant in this process.

The Safety Incident Management Team should give special consideration in the Look-back Review Action/Work Plan as to whether or not the cases of deceased persons meet the inclusion criteria, how their records should be handled and how best to communicate with their relatives.

The data collation tool is further described in **Appendix 2**. **Appendix 5** of this guideline also provides details of good practice in relation to the collection and storage of information, confidentiality and data protection.

As the data collation tool must be updated each time a person affected is being reviewed or has contact with the Look-back Review process, it is essential that the Look-back Review Action/Work Plan considers designated responsibility for data collation tool management, providing for constant validation of the data on the data collation tool, insurance against double entry etc. Meticulous attention to detail is required. It should also allow for noting persons affected who may wish to be excluded from the recall stage of the Look-back Review Process.

7.7.5 Undertaking the Audit

The objective of this audit is to identify the persons affected that must be included in the Recall Stage of the Look-back Review Process.

Service providers will be requested by the Safety Incident Management Team to audit the relevant records/ notes etc. of the persons affected identified by the Preliminary Risk Assessment, using the audit methodology and tools defined in the Look-back Review Action/Work Plan.

An audit lead should be identified by each Service Provider to coordinate the audit within their service. Service Providers may have the relevant expertise to undertake the audit themselves, they may seek the assistance of those with audit expertise to undertake the audit, or may commission relevant experts to undertake the audit if required.

In incidents involving large numbers, the Safety Incident Management Team will determine the order in which the audit should proceed, prioritising on the basis of risk.

Such audits must be conducted in line with legislation and good practice related to data protection and confidentiality.

As stated previously any immediate safety concerns that arise at any stage of the Look-back Review process are communicated to the Chair of the Safety Incident Management Team for appropriate onward communication and action.

7.7.6 Upon completion of the audit, Service Providers will provide the Safety Incident Management Team with the results of the audit which will inform the Safety Incident Management Team of the persons affected to be included in the Recall Stage of the Look-back Review Process.

7.7.7 The data collation tool established as per 7.7.4 above will be used by the Safety Incident Management Team to track records through the audit and to record the outcomes of the audit.

7.7.8 Establishment of a Recall Team

Following completion of the audit which will identify all the persons affected whose care/management requires further action/intervention related to the event/hazard covered by the Look-back Review process, the Safety Incident Management Team will establish the Recall Team(s) which will consist of experts in the subject area/ discipline which is the covered by the look back process. The Safety Incident Management Team must agree with the Recall Team(s) a realistic work-plan with timelines that reflect the urgency and complexity of the Look-back Review Process. Refer to section 7.8 which details the Recall Phase of the Look-back Review Process.

7.7.9 The Safety Incident Management Team rolls out the Communication Plan

The Safety Incident Management Team will commence rolling out the relevant elements of the Communications Plan as per the Look-back Review Action/Work Plan. Even the most routine and low risk Look-back Review Process will be a cause of concern for the people involved. From the outset, the HSE must ensure that information for and communication with all persons affected is handled sensitively with care and consideration. ***Please refer to section 7.11 of this guideline for specific guidance on the content and roll-out of the Communication Plan.***

Key Message: Findings in relation to the Look-back Review Process should not be released into the public domain until the Look-back Review Process is complete, all the findings are known and all persons affected are informed of the implications for them.

7.7.10 Establishment of an Information line

The Safety Incident Management Team must consider the establishment of an Information line as part of their communication strategy. People are usually informed of their inclusion in the Recall stage of the Look-back Review Process by letter (see section 7.11), which will give details of telephone numbers where they can call to acknowledge receipt, and for more information or support. The information line is a general information line, the function of which is to provide general information only about the Look-back Review Process and to make arrangements for the person ringing the information line to get a return call from the relevant service involved in the Look-back Review Process to discuss any queries/ concerns the caller may have.

It is recommended that site specific information lines be established for persons affected and a general HSE information line should be established for the wider public.

The Safety Incident Management Team should be prepared to deal with large numbers of calls to and from persons affected, their families and the wider public. The information line should staffed by HSE personnel (including nurses and midwives, allied health professionals and doctors) who are adequately trained and informed to manage the information line. An individual from Service User and Staff Engagement Advocacy section of the HSE may assist in this process.

Setting up the information line involves the following tasks:

- Identification of a suitable venue;
- Identification of dedicated telephone numbers and suitable equipment;
- Data collation tool access;
- Agreeing opening times;
- Staff briefing training and access to standardised documents including FAQ documents, press briefings, letters etc;
- Agreement on the information to be collected from those contacting the information line[2];
- Production of rotas.

Appendix 3 contains detailed guidance on information lines.

[2] To the extent that information is recorded arising from such calls, the data subject, the identifiable individual whose data is so recorded, can make an access request pursuant to Section 4 of the Data Protection Acts 1988 and 2003 and that may result in the data subject obtaining a copy of this information. This is an important consideration in terms of what is recorded and will necessitate that individuals have clear guidelines in terms of what they record about an individual, notably that they be careful that descriptions or statements that they make about an individual are accurate and reasonable.

7.8 Recall Stage

7.8.1 Announcing the Recall stage of the Look-back Review Process

The Recall stage is announced to the public by the relevant National Director in line with the communication strategy developed by the Safety Incident and Management Team (see Section 7.11 re Communications).

In accordance with the communication principles outlined in section 7.11, **the Safety Incident Management Team should strive to ensure that the Recall stage of the Look-back Review Process is not publicly announced until all persons affected have been notified.**

Regrettably this is not always possible so media communications should be prepared and ready for issue at all times. It is often the case that the Recall stage of the Look-back Review Process is announced when a person affected or a relative notifies the media upon receipt of a letter or call from the Safety Incident Management Team.

Timing of patient communication is critical and every effort should be made to notify the entire group to be reviewed within as short a timeframe as possible; preferably all on the same day. The method of arranging timely communication will depend on the numbers concerned. Practical considerations such as posting letters early in the working week to maximise the personnel available to deal with queries arising and minimise the risk of un-opened letters over the weekend should be taken into account. If a press release is planned then it should be timed for late evening on the day after letters have been posted, to ensure that letters have been delivered and opened.

It is also important to co-ordinate public information with communication with staff and other parties such as advocacy groups etc. Briefing sessions may be necessary for this purpose.

7.8.2 Planning the Recall Stage

Note: Where Recall Stage involves persons affected in multiple locations, the establishment of multiple Recall Teams should be considered. All Recall Teams will be overseen by the Safety Incident Management Team and will operate in line with the Look-back Review Action/Work Plan.

Prior to commencing the Recall Phase, a Terms of Reference for the Recall Phase must be agreed by the Safety Incident Management Team (see **Appendix 6C**). The Terms of Reference should include but is not limited to the following information:

- Purpose
- Scope
- Time frame
- Recall Team Members
- Recall Method
- How recommendations will be communicated and implemented
- Communication Strategy

In planning the Recall stage, the following factors must be considered by the Safety Incident Management Team:

- Terms of Reference (TOR) for the Recall Phase;
- Venue(s) for the conduct of the Recall stage;
- Administrative support, including:
    - Medical records staff support for the retrieval of notes/x-rays/test results;
    - Appointment system including DNA management;

    - Management arrangements for assisting persons affected to attend for recall stage e.g. maps, locations, public transport, taxis, meals and so forth;
    - Data collation tool management.
- Secure diagnostic clinical support i.e. laboratory/x-ray/pathology etc., including systems for transportation of samples and results;
- Systems for recording of results.

Ideally, a liaison person/team should be appointed to oversee the seamless conduct of each attendance a person affected has as part of the Recall stage, whether they are clinic appointments or repeat tests/x-rays etc. Responsibilities would include:

- Providing a point of contact for persons affected;
- Ensuring appropriate linkages with vulnerable groups e.g. minors, those without capacity, older persons etc.
- Ensuring the data collation tool is updated after each episode of care;
- Follow-up of non-attendees (DNAs (Did not Attend)) with repeat appointments*, etc;
- Quality assurance of the Look-back Review process e.g. administrative checks that the correct letter is sent to the correct person affected;
- Critically they would check that persons affected are appropriately referred into the "system" for subsequent follow-up.

* **Note: The service must ensure that every effort is made to follow up with persons affected that do not attend appointments scheduled with them as part of the Recall Stage. This may involve follow-up letters and phone calls to the person(s) affected and/or GPs. This will be guided by the policy in place within each relevant service for those person(s) affected that do not attend for their appointment(s) (DNAs).**

7.8.3 Undertaking the Recall Stage

Upon completion of the audit outlined in section 7.7.6, the group of potentially affected cases will have been identified for inclusion in the Recall stage of the Look-back Review Process.

The Recall Team will then:

- Examine the person affected and/ or review all relevant records in line with the Terms of Reference and will identify any deviations from required standards of care;
- Identify outcomes resulting from deviations from required standards of care;
- Identify if any further action is required;
- Inform the person affected of the outcomes of the look-back review process and adhere to the requirements of the National HSE Guidelines on Open Disclosure (2013);
- Where appropriate, implement actions to address deviations from required standard of care or advise the Safety Incident Management Team of the follow up that is required;
- Update the Look-back Review Process data collation tool to reflect all findings, actions and recommendations for actions.

7.8.4 The Recall Team will update the data collation tool to advise the Safety Incident Management Team on the follow–up required, which may include:

- No further action required;
- Update of patient records and reassurance to the person affected (i.e. that care provided to patient was appropriate and no further action is required)
- Recall/ referral of the person affected for further assessment, investigation and treatment.

7.8.5 Referral pathways: Special arrangements should be in place for situations where the Recall stage concludes that outcomes for the person affected have been adversely affected by the hazard/ incident. Individual case management teams may be required depending on the severity and complexity of each case. In addition to securing rapid access to the appropriate investigation and treatment services, senior clinicians may be

required to discuss clinical findings in light of the outcome of the Look-back Review Process and as much health and social support as appropriate should be offered. It is imperative that the Safety Incident Management Team is assured that the appropriate clinical service has taken over care of persons affected who require follow-up.

7.8.6 The Look-back Review Process may identify that an incident occurred to a person affected during the course of their treatment and care. Any incidents which are identified by a Look-back Review Process (i.e. not identified previously) should be managed and investigated further in accordance with the current HSE Safety Incident Management Policy and HSE Guidelines for the Systems Analysis Investigation of Incidents.

As stated previously any immediate safety concerns that arise at any stage of the Look-back Review process are communicated to the Chair of the Safety Incident Management Team for appropriate onward communication and action.

7.9 The Chair of the Safety Incident Management Team will communicate findings of the Recall stage to the National Director and the HSE as appropriate and as per the agreed communications strategy (section 7.11)

7.10 Closing the Look-back Review Process

7.10.1 When all persons affected been reviewed, the care of patients requiring clinical management has been transferred to the appropriate service, and all persons affected have been written to with the outcome of their review, the Safety Incident Management Team will prepare a detailed **anonymised** report on the completed Look-back Review Process. The HSE Guidelines for Systems Analysis Investigation of Incidents provides guidance on writing the investigation report and the same principles apply to the Look-back Review Process report. The following sections should also be considered:

- Section 7.7.3.1 related to factual accuracy checking, due process, natural and constitutional justice need to be followed here.
- Section 7.7.3.2 related to writing an apology
- Section 7.7.3.4. related to *"plain English"* checking

7.10.2 The Look-back Review Report Process should contain the following sections:

- Introduction including:
    - Details of Terms of Reference(s) (include Terms of Reference(s) in the Appendices section of the report)
    - Composition and roles of the Safety Incident Management Team
    - Composition and roles of the Audit Team
    - Composition and roles of the Recall Team
- Methodology applied to the Look-back Review Process including:
    - Methodology applied to Preliminary Risk Assessment
    - Clear audit methodology for the Audit Stage including:
        - Audit Criteria
        - Scope of Audit
        - Audit Methodology
        - Audit Tool
    - Procedures for ensuring the validity and reliability of the Audit stage to ensure that all auditors interpret and apply audit criteria in the same way.
    - Recall Stage methodology
    - Communications Plan
    - Information and Help Line Plan
    - Plans for follow up for persons affected following both the Audit and Recall Stages.
    - Quality and Safety Improvement Plan.
- Results/ Findings of the Preliminary Risk Assessment
- Results/ Findings of the Audit stage

- Results/ Findings of the Recall stage
- Actions taken to date to address findings
- Further recommended actions to address findings
- References
- Appendices

7.10.3 The identification of learning and recommended necessary changes to practice and procedures locally and systemically will be included in the Look-back Review Process Report.

7.10.4 The Look-back Review Commissioner is responsible for timely communication of recommended actions arising from the Look-back Review Process to the senior managers within the services included in the Look-back Review Process. He/She is also responsible for communicating nationally applicable recommendations to the National Director(s) for communication and national implementation.

7.10.5 The senior managers within each service assume responsibility for implementation of recommendations.

7.10.6 Peer review publication of issues relating to the Look-back Review Process, for instance; the development of an audit tool, logistics, communications etc. may be of benefit and is encouraged.

7.11 Communications Plan

A set of key messages should be agreed by the Safety Incident Management Team to ensure consistent accurate communication and provide confidence in the process. A spokesperson, ideally a senior clinical member of the Safety Incident Management Team, should be identified to act as media spokesperson and be available for interview. It is vital that media reports in relation to the issue, should they arise, are accurate and do not add to the anxiety of the persons affected and their families.

The Communications Manager on the Safety Incident Management Team should draw up a communications plan to include a suite of standard documents:

- Letter to all persons affected who are to be included in the Look-back Review Process (see **Appendix 4A** for sample letter).
- Letter to General Practitioners/other referrers to the service (see **Appendix 4B** for sample letter).
- Press Statements – holding statement and review phase statement. (Note: These should be developed as soon as it is determined that a Look-back Review Process is required and updated as required as the Look-back Review Process proceeds.)
- Frequently Asked Questions and Answers (FAQ document).
  - Media Q& A document which endeavours to anticipate questions that the incident might generate

Special attention should be given to the interdependent timing of communications to persons affected and media communications.

The principle behind all communication should balance reassurance with absolute disclosure. The following principles apply to all communications during a Look-back Review Process:

- People are informed of their inclusion in the Recall Stage of the Look-back Review Process before the Recall Stage is commenced
- Information on the Look-back Review Process is **first** given to the people whose care is being reviewed by the Recall Team
- Information subsequently given to media or others should not exceed what is shared with the people concerned
- The media should be provided with the FAQ document (after information is given to the people whose care is being reviewed by the Recall Team).
- Patient confidentiality should be respected and maintained in all media communications.
- The media should be educated on the communications process and its rationale.

7.11.1 Communicating with the people included in the Recall Stage

- In most instances, the persons affected who have been identified by the audit for inclusion in the Recall stage of the Look-back Review Process should be notified by letter, signed by a named senior member of staff and preferably the lead clinician. However, in incidents involving smaller numbers (or for particular subgroups of those being included in the Recall stage) telephone or face to face contact may be appropriate, written information should also be provided in such circumstances.
- Where potentially serious adverse outcomes are suspected, or the team suspects that a person affected may be in a vulnerable state, the Clinician/GP for the person affected should be consulted regarding how best to communicate with the person affected. In exceptional circumstances it may be appropriate to communicate with the person affected via their Clinician/ GP. This will be determined by the Safety Incident Management Team on a case by case basis.

- Letters should be sent in an envelope marked *Private and Confidential -To be opened by addressee only* and *If undelivered return* to a designated PO Box number.
- It is not advisable to use registered post as this may increase the likelihood of mail not being delivered in a timely manner (due to requirement for the recipient to sign for receipt of mail).
- The earlier validation of the data collation tool is important to prevent letters being posted to those who are deceased.
- The letter to persons affected should describe what has happened and that their case is being examined as part of the Recall Stage of the Look-back Review Process. It should apologise for any worry or distresses caused and stress the precautionary nature of the Look-back Review Process. It should provide the FAQ document and encourage persons affected to call the information line with any further queries. Finally it should make it clear that they will be contacted again by letter as soon as their case has been reviewed by the Recall Team.
- **The letter should also provide the persons affected with the option to indicate if they do not wish to be included as part of the Look-back Review Process.**
- The letter should include a unique identifier number. It is useful to include a reply slip with a pre-paid envelope in order for the persons affected to confirm that letters have been received. This will assist in the identification of those who were contacted successfully but who may not wish to call the information line. The reply slip should also allow persons affected to indicate that they do not wish to be included in the Look-back Review Process.
- **In circumstances where a person affected declines to be included in the Recall stage, this decision will should be respected unless they are statutorily required to participate in the Recall stage of the Look-back Review Process.** The replies should be recorded on the data collation tool so that people do not receive unwelcome further information; their details should be carefully segregated and highlighted on the data collation tool.

Depending on the scope of the Look-back Review Process, the service may need to identify vulnerable groups, those without capacity, minors, parents who are minors etc., in order to ensure that appropriate contact is made and support is provided in relation to their inclusion in the Look-back Review process. At all times the principles of the HSE Consent Policy must be adhered to.
Every reasonable effort should be made to contact all persons affected identified for inclusion in the Recall stage. People may have moved out of the area, or moved abroad.

With regard to infectious disease incidents, the Medical Officer of Health (i.e. Director of Public Health) should inform persons affected in line with relevant Public Health policies and guidelines. The HSE Health Protection Surveillance Centre (HPSC) can play a role in contacting people at risk who may be abroad. Contact should also be made with the National Director of Health and Well-being Division.

7.11.2 Media communication

Safety incidents, especially those involving Look-back Review Processes, generate intense media attention. Media communications, as is the case with all other communications, should be consistent and truthful. **Regardless of the nature or intensity of media queries, information given to them should never exceed that which has been shared with the persons affected.**
The media pack is developed by the Safety Incident Management Team in conjunction with relevant communication experts. Draft media statements should be prepared specific to each phase of the process, as time progresses, in anticipation of media interest. It is vital that media reports in relation to the issue, should they arise, are accurate and do not add to the anxiety of persons affected and their families.

In circumstances where a press statement is released (following notification to persons affected), it should state that a Look-back Review Process is being carried out, and immediately limit the area of concern to the time period, region and service area within which the Look-back Review Process is being conducted. It should detail the numbers of persons affected being included in the Recall stage of the process, and the expected timeframe for the completion of the Recall stage, if known.

It should state that all persons affected have already been contacted by letter, and that an information line has been established. It should give the opening time of the information line and a website reference. It should state when the media can expect an update, and should never contain any information that could identify patients included in the Recall stage of the Look-back Review. The FAQ document can also be issued to media, aligning with the briefing material used by the information line staff and ensuring consistent messages.

The prepared media pack is usually issued to all media once the issue becomes public. Alternatively, once everyone involved has been contacted, the communications staff may initiate contact with key media correspondents, advise them of the issue, and provide the media pack and relevant spokespeople as required.

In either case, the press material will be prepared in advance and checked by the Chair of the Safety Incident Management Team, the spokespeople will have committed his/her availability, and the consistent messages identified at the outset will be repeated in all public and media communications.

8.0 Implementation Plan

This Guideline will be implemented through the following channels:

- This guideline will be uploaded on to the National Incident Management and Learning Team section of the Quality Assurance and Verification section of the HSE website.
- Notification of the new revision of this guideline will be sent to all HSE staff through appropriate HSE communication channels.
- This guideline will be incorporated as appropriate into training courses provided by the National Incident Management and Learning Team and Quality Assurance and Verification Division.

9.0 Guideline Revision and Audit

- To facilitate regular review and audit of the guideline, all training and education on the HSE Look-back Review Guidelines will include a requirement to provide any feedback on the guideline for the attention of the National Incident Management and Learning Team to inform future revisions.
- The Audit Services section of the Quality Assurance and Verification Division will be requested to undertake audits of compliance with the HSE Look-back Review Guidelines.

10.0 References

- Brady A, Ó Laoide R, McCarthy P and McDermott R. (2012), Discrepancy and Error in Radiology: Concepts, Causes and Consequences. *Ulster Medical Journal*; 81(1):3-9.
- Nolan T and Provost L, (1990), Understanding Variation. *Quality Process*.
- Open Disclosure: National Guidelines (HSE, 2013)
- QPSD-D-060-1.1: HSE Safety Incident Management Policy (2014). http://www.hse.ie/eng/about/Who/qualityandpatientsafety/incidentrisk/Riskmanagement/SafetyIncidentMgtpolicy2014.pdf
- QPSD-GL-53_1: HSE Guideline for Systems Analysis Investigation of Incidents and Complaints (2012) http://www.hse.ie/eng/about/Who/qualityandpatientsafety/resourcesintelligence/Quality_and_Patient_Safety_Documents/QPSDGL5211.pdf
- Serious Incident Management Team Guidelines for Conducting Look-backs (Part 7) (2008).
- Supporting Staff Following and Adverse Event: The Assist Me Model (HSE/SCA, 2013).

11.0 Appendices

Note: Templates listed below may be accessed on the NIMLT website @ www.nimlt.ie

Appendix 1: Template for Preliminary Risk Assessment
Appendix 2: Developing a Data Collation Tool and Sample core dataset for Look-back Review
Appendix 3: Information Lines
Appendix 4A: Letter to Patient informing them of their inclusion in the Recall Stage of the Look-back Review Process.
Appendix 4B: Letter to GP informing them of their patient's inclusion in the Recall Stage of the Look-back Review Process.
Appendix 5: Collection and Storage of Information
Appendix 6A: Template Investigation Terms of Reference for Look-back Review Process
Appendix 6B: Template Investigation Terms of Reference for Audit Stage
Appendix 6C: Template Investigation Terms of Reference for Recall Stage
Appendix 7: Additional Reading to inform Look-back Review Processes
Appendix 8: Look-back Review Process Check List
Appendix 9: Guideline Consultation Process
Appendix 10: Key Changes to the Look-back Review Process Guideline

Appendix 1: Template for Preliminary Risk Assessment

Information about the issue that appears to give rise to the need for a look back review (include information in relation to any actual harm that has been caused as a result of this issue):

Information about the potential extent of the issue:
(Include information about the number of people that might be adversely affected by the issue)

Information about the potential outcomes of the issue:
(Include information about the potential consequences of the issue e.g. missed diagnosis / missed return appointments / harm from contaminated medicines / harm due to ineffective vaccines etc.)

Information about the potential impact of the issue:
(Include information about the severity of harm that might occur in the people adversely affected by the issue. Use the HSE Impact Table in the Safety Incident Management Policy 2014 to rate potential harm)

Please tick one

Extreme:	
Major:	
Moderate:	
Minor:	
Negligible:	

Additional Details:

Information about the potential cohort of service users affected:
(Include information about the number of people that might fall within the look back review; the gender; the age range; category of service user etc.)

Details of immediate action required:

Recommendations to Safety Incident Management Team regarding Look-back Review Process.

(Include recommendations for the Terms of Reference for the Look Back Review including recommended inclusion and exclusion criteria; and for scoping audit(s) of patients that might fall within the inclusion criteria)

Details of personnel who undertook the Preliminary Risk Assessment:

Name	Title

Date of Preliminary Risk Assessment (dd/mm/yy):_____

Appendix 2: Developing a Data Collation Tool and Sample core dataset for Look-back Review

In designing the data collation tool it is helpful to consider that it will be used for administrative, clinical and safety incident management purposes. For instance:

- Administration:
    - Generating initial and follow up letters to the people affected and telephone contacts if required
    - GP contact
    - Confirming that patients have made contact
    - Tracking attendance, scheduling follow-up investigation and appointment
    - DNA policy assurance
- Clinical:
    - Monitoring adherence to clinical protocol
    - Recording results
    - Consensus on review findings – standards met; minor departure from standard but outcome not adversely affected; serious departure from standard and further investigation/ treatment/ intervention required
- Safety Incident Management Team:
    - Status updates to inform updates, briefings, press releases etc.
    - Look-back Review analysis and final report writing
    - Evaluation and the debriefing process when the Look-back Review has concluded

Some safety incidents require the use of web-enabled systems, shared folders etc. All appropriate actions essential to ensure the security of the data collation tool and the protection of confidentiality must be taken.

Sample Core Dataset:

- Unique identifier number
- Surname
- Forename
- Title
- Date of birth
- Sex
- Address line one (House name, number and road name)
- Address line two (town)
- Address line three (county)
- Phone number
- GP name
- GP address line one
- GP address line two
- GP address line three
- GP phone number
- Named consultant (i.e. treating consultant)
- Inclusion Criteria parameters met
- Exclusion Criteria parameters met
- Audit criteria and outcomes
- Inclusion in Look-back Review Yes/No
- Date of appointment/procedure 1/Investigation
- Date of appointment/procedure 2/Investigation
- Date of appointment/procedure 3/Investigation
- Procedure one/Investigation description
- Procedure two/Investigation description
- Procedure three description
- Reviewer 1 identification
- Reviewer 2 identification

- Data entered by -identification
- Data updated 1 by – identification
- Data updated 2 by – identification
- Data updated 3 by – identification

Note: The data above is a suggested minimum dataset. It is however subject to change depending on the individual situation.

Appendix 3: Information Lines

Identification of venue for information lines

- Ideally the Information line should not be isolated from the main hub of the organisation, to allow easy access to the Safety Incident Management team for advice and information while the line is operational.
- Cabling to allow sufficient telephones is required.
- Once letters are sent, there is likely to be an influx of calls.
- Each telephone line should be able to handle 100 calls in a 12 hour period. Additional capacity is required during the initial days, with surges of activity following each news bulletin.
- It is advisable to have a failsafe system to capture additional calls if the information line becomes blocked with calls and a good telephone queuing system with an appropriate message is required.
- Personal computers are required for each person to facilitate easy access to patient information. IT staff should assist in accessing the necessary cabling and hardware.

Briefing and back-up documentation for information line personnel

It is important that those providing the telephone information are trained and briefed on the circumstances surrounding the Look-back Review.

The people whose care is being reviewed need to get a consistent message from all our staff, all our letters, all our media interviews and reports. Information line personnel need to be confident in the messages they are giving to callers. An information pack should be provided to each staff member containing:

⇒ Letters sent to everyone affected by the Look-back Review
⇒ Press Release (and any updates)
⇒ FAQ document (updated as queries arise)
⇒ Standard Form for recording caller details
⇒ Algorithms, to help staff to know what to say in given circumstances

Production of Pro forma for information line personnel

As each call is received it is important to maintain a record. A pro forma should be designed to capture the relevant information. It should not be so detailed that the caller feels annoyed, however there needs to be sufficient information to ascertain if follow up action is required.

If the information line personnel believe that follow up is required then a system needs to be agreed to segregate pro-formas, perhaps by identifying follow up calls with a red dot. By the following day these need to have been actively followed up, probably by clinical staff in the speciality being reviewed.

Production of rotas for information line personnel

The information line opening times need to be agreed at the outset so that rotas can be produced. Media coverage tends to impact on when calls are made, so some flexibility and unsocial hours might be required.

As far as possible the information line should be staffed by experienced people with an understanding of how to help worried callers. It is essential to have staff with good communication skills. Staff may need to be released very quickly from their normal duties to assist with this work. There may need to be back filling of these posts to release these staff to assist.

APPENDIX 4A: Letter to Patient informing them of their inclusion in the Recall Stage of the Look-back Review Process.

Note: *Appendix 4A and 4B are* ***sample letters*** *only and may be amended as required to reflect individual persons affected and look-back review process requirements.*

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Commissioner name & address
Date

Patient name& address

Dear [name of person affected],

You recently had a [Procedure] in [Location].

We have reviewed [Procedure] undertaken at the [Location] in [Date(s)/Year(s)] as part of its quality assurance process as we were not satisfied with the quality of a number of PROCEDURES carried out.

I am writing to you because your file has been reviewed as part of this process and our clinical team would like to meet with you to check that your procedure was satisfactory and you have no concerns in this regard.

An appointment has been made for you at [Time] on [Date] in the [Location].

The [Location] is situated [Directions]

On arrival please report to [Location] where some details will be taken. You are asked to bring the following with you:

- Contact telephone number
- List of current medications (name and dose)
- Medical card, if you are the holder of one

I apologise for any anxiety this might cause but wish to reassure you that this is a precautionary measure to ensure your care is of the highest possible standard.

If this time or date above does not suit you, please contact [Name liaison person and contact details]

Kind regards.

Yours sincerely

_____

[Look-back Review Commissioner Name/ Title]

APPENDIX 4B: Letter to Clinician/ General Practitioner (Informing them of the inclusion of their patient(s) in the Recall Stage of the Look-back Review Process)

Note: *Appendix 4A and 4B are* ***sample letters*** *only and may be amended as required to reflect individual look-back review process requirements.*

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Commissioner name & address
Date

Patient name& address

Dear [Doctor Name],

[Service Name] recently reviewed [Procedure] undertaken at the hospital in [Date(s)/Year(s)]. This review was part of a quality assurance process as we were not satisfied with the quality of a number of [Procedure(s)] carried out. As a precautionary measure our medical advisors have recommended that a number of patients who attended for [Procedure] are offered a [Specialty] outpatients appointment.

Our records show that your patient [Name] previously attended [name of location] for [name of procedure]. We have written to your patient to advise them that their file was reviewed as part of this process and to offer them an outpatient appointment.

If you have any queries about this letter, please contact [Name person and contact details]

Yours Sincerely

_____

[Look-back Review Commissioner Name/ Title]

Appendix 5: Collection and Storage of Information

General Guidance for Investigations/ Look-back Review Process

Investigations into safety incidents/ Look-back Reviews are conducted in private and all information obtained by an investigator/persons undertaking any stage of the Look-back Review Process shall be deemed to be confidential information which he/she may not discuss, communicate or disclose except as is necessary for the proper investigation of the safety incident/ implementation of the Look-back Review Process. The information gathered must be treated as confidential at all times and stored away in a locked filing cabinet when not in use.

For the purposes of data classification and handling, all information received, processed and stored as part of an investigation/ Look-back Review Process is considered highly sensitive and should be treated as confidential and restricted information in line with the HSE Information Classification and Handling Policy version 1.1 (2013).

At all stages during the investigation process/ Look-back Review Process, the collection and storage of information must comply with our obligations under the Data Protection Acts 1988 and 2003. That is, the information must be obtained and processed fairly; kept only for one or more specified, explicit and lawful purposes; used and disclosed only in ways compatible with these purposes; kept safe and secure; kept accurate, complete and up-to-date; adequate, relevant and not excessive; retained for no longer than is necessary for the purpose or purposes for which it was collected and a copy given to the individual of his/her personal data on request.

Look-back Review Audit

The audit of patient/service user's healthcare records should be undertaken by the healthcare team who would ordinarily have the right to access the patient/service user's healthcare records as part of the delivery of healthcare.
However, if the audit team is extended to include healthcare personnel who would not have a right to access the patient/service user's healthcare records, and consent has not been provided by the patient/service user for these personnel to access their records, then these records must be sufficiently anonymised, such that an individual is not identifiable to those undertaking the audit.

Data Collation Tool

Patient/service user's personal information must be treated in the strictest confidence. Patient personal information may be entered on to the data collation tool if access to the data collation tool is strictly limited to the healthcare team who would ordinarily have the right to access the patient/service user's personal information as part of the delivery of healthcare.
However, if the data collation tool may be accessed by healthcare personnel who would not have a right to access the patient/service user's personal information, and consent has not been provided by the patient/service user for these personnel to access their personal information, then patient/service user details must be sufficiently anonymised, such that an individual is not identifiable to those viewing the data collation tool. A coding system will be required for the data collation tool in order for the patient/ service user's healthcare team to identify the patient/ service user where required and where they have a right to do so.

Electronic means of sending and storing information

The use of electronic means for sending and storing this information must be done in compliance with the Health Service Executive's Information & Communication Technology Policies for the use of Information Technology (I.T.) Resources. Sensitive information such as draft investigation report findings and notes of interview should be stored on a secure segment of a local area network or within a separate dedicated network for sensitive information with restricted access rights. Consideration should be given to the encryption of investigation data using appropriate encryption software.

Where at all possible, sensitive documentation should not be transmitted via email. Where it is deemed absolutely necessary to use email the following guidance is recommended:

- Sensitive and confidential information should only be sent to an email address which ends in: @hse.ie (or for HSE funded services, this information should only be sent within the organisation's internal email structure).
- In exceptional circumstances where it is necessary to send sensitive and confidential documents to an email address that is not within the HSE domain, the documents must be encrypted[3]. The transfer of such information outside of the HSE domain must be authorised by a HSE line manager (at Grade 8 level or above).
- Emails containing sensitive information should be tracked and monitored.
- Emails should be addressed to named individuals and should not be copied or accessed by an authorised recipients' support staff or personal assistant.
- Recipients should be asked to confirm secure receipt of sensitive and confidential information sent via email, as advised in the HSE Electronic Communications Policy.
- Passwords should not be communicated to recipients via the same medium used to send the confidential and sensitive information. Passwords should comply with the HSE Passwords Standards Policy.
- It is preferable for passwords to be communicated via a personal telephone call to the authorised recipient.

In particular the following HSE National policies are most relevant to electronically held and transmitted information:

- Information Security Policy
  http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_I_T_Security_Policy.pdf
- I.T. Acceptable Usage Policy
  http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_I_T_Acceptable_Use_Policy.pdf
- Electronic Communications Policy
  http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_Electronic_Communications_Policy.pdf
- Encryption Policy
  http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_Encryption_Policy.pdf
- Password Standard Policy
  http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_Password_Policy.pdf

In short, the information gathered as part of an investigation/Look-back Review Process should not be held outside of HSE offices and must be adequately protected and stored while in the possession of the HSE.

[3] Encryption software is available through HSE Information Communication Technology departments. Requests should be made, with line manager approval, via ICT Department helpdesks.

Appendix 6A: Template Investigation Terms of Reference for Look-back Review Process

Introduction
These are the terms of reference for the Look-back Review Process commissioned by [xxx] into [a hazard (describe) that arose at … on … (include date)]

Purpose
The purpose of this Look-back Review Process is to identify anyone who has potentially been exposed to the hazard detailed above and to identify if any of those exposed have been harmed in order to identify how to take care of them.

The Look-back Review Process will consist of three distinct stages:
- The Preliminary Risk Assessment Stage
- The Audit Stage
- The Recall Stage

The Preliminary Risk Assessment will be undertaken by the Safety Incident Management Team and will determine if the Look-back Review Process should progress to the Audit Stage. The Audit Stage will determine the patients/ service users/ persons affected that should be included in the Recall Stage of the Look-back Review Process.

The Preliminary Risk Assessment will look at:
- The potential extent of the issue and the level of exposure to the hazard.
- Evidence of harm that has occurred.
- The likelihood of future harm occurring.
- The potential and actual (if relevant) outcomes of the issue e.g. missed diagnosis/ missed return appointments for follow up etc.
- The potential impact of the issue
- The potential cohort of service users affected.
- If the Look-back Review Process is limited to one HSE site or if the process will involve a number of HSE sites.

If the Look-back Review Process proceeds to the Audit and Recall Phases, a specific Terms of Reference will be established for the Audit Stage and for the Recall Stage of the Look-back Review Process.

The Safety Incident Management Team includes [add names and titles as appropriate]:
- Chair (Look-back Review Commissioner) [name/title]
- Other team members [names/titles]

Non-HSE members of patient representative groups are included as members of the Safety Incident Management Team. In these instances, a confidentiality agreement has been signed.
These members are:
- [names/ titles]

Sub teams have been established within the Safety Incident Management Team to support the Look-back Review Process. These are as follows
- [list teams]

If experts external to the HSE are required to support any stage of this process, this will be discussed with the Look-back Review Commissioner who will make a decision in relation to the requirement for external experts.

Scope of the Look-back Review Process

The time frame of the Look-back Review Process will be [include the time frame]
Please note:

- The *"time frame"* in question here is the *"scope in time"* that was considered appropriate for the Look-back Review Process.
- The timeframe must be the shortest sufficient period of time to ensure the purposes of the Look-back Review Process as outlined will be achieved.
- The final timeframe will be stipulated and adhered to unless good and valid reasons for extending this timeframe become apparent during any of the three stages of the Look-back Review Process.

Immediate Safety Concerns
Should immediate safety concerns arise during any stage of the Look-back Review Process the Look-back Review Commissioner will ensure that appropriate actions are implemented within the shortest time frame possible.

Look-back Review Process Methodology
The Look-back Review Process will follow the methodology as per the Look-back Review Action/Work Plan and the HSE Look-back Review Process Guideline and will be cognisant of the rights of all involved to privacy and confidentiality.

Look-back Review Report
Once the Look-back Review process is concluded the Safety Incident Management Team will prepare a detailed and **anonymised** report on the completed Look-back Review Process. This report will include:

- The Results/ Findings of the Recall stage
- Actions taken to date to address findings
- Further recommended actions to address findings

The anonymised report may be published. No guarantee can be given by the HSE that information received as part of a look-back review process will be fully protected from legal discovery and / or disclosure.

Recommendations and Implementation
The report, when finalised, will be presented to the Commissioner of the Look-back Review Process.
The identification of learning and recommended changes to practice and procedures locally and systemically will be included in the Look-back Review Process Report.
The Commissioner of the Look-back Review Process will ensure that local managers responsible for the services included in the Look-back Review Process implement the recommendations of the Look-back Review Process.
The Commissioner will also communicate nationally applicable recommendations to the relevant National Directors for national implementation.
Peer review publication of issues relating to the Look-back Review Process, for instance; the development of an audit tool, logistics, communications etc. may be required.

Communication Strategy for the Look-back Review Process.
A communication strategy will be determined. [Give name of Liaison person], will be appointed for the purpose of communicating information pertaining to the Look-back Review Process to the patient/family/staff member(s) (delete as appropriate) affected by and/or involved in the Look-back Review Process .

Reference:

- HSE Safety Incident Management Policy (2014, and any subsequent revisions)
- HSE Guideline for Systems Analysis Investigation of Incidents and Complaints (2015)
- HSE Look-back Review Process Guideline (2015)

Appendix 6B: Template Investigation Terms of Reference for Audit Stage

Introduction
These are the terms of reference for the Audit Stage of a Look-back Review Process commissioned by [xxx] into [an incident/complaint/allegation of … that arose at … on … (include date)]

Purpose
The purpose of this Audit stage is as follows:
The audit team will
→ Evaluate the [diagnostic accuracy/ quality of procedure etc. – add text here appropriate to the hazard identified]
→ Make recommendations in respect to any additional follow-up required
→ Make recommendations in respect to the requirement for the patient/ service user to be included in the Recall Stage of the Look-back Review Process

Scope of the Audit stage

The time frame of the Audit Stage will be [include the time frame of the audit stage here]

Please note:
- The *"time frame"* in question here is the *"scope in time"* that was considered for inclusion in the Audit Stage of the Look-back Review Process.
- The timeframe must be the shortest sufficient period of time to ensure the purposes of the Audit Stage as outlined will be achieved.
- The final timeframe will be stipulated and adhered to unless good and valid reasons for extending this timeframe become apparent during the Audit Stage.

The Audit Team members
Note: [X number] of Audit Teams are required for the Audit stage of this Look-back Review Process in [X number] of locations in the HSE. The number of Audit Teams required was determined by the Look-back Review Commissioner/ Safety Incident Management Team and informed by the Preliminary Risk Assessment Stage.

The Locations and Membership of the Audit team are as follows:
❖ Audit Team Lead [detail]
❖ Other members of the Audit team [detail]

Through the Commissioner of the Look-back Review, the Audit Team will:
❖ Be afforded the assistance of all relevant staff (including former staff) and other relevant personnel.
❖ Have access to all relevant files and records (subject to any necessary consent/data protection requirements including court applications, where necessary).

Should immediate safety concerns arise, the Lead of the Audit Team will convey the details of these safety concerns to the Look-back Review Commissioner as soon as possible.
Should the Audit Team require external expert input, the Lead of the Audit Team will discuss and agree this with the Look-back Review Commissioner.

Audit Stage methodology
The Audit stage will follow the methodology as per the Look-back Review Action/Work Plan and the HSE Look-back Review Process Guideline and will be cognisant of the rights of all involved to privacy and confidentiality.

The Audit stage will commence on [xxx] and will be expected to last for a period of approximately [xxx], provided unforeseen circumstance does not arise.

The Audit Team will advise the Look-back Review Commissioner on the follow–up required, which may include:
• No further action required;
• Update of patient records and reassurance to patient (i.e. that care provided to patient was appropriate and no further action is required)
• Recall/ referral of patient for further assessment, investigation and treatment.

The Audit Stage may identify that an incident occurred to a patient during the course of their treatment and care. Any incidents which are identified by the Audit Stage (i.e. not identified previously) should be considered for further investigation in accordance with the current HSE Safety Incident Management Policy and HSE Guidelines for the Systems Analysis Investigation of Incidents.

Upon completion of the audit, the audit team will provide the Look-back Review Commissioner with the results and recommendations of the audit which will inform the Look-back Review Commissioner of those patients/ service users to be included in the Recall Stage of the Look-back Review Process.
The audit results and recommendations will include:

- The Results/ Findings of the Audit stage
- Actions taken to date to address findings
- Further recommended actions to address findings

The anonymised audit report may be published. No guarantee can be given by the HSE that information received as part of a look-back review process will be fully protected from legal discovery and / or disclosure.

Communication Strategy for the Look-back Review Process.
A communication strategy will be determined for each stage of the Look-back Review Process. [Give name of Liaison person], will be appointed for the purpose of communicating information pertaining to the Look-back Review Process to the patient/family/staff member(s) (delete as appropriate) affected by and/or involved in the Look-back Review Process .

Reference:

- HSE Safety Incident Management Policy (2014, and any subsequent revisions)
- HSE Guideline for Systems Analysis Investigation of Incidents and Complaints (2015)
- HSE Look-back Review Process Guideline (2015)

Appendix 6C: Template Investigation Terms of Reference for the Recall Stage

Introduction
These are the terms of reference for the Recall Stage of a Look-back Review Process commissioned by [xxx] into [an incident/complaint/allegation of … that arose at … on … (include date)]

Purpose
The purpose of this Recall stage is to:
→ Undertake an examination of the patient/ service user and/or review relevant patient information/ results etc. in line with the Look-back Review Action/Work Plan and the requirements of the HSE Look-back Review Process Guideline.
→ Identify actions to be taken as a result of the findings of the Recall stage of the Look-back Review Process.
→ Implement any corrective actions as appropriate and will communicate any additional actions to be taken to the Safety Incident Management Team for further action.

Scope of this Recall stage

The time frame of this recall stage will be [include the time frame of the recall stage here]

Please note:
- The *"time frame"* in question here is the *"scope in time"* for the Recall Stage that was determined by the findings of the Audit Stage The timeframe must be the shortest sufficient period of time to ensure the purposes of the Recall stage as outlined will be achieved.
- The final timeframe will be stipulated and adhered to unless good and valid reasons for extending this timeframe become apparent during the recall process.

The Recall Team members

Note: [X number] of Recall Teams are required for the Recall stage of this Look-back Review Process in [X number] of locations in the HSE. The number of Recall Teams required was determined by the Look-back Review Commissioner following the outcome of the Audit stage of the Look-back Review Process.

The Locations and Membership of the Recall team are as follows:
→ Recall Team Lead (detail)
→ Other members of the Recall Team (detail)

Through the Commissioner of the Look-back Review, the Recall Team will:
→ Be afforded the assistance of all relevant staff (including former staff) and other relevant personnel.
→ Have access to all relevant files and records (subject to any necessary consent/data protection requirements including court applications, where necessary).

Should immediate safety concerns arise, the Recall Team Lead will convey the details of these safety concerns to the Commissioner as soon as possible.

Recall Stage methodology
The recall stage will follow the methodology as per the Look-back Review Action/Work Plan and the HSE Look-back Review Process Guideline and will be cognisant of the rights of all involved to privacy and confidentiality.

The Recall stage will commence on [xxx] and will be expected to last for a period of approximately [xxx], provided unforeseen circumstance does not arise.

The Recall Team will advise the Look-back Review Commissioner on the follow–up required, which may include:

- No further action required;
- Update of patient records and reassurance to patient (i.e. that care provided to patient was appropriate and no further action is required)
- Recall/ referral of patient for further assessment, investigation and treatment.

The Recall stage may identify that an incident occurred to a patient during the course of their treatment and care. Any incidents which are identified by the Recall stage (i.e. not identified previously) should be investigated further in accordance with the current HSE Safety Incident Management Policy and HSE Guidelines for the Systems Analysis Investigation of Incidents.

Once the Recall stage has been completed the Safety Incident Management Team will prepare a detailed and **anonymised** report on the completed Look-back Review Process. This report will include:

- The Results/ Findings of the Recall stage
- Actions taken to date to address findings
- Further recommended actions to address findings

The anonymised report may be published. No guarantee can be given by the HSE that information received as part of a look-back review process will be fully protected from legal discovery and / or disclosure.

Recommendations and Implementation

The report, when finalised, will be presented to the Commissioner of the Look-back Review Process.

The identification of learning and recommended necessary changes to practice and procedures locally and systemically will be included in the Look-back Review Process Report.

The Commissioner of the Look-back Review Process will ensure that local managers responsible for the services included in the Look-back Review Process implement the recommendations of the Look-back Review Process.

The Commissioner will also communicate nationally applicable recommendations to the relevant National Directors for national implementation.

Peer review publication of issues relating to the Look-back Review Process, for instance; the development of an audit tool, logistics, communications etc. may be required.

Communication Strategy for the Recall stage of the Look-back Review Process.

A communication strategy will be determined. (Give the name of an individual, who is not directly involved in the recall process but who understands the process and is continually updated on the progress of the process - here), will be appointed for the purpose of communicating information pertaining to the Recall stage to the patient/family/staff member(s) (delete as appropriate) affected by and/or involved in the Recall-stage (delete as appropriate). .

Reference:

- HSE Safety Incident Management Policy (2014, and any subsequent revisions)
- HSE Guideline for Systems Analysis Investigation of Incidents and Complaints (2015)
- HSE Look-back Review Process Guideline (2015)

Appendix 7: Additional Reading to inform Look-back Review Processes

- HSE North East Radiology Look-Back Review Steering Group (October 2008), Review of Chest X-rays and CT scans reported by a Locum Consultant Radiologist at Louth Meath Hospitals from August 2006 to August 2007 (http://www.hse.ie/eng/services/publications/Hospitals/NERadiologyReview.pdf)
- HSE Response to HSE North East Radiology Look-Back Review (2009), http://hse.ie/eng/services/news/media/pressrel/newsarchive/200920082007Archive/June_2009/08reviewxray.html
- HSE South Audiology Review http://www.hse.ie/eng/services/Publications/corporate/HSE_South_Audiology_Review_2009.pdf
- Nugent M, Galbraith JG, Fitzgerald AP, Gul R, Healy NO., (2014), *Outcomes of a patient recall following early failure of hip hemiarthroplasty.* Ir J Med Sci. 183(4):521-4.

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Appendix 8: Look-back Review Process Guideline
Process Checklist

	Look-back Review Process **The purpose of the check-list is to act as an aide memoir to managers and staff to assist them to ensure compliance with the HSE Look-back Review Process Guidelines.** **The check-list must always be used in conjunction with the HSE Look-back Review Process Guidelines. References to the relevant sections of the Guideline have been included in the check-list.**	**You should refer to the relevant Guideline Section(s) for guidance on each stage of the process.**	**Tick as appropriate**		
1	**Stage 1: Preliminary Risk Assessment**	**Section**	**Yes**	**No**	**N/A**
1.1	Senior Accountable Officer was notified that a Look-back Review Process may be required	**7.2**			
1.2	Senior Accountable Officer established a Safety Incident Management Team within 24 hours of being notified	**7.3-7.4**			
1.3	The Preliminary Risk Assessment was commissioned by the Safety Incident Management Team	**7.6**			
1.4	Using the information obtained from the Preliminary Risk Assessment, the Safety Incident Management Team made a decision to progress to the Audit and Recall stages of the Look-back Review Process	**7.6.5**			
1.5	The Safety Incident Management Team informed the relevant National Director of the decision to progress with the Look-back Review Process	**7.6.6**			
2	**Stage 2: Audit Stage**	**Section**	**Yes**	**No**	**N/A**
2.1	The Safety Incident Management Team agreed the Scope and the Terms of Reference of the Audit and Recall stages of the Look-back Review Process	**7.7**			
2.2	The Safety Incident Management Team developed a Look-back Review Action/Work Plan to inform the Audit and Recall Stages of the Look-back Review Process	**7.7**			
2.3	A data collation tool was established collate and track the information gathered by the Look-back Review Process	**7.7**			
2.4	The Audit was undertaken by Service Providers or experts commissioned by the Service Providers	**7.7**			
2.5	The Audit identified persons affected to be included in the Recall stage	**7.7**			
2.6	The Communication Plan was rolled out by the Safety Incident Management Team	**7.7**			
2.7	The Information Line was established by the Safety Incident Management Team	**7.7**			
2.8	The Safety Incident Management Team established Recall Team(s)	**7.7**			

3	Stage 3: Recall Stage	Section	Yes	No	N/A
3.1	The Recall stage was announced by the relevant National Director	**7.8**			
3.2	The Recall stage was announced after persons affected had been informed of their inclusion in the Recall stage of the Look-back Review Process	**7.8**			
3.3	The Recall Team(s) implemented the Recall stage as per the Look-back Review Action/Work Plan	**7.8**			
3.4	The Recall Team identified actions to be taken to address any deviations from required standards of care	**7.8**			
3.5	The Recall Team implemented actions and/ or communicated required actions to the Safety Incident Management Team	**7.8**			
3.6	The Safety Incident Management Team developed an anonymised report of the Look-back Review Process	**7.8**			
3.7	The Chair of the Safety Incident Management Team submitted the anonymised report of the Look-back Review Process to the Senior Accountable Officer, the National Director and any others identified in the Look-back Review Action/Work Plan	**7.8**			
3.8	The Chair of the Safety Incident Management Team communicated recommendations arising from the Look-back Review Process to the Senior Accountable Officer and national Director	**7.8**			

Appendix 9: Guideline Consultation Process

Between February and April 2015, a consultation process was undertaken in order to obtain feedback and observations in relation to the content of the new revision of this Guideline.
All feedback was considered and changes were made to the guideline by the National Incident Management and Learning Team as appropriate.

The following table details the people/ services/ organisations that were included in the consultation process. Where appropriate, managers/ organisations were asked to disseminate the guideline to relevant staff such as Service Managers, Quality Managers, Risk Managers, staff with a role in incident investigation etc., within their service/ organisation for their consideration and feedback.

HSE Leadership Team	
Director General of the HSE	Mr. Tony O'Brien
Deputy Director General	Ms. Laverne McGuiness,
Chief Financial Officer	Mr. Stephen Mulvany
National Director of Primary Care	Mr. John Hennessy
National Director of Social Care	Mr. Pat Healy
National Director for Health and Wellbeing	Dr. Stephanie O'Keeffe
National Director of Mental Health	Ms. Anne O'Connor
Interim National Director of Acute Hospitals	Mr. Liam Woods
National Director of Clinical Programmes	Dr. Áine Carroll
National Director of Health Business Services	Ms Jane Carolan
National Director of Human Resources	Mr. Ian Tegerdine
National Director of Quality Improvement	Dr. Philip Crowley
National Director of Communications	Dr. Paul Connors
National Director of the National Cancer Control Programme	Dr. Jerome Coffey
Internal Audit	Mr. Michael Flynn
National Director Quality Assurance and Verification	Mr. Patrick Lynch
National Lead for Transformation and Change	Mr. Leo Kearns
Quality and Patient Safety Leads	
Acute Services	Ms. Deirdre O' Keefe
Social Care	Mr. Gerry Clerkin
Primary Care	Ms. Angela Alder
Mental Health	Ms. Margaret Brennan
Health and Wellbeing	Dr. Kevin Kelleher
Finance Directorate	Ms. Valerie Plant
HR Directorate	Mr. Andrew Condon
	Ms. Norah Mason
	Ms. Anna Killilea
Communications	Ms. Fidelma Browne
	Ms. Kirsten Connolly
National Cancer Control Programme	Dr. Mary Hynes
	Ms. Niamh O' Rourke
National Ambulance Service	Dr. Cathal O' Donnell, Clinical Director
Community Health Offices	
Area 1: Donegal LHO, Sligo/Leitrim/West Cavan LHO and Cavan/Monaghan LHO.	Mr John Hayes, CHO Manager
Area 2: Galway, Roscommon and Mayo LHOs.	Vacant at time of consultation
Area 3: Clare LHO, Limerick LHO and North Tipperary/East Limerick LHO.	Mr Bernard Gloster, CHO Manager
Area 4: Kerry LHO, North Cork LHO, North Lee LHO, South Lee LHO and West Cork LHO.	Mr Ger Reaney, CHO Manager
Area 5: South Tipperary LHO, Carlow/Kilkenny LHO, Waterford LHO and Wexford LHO	Vacant at time of consultation
Area 6: Wicklow LHO, Dun Laoghaire LHO and Dublin South East LHO.	Ms Martina Queally, CHO Manager
Area 7: Kildare/West Wicklow LHO, Dublin West LHO, Dublin South City LHO and Dublin South	Mr David Walsh, CHO Manager

West LHO.	
Area 8: Laois/Offaly LHO, Longford/Westmeath LHO, Louth LHO and Meath LHO.	Mr Pat Bennett, CHO Manager
Area 9: Dublin North LHO, Dublin North Central LHO and Dublin North West LHO.	Mr Gerry O'Neill, CHO Manager
Acute Hospital Groups	**CEOs**
South South-West	Mr. Gerry O' Dwyer
RCSI Dublin North East	Mr. Bill Maher
Dublin Midlands	Dr. Susan O' Reilly
Ireland East	Ms. Mary Day
UL Hospitals	Ms. Collette Cowan
Children's Hospital	Ms. Eilish Hardiman
West North West	Mr. Maurice Power (Acting)
Members of the Investigation Process Working Group (instrumental in the development of the 2012 Guideline for the Systems Analysis Investigation of Incidents and Complaints	Mr. Andrew Condon
	Professor Brian Toft
	Ms Cathriona Molloy (service user representative)
	Dr. Declan McKeon
	Mr. Des Pearson
	Ms. Fidelma Browne
	Ms. Juanita Guidera
	Ms. Debbie Keyes
	Dr. Samantha Hughes
	Dr. Mary Morrisey
	Professor Sam Cromie
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Groups / Organisations/ Committees
Health and Safety Advisory Group
Healthcare Risk Managers Forum
Dublin Academic Teaching Hospitals Risk Managers Forum
National Joint Committee (HR and Trade Unions)
Department of Health (via Dr. Eibhlin Connelly)
Forum of Irish Post-graduate Medical Training Bodies
Irish Medical Council (via Mr. William Kennedy and Ms. Niamh Muldoon)
Forum of Health and Social Care Regulators *(This group includes HIQA, the Mental Health Commission, the Health and Safety Authority, An Bord Altranais, Irish Dental Society, The Pharmaceutical Society of Ireland, The Pre-hospital Emergency Care Council and the Health and Social Care Professionals regulated by CORU including Clinical Biochemists, Dieticians, Medical Scientists, Occupational Therapists, Podiatrists, Psychologists, Physiotherapists, Orthotists, Radiographers, Social Care Workers, Social Workers, Speech and Language Therapists)*
Health Products Regulatory Authority (formerly Irish Medicines Board)
Radiological Protection Institute of Ireland (RPII)
National Haemovigilance Office (Within the Irish Blood Transfusion Service)
Data Protection Commissioner/ Information Commissioner
Ombudsman
Ombudsman for Children
Indemnifiers: Willis
State Claims Agency

Experts in Systems Analysis

Professor Sam Cromie, Aerospace Research Psychology Programme, School of Psychology
Professor Nick McDonald, Aerospace Research Psychology Programme, School of Psychology
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Professor Brian Toft, Principal – Risk Partnerships ; Visiting Professor of Patient Safety, Brighton and Sussex Medical School and Emeritus Professor of Patient Safety Coventry University

Appendix 10: Key Changes to this Guideline

Changes have been made to wording throughout this entire document with the aim of providing greater clarification and definition to users of this guideline. The layout of the sections of this guideline has also been changed to facilitate easier implementation of the 3 key phases of the Look-back Review process: Preliminary Risk Assessment Phase, Audit Phase and Recall Phase. As every change cannot be detailed below, it is vital that this newly revised draft guideline is read in its entirety.
Changes made were informed by:

- **Consultation on Revision 1 of the guideline between February and April 2015**
- **Feedback received at both the Incident Management and Systems Analysis Investigation training sessions provided by the National Incident Management and Learning Team.**

The following outlines the main changes made to this guideline:

Section	Outline of Change
1.0	Policy Statement: New addition
2.0	Purpose: New addition
3.0	Scope: New addition
4.0	Policy and Legislative context: New addition
5.0	Glossary: New definitions added in line with the HSE Safety incident Management Policy (2014) and to reflect new terminology used.
6.0	New section to outline the responsibilities of all staff in undertaking a Look-back Review Process
7.0	Process Map: New addition to give overview of new look-back review process
7.1 -7.4	New addition – outlining the steps required to initiate a look-back review officer. This guideline includes the roles of the senior accountable officer and the safety incident management team in line with the principles of the HSE Safety incident Management Policy (2014)
7.5	Introduction of the 3 phases of the look-back review process o Preliminary Risk Assessment Phase; o Audit Phase; o Recall Phase.
7.6	New section: Details of the Preliminary Risk Assessment Phase
7.7	New section: Details of the Audit Phase
7.7.3	Introduction of the Look-back Review Action/Work Plan
7.7.8	Establishment of a Recall Team
7.8	New Section: Details of the Recall Phase
7.10	Closing the Look-back Review Process: Expansion of this section to provide greater detail
7.11	New addition on communication strategy to support the Look-back Review Process
8.0	New Section: Implementation Plan
9.0	New Section: Review and Audit
Appendix 1	New Template: Template for Preliminary Risk Assessment
Appendix 2	Updated Appendix: Developing a Data Collation Tool and Sample core dataset for Look-back Review
Appendix 3	Updated Appendix: Information Lines
Appendix 4a	New Appendix: Letter to Patient informing them of their inclusion in the Recall Stage of the Look-back Review Process.
Appendix 4b	New Appendix: Letter to Clinician/ General Practitioner (Informing them of the inclusion of their patient(s) in the Recall Stage of the Look-back Review Process)
Appendix 5	New Appendix: Collection and Storage of Information
Appendix 6a	New Appendix: Template Investigation Terms of Reference for Look-back Review Process
Appendix 6b	New Appendix: Template Investigation Terms of Reference for Audit Phase
Appendix 6c	New Appendix: Template Investigation Terms of Reference for Recall Phase
Appendix 7	New Appendix: Additional Reading to inform Look-back Review Processes
Appendix 8	New Appendix: Look-back Review Process Check List