Incident Management Operational Procedure

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1 INTRODUCTION

This document is complementary to, and should be read in conjunction with, the NHS Lothian Incident Management Policy. The operational procedure is designed to ensure consistency of approach in operational management of incidents, which will, in turn, facilitate best quality consistent data that is crucial to identifying dysfunctional and poor systems and improving processes and practices.
For guidance in relation to Adverse Events and Escalation see Appendices 1a & 1b.

2 INCIDENT REPORTING

2.1 Responsibilities

2.1.1 Lead Director

The management of incidents and consequences needs to remain within the current line management structure to ensure the appropriate management and change. The Lead Director is defined as the Chief Operating Officer and CH(C)P General Managers for Primary Care and is responsible for Incident Management, including family liaison, and will be supported professionally by medical or nursing colleagues at local or board level as appropriate.

2.1.2 Individual

The priority following any incident is to ensure the safety of the person(s) affected.

When an individual member of staff becomes aware of an incident, they must act immediately to ensure that:

- they do not put themselves in situations of danger;
- individuals involved (clients, visitors or staff) and the environment, are made safe;
- the appropriate line manager/supervisor, person in charge is contacted;
- the event is recorded via the electronic Incident Report Form on Datix (to include a record of action taken within 24 hours).

2.1.3 Line Manager

When the line manager/supervisor or deputy becomes aware that an incident has taken place, they must act to ensure that:

- individuals involved and the immediate environment have been made safe;
- identifying incidents reportable under RIDDOR. All RIDDOR reportable incidents should be graded as orange and reported by managers to the Health and Safety Executive (see Appendix 2 for reporting requirements under RIDDOR)
- the documentation (Incident Report Form and patient's/staff Health Record if applicable) has been completed;
- the appropriate Director or Management Team members are made aware of the event and of any action taken to date, and that significant adverse events /incidents are escalated quickly
- the need for further investigation of the circumstances surrounding the event is assessed;
- a record, if appropriate of any action taken at time of incident or thereafter, is maintained including securing of clinical records;
- feedback is given to staff including NHS Lothian volunteers, either individually or collectively;
- support is given to staff including NHS Lothian volunteers who have been directly or indirectly involved in an incident;

- the patient relatives and carers, where appropriate, are informed by the responsible person (**see Section 5 of the NHS Lothian Incident Management Policy**)

2.1.4 Health & Safety Advisor

Health and Safety is responsible for:

- assisting managers in the investigation of incidents when requested by the relevant manager;

- producing statistical information on staff and RIDDOR incident trends and collating information relating to significant adverse events for deliberation and action planning by relevant groups and managers, including Health & Safety Committees;

- providing appropriate training for managers, staff and their representatives in relation to the requirements of this policy.

2.1.5 NHS Lothian

NHS Lothian must ensure that managerial staff are provided with appropriate training in the conduct of investigations**.**

Health and Safety provide training in incident investigation for managers, to meet both Health and Safety legislative and policy requirements.

All staff are required to undertake training sessions on the content, implementation and management of this policy, procedures and local protocol. This will be covered at induction and through local orientation. Further training will be provided with any amendments to policy or documentation as necessary and at appropriate times.

The Clinical Governance & Risk Management Team provides training in incident investigation. This is available to all managers, partnership representatives and any member of staff who may be required to undertake investigations. It is recommended that all staff with management responsibility should attend as part of their training in health and safety and risk management.

An investigation team must have at least one member who has had training in incident investigation. For significant events the team leader should be experienced in incident investigation and a significant number of the team should also have had incident investigation training.

2.2 Specific Types of Incidents

2.2.1 Incidents involving equipment

Immediately remove from use and retain all equipment/product(s) involved in the incident, including any fluid administration set, syringes or other disposables/consumables attached to any equipment concerned at time of the incident. **Do not separate and do not change configuration settings.**

Make a record of the make, model, serial/lot number/batch number/unique identifier, date of manufacture, supplier, and expiry date if applicable.

Notify relevant department responsible for device immediately e.g. Medical Physics. Investigations are often helped by seeing the equipment in situ.

Store equipment in a secure place for inspection and ensure that it cannot cause harm to any person or be tampered with. Label the equipment as 'quarantined – do not touch/use' and include contact details of the person who quarantined the equipment.

Equipment should not be removed from the premises or interfered with until it has been inspected by the relevant internal technical department. Exceptions to this are the Police and the Health and Safety Executive who are empowered to remove anything relevant to their investigations.

2.2.2 Incidents involving weapons

There may be incidents where weapons are used and the Police may be called. Where an incident is considered to be criminal or suspicious in nature, **or** is likely to become a fatal event, **or** where a criminal act is evident, then it must be considered a potential crime scene. In such cases, as far as possible, the scene of the incident and any articles involved should be left intact until the Police or Health and Safety Executive advise otherwise. The area should be made safe and off limits until the official investigation is concluded.

Similar steps should be taken in cases of suicide or self harm.

2.2.3 Incidents involving Defective Medicines

If an incident is thought to be medicine-related, every effort should be made to establish - as far as is reasonably practicable - that the incident is due to a defect and not due to an accident, error in the administration of the medicine, or an adverse patient reaction to a non-defective medicine.

If a defect is discovered or suspected:

- Remove the medicine from use.
- Label and keep the medicine, together with its original packaging, labelling and any administration equipment. Keep in a safe place.
- Record the nature of the defect and reasons for doubts as to the medicine's efficacy or safety.

Report immediately to:

- The patient's medical team;
- A Senior Pharmacist. N.B If out-of-hours report to the On-call Pharmacist and monitor the patient as appropriate.

Should an adverse reaction be suspected, follow the Yellow Card Scheme - for voluntary reporting of suspected adverse drug reactions by doctors, nurses, midwives and dentists.

2.2.4 Incidents Involving Controlled Drugs

All incidents involving CDs should be recorded and investigated. The Accountable Officer must be notified of the incident as soon as possible, without compromising the steps needed to ensure patient safety. The Accountable Officer must then be notified of the outcome of all incidents involving CDs, any learning points identified and the actions taken to prevent recurrence. Where there is suspicion of criminal activity, Lothian & Borders Police should be notified.

2.2.5 Incidents Involving Loss of Confidential Data

Should an incident involve confidential data the Information Governance Team must also be immediately informed. They will assess the level of risk, and if necessary escalate to the Information Commissioners Office.

2.3 Reporting to External Agencies

There may be a requirement to report certain categories of incident to external agencies. **Appendix 3** lists a range of agencies. Advice on reporting requirements can be sought from the Health and Safety Advisors or the Clinical Governance & Risk Management team.

In the case of incidents involving patients in Mental Health Services, the Consultant is responsible for notifying the Mental Welfare Commission, arranging an incident review and reporting this to the Mental Welfare Commission. Such reports must be copied to the Clinical Director / Executive Director with responsibility for Mental Health Services.

3 COMPLETION OF INCIDENT REPORT FORM

3.1 Good Practice Principles:

- Complete **all** relevant sections on the NHS Lothian electronic Incident Report Form on Datix **N.B.** Failure to complete all relevant sections can significantly delay incident analysis and follow up.
- Record facts. Opinions may be recorded where appropriate if it adds greater insight into how the incident occurred or how to prevent re-occurrence
- Avoid selecting the term “other” when selecting a descriptor for the incident
- Avoid speculation and subjective statements – incident reports can become “public documents” under Freedom of Information. It is very important not to make inappropriate comments, as these may reflect poorly on the individual, department or service.
- Avoid the use of abbreviations and/or jargon
- Attach or submit any supplementary information to the Line Manager as required, e.g. photograph, additional information sheet, and witness statements.

3.2 What to report

Any incident/near miss, event or circumstance arising during NHS service provision that **could have** or **did** lead to unexpected harm, loss or damage should be reported. Harm need not always be of a physical nature; it may be emotional or psychological, and therefore verbal/ emotional abuse and child/vulnerable adult protection issues should also be reported.

Incidents/near misses which happen in the course of a patient’s care or clinical treatment should be reported, e.g. misdiagnosis, medication error, failure to act on results, and intervention without informed consent.

N.B. Sometimes an incident is not immediately apparent but identified at a later stage, e.g. a person may experience back pain a few days after a manual-handling manoeuvre. It is important that this kind of incident is reported, albeit retrospectively.

The following types of incidents/near misses should be reported:

- Personal accidents to patients or staff e.g. slips or falls, needle stick injury
- Clinical incidents/near misses regarding patient care or treatment e.g. medication error, misdiagnosis, infection, x-ray
- Security incident e.g. missing patient, intrusion, theft and fraud
- Violence, abuse, harassment

- Any incident which may be experienced as harassment on the grounds of age, disability, ethnicity or race, gender, religion or belief or sexuality[1]
- Fire/environmental e.g. waste disposal.

This list is not exhaustive

3.3 When to report

It is important that all incidents / near misses are reported as soon as possible and ideally within 24 hours of occurrence. **(See Appendices 1a & 1b)**

3.4 How to report

You should report using the NHS Lothian electronic Incident Report Form.

If it is not possible for the person(s) involved to complete a form, it should be completed by the Line Manager with assistance from witnesses where required. If the member of staff has been injured, the supervisor/line manager should complete the Incident Report Form.

Wherever possible, you should report an incident or near miss in the department where the event has occurred. If this occurs in an external area this should be recorded in the incident report and if appropriate the manager for that area contacted.

Staff working in the community should report an incident as soon as possible after returning to their base. Staff working in areas provided by other agencies should report the incident to the relevant external facilities manager as well as their line manager.

NHS Lothian electronic Incident Report Form

This form is available on the home page of the NHS Lothian Intranet.

Guidance for completing the form is available on the Intranet.

When the form is submitted it is sent electronically to an appropriate manager/senior clinician based on the location of the incident.

If the electronic Incident Report Form is unavailable DUE TO SYSTEMS FAILURE, a paper record of the incident should be made and submitted to the Line Manager, who is responsible for it being submitted electronically as soon as possible.

4 INCIDENT GRADING

There are 2 stages to grading the incident (**the tables referred to below are in Appendix 4**)

1) The severity of the actual outcome in terms of harm. This should be identified at the time of reporting the incident. Use the NHS Lothian Risk Matrix Table 1 – impact/consequence definitions and be used to determine escalation.
   At this point a check should be made of the decisions to escalate (or pass information to others) and/or investigate (see Appendix 1b).

2) The risk associated with the recurrence of the event. This should happen as soon as possible after the incident has been reported and the investigation has commenced. Determine the risk grading by assessing the **likelihood** (**Table 2**) of this incident happening again (recurrence) and then use the matrix shown in Table 3 which assesses likelihood against consequences and impact and impact of risk grading.

[1] It is important to consider at the time of any incident whether it could have been motivated by racism, sexism etc and this should be included in the report and investigated appropriately.

The consequence if the incident happened again may be more severe than what actually happened and this should be reflected in the risk grade so that serious near misses get the appropriate level of escalation and investigation.

The grading is used to inform decisions regarding escalation at the time of the incident – refer to Lothian Risk Matrix Table 1 in Appendix 4. The level of action, incident review and analysis required will be determined both by the severity of the impact and, where appropriate, the future potential risk. Grading is used by the clinical and management teams in the process of reviewing incidents in order to assist with the prioritising of attention given to particular incidents.

5 INCIDENT INVESTIGATION

5.1 Purpose of incident investigation

The purpose of any incident investigation is to:

1. Help learning from experience to facilitate improvement by:
   - knowing the facts of the incident;
   - identifying causes, especially system faults;
   - clarifying the nature of changes and improvements which may be justified.
2. Collect information for the purposes of litigation;
3. Demonstrate the organisation's concern over the actual or potential harmful effects;
4. Enable support to be provided for the staff involved;
5. Consider whether there are underlying aspects of the incident which might be attributable to discrimination or harassment.

An investigation report should reflect these purposes to provide a suitable record and to facilitate communication with other staff, others in the organisation, and members of the public, as required.

5.2 Level and Investigation Protocol

All incidents are investigated to some extent to permit the completion of an incident report. Some should be investigated in greater depth because:

- they are more complex;
- the actual or potential effects are serious;
- the incident was highly unexpected;
- it was of a type representing a serious risk area for that department.

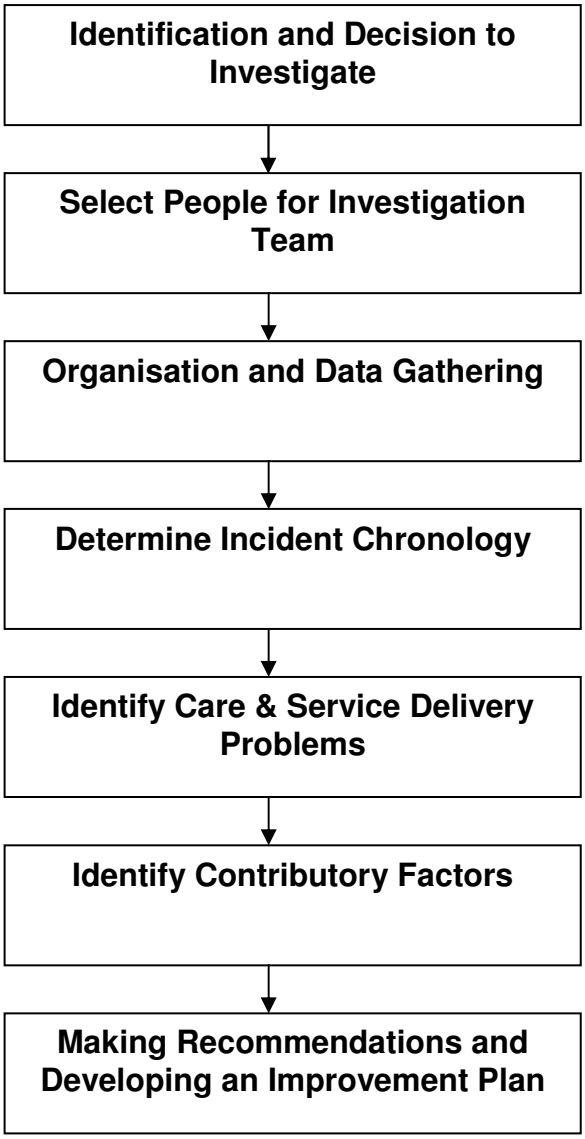
The level of investigation will be dependent on the risk grading applied to the incident and is summarised in Table 1 below.

Table 1: Incident Grading Table – Identification and decision to investigate

Grading of Incident	**Level of Investigation**	**Investigation Team**	**Investigation Template**	**Improvement Plan Template**	**Timescale/Key Performance Indicators**
Red Incidents in which severity in terms of actual harm is extreme and/or graded as very high including RIDDOR	Comprehensive investigation. Requires escalation – see Adverse Event Operational Procedure, Appendices 1a & 1b	Senior Management involvement in deciding who investigates the incident	Complete investigation template (see Appendix 2, Investigation Protocol)	Complete improvement plan (see Appendix 2, Investigation Protocol)	Commence formal investigation within 12 working days. Complete within 60 days.
Orange Incidents in which severity is major, e.g. major injury, long-term incapacity requiring medical treatment and/or counselling/ RIDDOR and/or graded as high	Comprehensive investigation. Requires escalation – see Adverse Event Operational Procedure (Appendices 1a & 1b)	Senior Management involvement in deciding who investigates the incident	Complete investigation template. As above	Complete improvement plan. As above	Commence formal investigation within 12 working days. Complete within 60 days.
Yellow Incidents in which severity is moderate, e.g. short-term affects and/or graded as low or medium risk.	Concise investigation.	Person in charge of the department/ area to lead investigation and document on outcome.	Complete investigation template.	Complete improvement plan template.	Commence formal local investigation within 12 working days. Closed within 28 days
Green – no harm or minor injury and/or graded as low risk.	No further action required. Incident clusters should however be investigated for this grade of incident	N/A	N/A	N/A	Incident approved within 10 working days of being reported/closed within 20 days

When investigating incidents, follow NHS Lothian's Incident Investigation Protocol (see Appendix 5 for the investigation protocol) summarised below in Figure 1.

Figure 1: Incident Investigation and Analysis Process Flowchart



5.3 Fairly dealing with staff who are involved in Significant Adverse Events

Any investigation into a serious clinical incident will not, and cannot, preclude use of the disciplinary process where there has been a serious breach of professional practice; however, in the event that a disciplinary procedure is invoked, the reasoning for its use will be discussed with the Investigation Team.

The spirit of the investigation will be characterised by an open and fair culture.

'Open and fair culture' in this context means that the purpose of the Investigation is to identify causes or system failures. Staff will not be reprimanded or such failures or their consequences; however, they retain individual responsibility for their own actions or inactions in accordance with the professional codes that apply to them and their professional practice.

All staff interviewed as part of the investigation must be made aware of these principles and of the fact that transcripts of any interviews and copies of any statements made by them as part of the investigation will be kept confidential. Staff should be advised that the only exceptions will be the transcript or statement needs to be used as part of a

disciplinary process (with the permission of individual) or when it is required by the Police or under a court order.

Although the investigation is not in itself a disciplinary process, staff are entitled to request support from their trade union or professional regulating body.

5.3.1 Parameters of the Investigation

- In the unlikely event that the investigation uncovers any criminal, potentially criminal or reckless behaviour, then the investigation must stop and the appropriate criminal investigation process should be used.

- If the investigation uncovers professional misconduct, including malicious or reckless behaviour, which may be construed as gross misconduct or a serious breach of the individual's professional code of conduct, then the disciplinary process will be invoked. The two processes may proceed in parallel, provided the rights of the individual are not compromised.

- The investigation team's report and recommendations will be provided to any disciplinary investigation but individual interview transcriptions and statements recorded by the investigation team will only be released with the permission of the individual. This may result in individuals being interviewed/asked for statements more than once.

5.4 What confidentiality means in this context

Confidentiality in the context of the investigation means:

I. That any statement or interview given by a member of staff will remain confidential to the Investigation Team.

II. Transcripts or interviews and statements may be made available to the Police if required or when requested under a court order. This will normally be done with the individual's knowledge and consent although a lack of consent cannot override due legal process.

III. The findings of the Investigation Team will at all times be dealt with in a manner that respects the confidentiality of individual patients, families and staff.

5.5 Strategic Reporting and Review Process

All completed reports must be approved by the appropriate management team and where appropriate be sent to the Chairs of UHD and CHP/CH(C)P Healthcare Governance and Risk Management groups and the report will be reviewed by that group to ensure that lessons learned at local level are identified and shared and assuring implementation of and compliance with the process.

5.5.1 All Significant Adverse Event reports should be signed-off by the Chief Operating Officer and CHP/CH(C)P General Manager and sent to the Nurse and Medical Directors on a monthly basis for review.

5.5.2 The management team is responsible for:

- Monitoring the process and outcomes, confirmation of appropriate actions having been completed or remitting outstanding issues to an appropriate channel for further action.

- The HCGRM team will produce anonymised quarterly NHS Lothian Incident reports for consideration at Divisional/CHP/CH(C)P and Board Healthcare Governance & Risk Management committees.

6 LEARNING FROM INCIDENTS

The use of quantitative and qualitative information on incidents as well as effective communication of trends and outcomes of incidents, including near misses, is crucial in order to drive the improvement of current processes, practices and systems including identification of contributing factors.

The review of incidents is a formal part of the review process to be undertaken by every team and levels of management throughout the organisation. Unless it is essential, when reports are being produced for wide dissemination, staff should make every attempt to remove patient and staff identification.

The outcomes of incident reviews are:

- to provide information, trends etc to inform action planning;
- to identify the need for further attention by multi-disciplinary teams;
- to lead to local learning groups, when appropriate;
- to lead to the sharing of information which could be useful to others.

6.1 Responsibilities

6.1.1 Directorates/Departments

Directorates and departments will review the incidents reported, monitor actions taken and encourage regular discussion of incidents at the appropriate risk management /senior management group meetings as appropriate to prevent/reduce reoccurrence.

These will be escalated to Divisional/ CH(C)P Management team meetings where lessons learned which have wider implications beyond the directorate /department have been identified

6.1.2 Divisional/CH(C)P Management team

The management teams will review all investigation reports on red and orange incidents, incident statistics, monitor trends and play an integral part in the process of accident/incident minimisation.

They will have a systematic review process in place to review all serious incidents, trends /clusters and ensure that lessons learned are disseminated appropriately and timeously, with actions/recommendations systematically monitored until they have been completed.

They are responsible for escalation of serious incidents and risk to NHS Lothian Board (**see Appendix 1b**).

6.1.3 NHS Lothian Executive Management Team

The NHS Lothian Executive Management Team will be provided, on a weekly basis, with a report on all incidents involving serious harm. Some incidents may, as per Policy, be also escalated immediately to this level.

6.1.4 NHS Lothian Healthcare Governance and Risk Management and NHS Lothian Health and Safety Committees

These Committees will be provided with examples of incident investigation reports and associated action plans, on a quarterly basis.

The Healthcare Governance and Risk Management Committee will review all incident statistics, monitor trends and play an integral part in the process of accident / incident minimisation. It will also ensure full liaison with staff-side representation, professional groups and staff associations prior to and during the implementation of safety initiatives.

Operational groups and committees with responsibility for risk management and Health and Safety i.e. for the Division, Directorates, CHPs and CHP-managed/hosted services will periodically discuss incident statistics and use these to inform organisational objective-setting and the production of documented action plans action plans.

6.1.5 Clinical Governance & Risk Management Team

The Clinical Governance Support Team is responsible for:

- ensuring processes and structures are in place to facilitate incident management;
- facilitating incident reviews and investigation if required;
- encouraging an incident reporting culture that is open, honest and focuses on improving practice
- undertaking independent review of the quality of incident investigations and reporting.

6.1.6 Quality Improvement Teams

Quality Improvement teams will be responsible for identifying and taking forward improvement actions to address issues raised through incident investigations and showing learning from these investigations.

6.1.7 Healthcare Governance, Risk Management and Health and Safety

Incident statistics are produced by the Health and Safety Department and Clinical Governance & Risk Management Team at regular intervals and in response to specific requests. This statistical data will be an aggregation of local incident statistical reports produced for local operational groups to ensure that there is an upward flow of information from operational to a corporate level. Conversely, to ensure that there is a downward and lateral flow of information, the report to the Healthcare Governance and Risk Committee will be disseminated back down to these local groups.

6.1.8 Mutuality and Equality Governance/Staff Governance Committees

Incidents which relate to harassment on the grounds of age, disability, ethnicity / race, gender, religion / belief or sexuality must be reported separately and will be reviewed by the Mutuality & Equality Governance Committee/Staff Governance Committee annually.

7 MEDIA ENQUIRIES

In all instances, external enquiries regarding any incident **must** be referred to the Communications Manager (see Key Contacts - section 8.0 below). He/she, along with the appropriate Executive Director, will agree a response to media enquiries. Communications with the media **will only be** via the Chief Operating Officer / CHP General Manager, the Head of Communications or another designated senior manager.

Managers should expect and prepare for media interest in any serious incident within NHS Lothian. Such interest is most likely where a child or a vulnerable adult is involved, wrong treatment is given or where groups of people are put at risk as a result of service

failures, e.g. in a diagnostic reporting process or where there has been an outbreak of food poisoning. Therefore, inform Communications Team when escalation of an incident takes place so they are prepared.

Media contact can be achieved through a variety of means, including a press conference, the releasing of a press statement or being available for ad hoc press enquiries.

8 KEY PERFORMANCE INDICATORS

Managers are responsible for ensuring compliance with the procedures against the following Key Performance Indicators set out in table 1 of Appendix 6.

9 REVIEW OF PROCEDURE

The procedure will be reviewed annually by the Health and Safety Department and Clinical Governance & Risk Management Team. Changes may also be made by exception and through an annual review by any of the groups with oversight responsibility.

August 2011

APPENDIX 1a

Definition of Significant Adverse Events (SAE)
(Use operational procedure for SAE incident investigation and communication)

Definition of a Significant Adverse Event

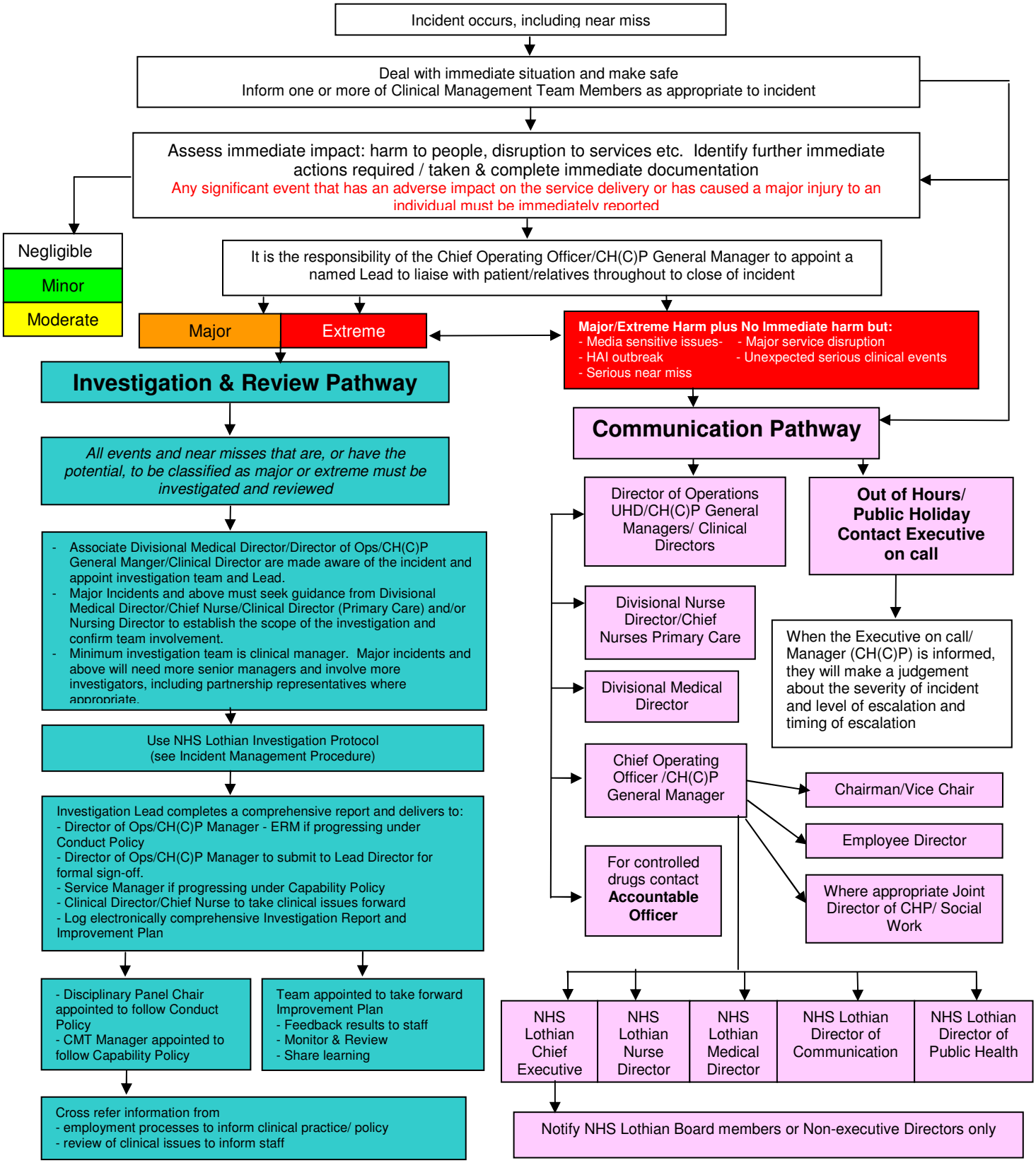
A significant adverse event is defined as an extraordinary event that could have, or did have serious consequences, including immediate or delayed emotional reactions, physical or psychological harm for patients, public, staff or organisation. The severity of the actual outcome of such incidents in terms of harm will either be Extreme or Major. Occasionally a Significant Adverse Event will have no actual harm, but is deemed significant because there is a Very High Likelihood of recurrence with serious consequences or if it is a media sensitive issue.

For example:

- Death or major injury connected with employment, care, treatment or related to participation in research activity
- Death or injury of patient, member of staff / visitor / other where foul play is suspected
- Death of a patient where suicide may have been the cause
- Patient / staff member / other person's death resulting from violent, suspicious or unexplained cause
- Verbal, physical or psychological abuse of a patient, member of staff / other person including racism, etc
- 'Near miss' events such as a patient absconding, an accident, violent, suspicious or unexplained incident which may not result in injury or disability but which could be an indicator of potential suicide or danger to others
- Major outbreaks of infection
- Serious medication incidents
- Major clinical errors
- Systematic screening / diagnostic errors
- Failure in infrastructure putting people at risk e.g. electricity, medical gases
- Fire involving injury and or financial loss
- Unauthorised interference with or malfunctioning of medical equipment or supplies
- Loss of patient confidential data
- Suspected fraud

APPENDIX 1b

OPERATIONAL PROCEDURE FOR INVESTIGATION & COMMUNICATION OF ADVERSE EVENT OR INCIDENT



Director of Operations to consider informing / escalating to:

- University Deanery if involves Junior Doctor
- Central Legal Office
- Environmental Health
- Food Standards Agency
- Health & Safety Executive – Reporting of Injuries, Diseases and Dangerous Occurrences
- NHS Quality Improvement Scotland
- Police
- Procurator Fiscal
- Scottish Centre for Infection & Environmental Health (SCIEH)
- Scottish Healthcare Supplies (SHS)
- Serious Hazards of Transfusion (SHOT)
- Scottish Environmental Protection Agency (SEPA)

APPENDIX 2

REPORTING REQUIREMENTS UNDER RIDDOR

NHSL has a legal duty to report certain accidents/incidents within a set timescale. To assist you in awareness of the incidents that require to be reported, here are listings as set out in RIDDOR – Reporting of Injuries, Diseases and Dangerous Occurrence Regulations 1995

Reporting on Datix does not automatically report to the HSE (Health and Safety Executive), or your manager. Contact them with the Datix number to inform them of situation

Various incidents/accidents need reported, including:-

- any fatal injuries to employees or other people in an accident connected with your business
- any major injuries to employees or other people in an accident connected with your business
- any of the dangerous occurrences listed in the regs

Your managers are now reporting directly to the HSE. Occupational Health and Safety Advisers (OH&S) will continue to support.

The incident needs to be submitted on a report to the HSE within a 15 day time period – done electronically. Information required included, Persons full name, home address, home phone number, date of birth, actual injury sustained, first aid if given, estimated time off work. Other information, i.e. if related to assault or Moving and handling, were they up to date on specific training?

1.1 Major Injuries

- Fracture other than to fingers, thumbs or toes
- Amputation
- Dislocation of the shoulder, hip, knee or spine
- Loss of sight – temp or permanent
- Chemical or hot metal burn to the eye or any penetrating injury to the eye
- Injury resulting from electrical stock/electrical burn leading to unconsciousness; or requiring resus; or admission to hospital for more than 24 hrs
- Any other injury requiring admission to hospital for over 24 hrs; or absence from work for more than 7 days; or on restricted duties for more than 7 days
- Unconsciousness caused by asphyxia or exposure to harmful substance or biological agent (i.e. needle stick injury from known high risk pt, with identifiable BBV)

1.2 Dangerous Occurrences

- Collapse, overturning or failure of load bearing parts of lifts and lifting equipment
- Electrical short – circuit or overload causing fire or explosion
- Collapse or partial collapse of scaffolding over 5 meters high, or erected near water where there could be a risk of drowning from the fall
- Explosion or fire causing suspension of normal work for over 24 hrs

2 Reportable Diseases

- Certain poisonings
- Some skin diseases such as occupational dermatitis (when diagnosed by OH)
- Lung diseases such as occupational asthma, asbestosis, pneumoconiosis, mesothelioma
- Infections such as leptospirosis, hepatitis, tuberculosis, legionellosis, tetanus
- Occupational cancers, certain muscular disorders, Hand arm vibration/whole body vibration syndrome

<u>Please ask your local OH&S adviser, if more advice/direction is sought.</u>

APPENDIX 3

Reporting Bodies

External bodies and organisations who may need to be informed of specific incidents

National Services Scotland (NSS) Central Legal Office www.clo.scot.nhs.uk

Environmental Health

Food Standards Agency www.food.gov.uk/scotland

Health and Safety Executive (HSE) – RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (1995) www.hse.gov.uk/scotland/index.htm

Mental Welfare Commission www.mwcscot.org.uk *

NHS Healthcare Improvement Scotland www.healthcareimprovementscotland.org/

Police www.lbp.police.uk

Procurator Fiscal www.crownoffice.gov.uk

Scottish Centre for Infection and Environmental Health (SCIEH)
www.show.scot.nhs.uk/scieh

Scottish Healthcare Supplies (SHS)
http://www.show.scot.nhs.uk/shs/hazards_safety/adverse.html

Serious Hazards of Transfusion (SHOT)

Scottish Environmental Protection Agency (SEPA) www.sepa.org.uk

Child Protection (see Lothian Child Protection Policy)

Vulnerable Adults www.scotland.gov.uk/Topics/Health/care/VAUnit/ProtectingVA

Counter Fraud Services (part of NHSNSS)
http://www.nhsnss.org/pages/services/counter_fraud_services.php

Please note: The EHRC (Equality and Human Rights Commission) have a legal right to request information on incidents of harassment and discrimination.

This list is not exhaustive, but are those most commonly considered.

* Responsibility will transfer to NHS HIS from 1st April 2008

GRADING MATRIX

Table 1 – Impact/Consequence Definitions

Descriptor	Negligible	Minor	Moderate	Major	Extreme
Patient Experience	Reduced quality of patient experience /clinical outcome not directly related to delivery of clinical care.	Unsatisfactory patient experience/clinical outcome directly related to care provision – readily resolvable	Unsatisfactory patient experience/ clinical outcome; short term effects – expect recovery <1wk.	Unsatisfactory patient experience/ clinical outcome; long term effects – expect recovery >1wk.	Unsatisfactory patient experience/ clinical outcome; continued ongoing long term effects
Objectives / Project	Barely noticeable reduction in scope, quality or schedule	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Significant project over-run.	Inability to meet project objectives; reputation of the organisation seriously damaged.
Injury (physical and psychological) to patient/visitor/staff	Adverse event leading to minor injury not requiring first aid.	Minor injury or illness, first aid treatment required.	Agency reportable, e.g. Police (violent and aggressive acts). Significant injury requiring medical treatment and/or counselling.	Major injuries/long term incapacity or disability (loss of limbs) requiring medical treatment and/or counselling. RIDDOR.	Incident leading to death or major permanent incapacity.
Complaints / claims	Locally resolved verbal complaint.	Justified written complaint peripheral to clinical care.	Below excess claim. Justified complaint involving lack of appropriate care.	Claim above excess level. Multiple justified complaints.	Multiple claims or single major claim Complex justified complaint
Service / Business interruption	Interruption in a service which does not impact on the delivery of patient care or the ability to continue to provide service	Short term disruption to service with minor impact on patient care.	Some disruption in service with unacceptable impact on patient care. Temporary loss of ability to provide service.	Sustained loss of service which has serious impact on delivery of patient care resulting in major contingency plans being invoked.	Permanent loss of core service or facility. Disruption to facility leading to significant "knock on" effect
Staffing and Competence	Short term low staffing level temporarily reduces service quality (< 1 day). Short term low staffing level (>1 day), where there is no disruption to patient care.	Ongoing low staffing level reduces service quality. **Minor error** due to ineffective training/implementation of training.	Late delivery of key objective / service due to lack of staff. **Moderate error** due to ineffective training/implementation of training. Ongoing problems with staffing levels.	Uncertain delivery of key objective/ service due to lack of staff. **Major error** due to ineffective training/ implementation of training.	Non-delivery of key objective/service due to lack of staff. Loss of key staff. **Critical** error due to ineffective training/ implementation of training.
Financial (including damage/loss/fraud	Negligible organisational/ personal financial loss. (£<1k). (**NB.** Please adjust for context	Minor organisational/personal financial loss (£1-10k).	Significant organisational/personal financial loss (£10-100k).	Major organisational/personal financial loss (£100k-1m).	Severe organisational/personal financial loss (£>1m).
Inspection / Audi	Small number of recommendations which focus on minor quality improvement issues.	Recommendations made which can be addressed by low level of management action.	Challenging recommendations that can be addressed with appropriate action plan.	Enforcement action. Low rating. Critical report.	Prosecution. Zero rating. Severely critical report.
Adverse Publicity / Reputation	Rumours, no media coverage. Little effect on staff morale.	Local media coverage – short term. Some public embarrassment. Minor effect on staff morale/public attitudes.	Local media – long-term adverse publicity. Significant effect on staff morale and public perception of the organisation.	National media/adverse publicity, less than 3 days. Public confidence in the organisation undermined. Use of services affected.	National/international media/adverse publicity, more than 3 days. MSP/MP concern (Questions in Parliament). Court Enforcement. Public Inquiry/ FAI.

Table 2 – Likelihood Definitions

Descriptor	Rare	Unlikely	Possible	Likely	Almost Certain
Probability	Can't believe this event would happen– will only happen in exceptional circumstances.	Not expected to happen but definite potential exists – unlikely to occur.	May occur occasionally, has happened before on occasions – reasonable chance of occurring.	Strong possibility that this could occur– likely to occur.	This is expected to occur frequently / in most circumstances – more likely to occur than not how often.

Table 3 Risk Matrix

Likelihood	Consequences / Impact				
	Negligible	Minor	Moderate	Major	Extreme
Almost Certain	**Medium**	**High**	**High**	**V High**	**V High**
Likely	**Medium**	**Medium**	**High**	**High**	**V High**
Possible	**Low**	**Medium**	**Medium**	**High**	**High**
Unlikely	**Low**	**Medium**	**Medium**	**Medium**	**High**
Rare	**Low**	**Low**	**Low**	**Medium**	**Medium**

Grading Matrix - AS/NZS 4360:2005

APPENDIX 5

NHS Lothian

Incident Investigation Protocol *

** Based on the London Protocol – Systems Analysis of Clinical Incidents*

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Section B Select the people for the investigation team
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Section F Identify the contributory factors
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4. APPENDICES

Appendix 1 – Incident Investigation Template
Appendix 2 – Incident Investigation Improvement Plan Template

1 INTRODUCTION

- This protocol outlines a process of incident investigation and has been developed in the light of experience and research (Reason JT1993)[2] into incident investigation both within and outside healthcare. **The protocol focuses on clinical incidents but is suitable for all investigations be they clinical or non-clinical and can be used for all grades of investigation.**

- The purpose of the protocol is to ensure a consistent and systematic thoughtful approach to the investigation of incidents. To promote a greater climate of openness and to move away from finger pointing and the routine assignation of blame.

- This protocol should be separated from any disciplinary or other procedures used for dealing with persistent poor performance by individuals.

2 KEY INVESTIGATION CONCEPTS

To use this protocol, the following concepts need to be understood.

2.1 Care & Service Delivery Problems

Care & Service Delivery Problems are problems that arise in the process of care, usually actions or omissions by members of staff. Several Care & Service Delivery Problems may be involved in one incident. They have two essential features:

- Care deviated beyond safe limits of practice
- The deviation had at least a potential direct or indirect effect on the eventual adverse outcome for the patient, member of staff or general public.

Examples of Care & Service Delivery Problems are:

- Failure to monitor, observe or act
- Incorrect (with hindsight) decision
- Not seeking help when necessary

2.2 Clinical Context

Salient clinical events and the clinical condition of the patient at the time of the Care & Service Delivery Problem (e.g. bleeding heavily, blood pressure falling). The essential information required to understand the clinical context of the Care & Service Delivery Problem.

2.3 Contributory Factors

Many factors may contribute to a Care & Service Delivery Problem. For example:

- Patient factors might include that fact that the patient was very distressed or unable to understand instructions.
- Task and technology factors might include poor equipment design or the absence of protocols
- Individual factors may include lack of knowledge or experience of particular staff
- Team factors might include poor communication between staff

[2] Reason, J.T. The human factor in medical accidents. In Vincent C.A. editor. Medical Accidents. Oxford: Oxford Medical Publications; 1993.

- Work environment factors might include an unusually high workload or inadequate staffing

Table 1 below sets out contributory factors which can impact on Care and Service providers.

Table 1: Framework of Contributory Factors Influencing Clinical Practice

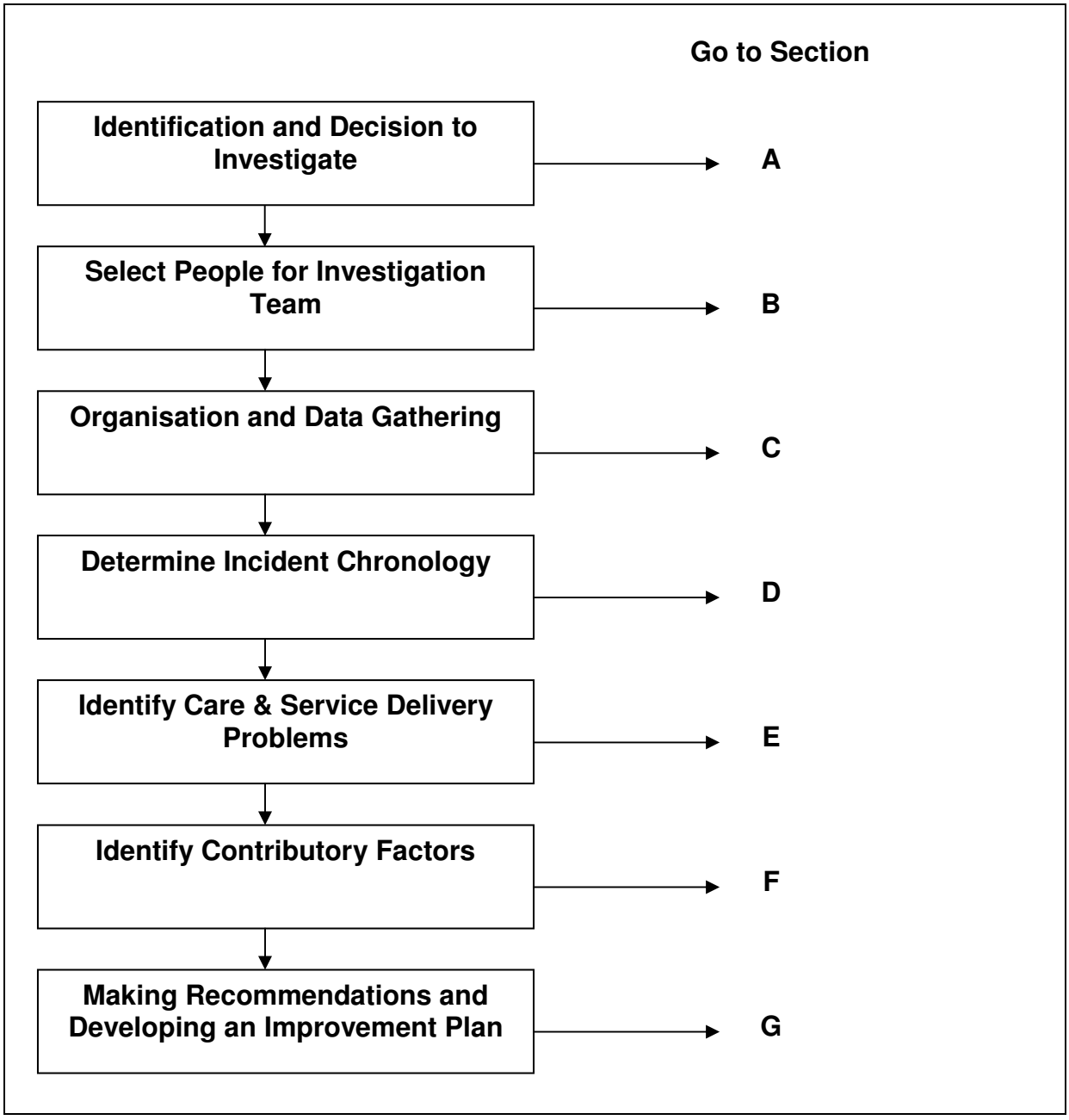
FACTOR TYPES	CONTRIBUTORY INFLUENCING FACTOR
Patient factors	- condition (complexity and seriousness) - language and communication - personality and social factors
Task and Technology factors	- task design and clarity of structure - availability and use of protocols - availability and accuracy of test results - decision making aids
Individual (staff) factors	- knowledge and skills - competence - physical and mental health
Team factors	- verbal communication - written communication - supervision and seeking help - team structure (congruence, consistency, leadership etc)
Work Environmental factors	- staffing levels and skill mix - workload and shift patterns - design, availability and maintenance of equipment - administrative and managerial support - physical environment
Organisational and Management factors	- financial resources and constraints - organisational structure - policy, standards and goals - safety culture - priorities
Institutional Context factors	- economic and regulatory context - National Health Service executive - Links with external organisations

3 INCIDENT INVESTIGATION & ANALYSIS PROCESS

The incident investigation and analysis process flowchart (see figure 2) provides an overview of all the stages of the incident investigation and analysis process. The flowchart shows the objectives of each stage and how each objective is achieved.

The basic process of incident investigation and analysis is standardised, and will be followed whether investigating a minor incident or a significant adverse incident; the process is essentially the same where an individual or a large team are responsible for the investigation.

Figure 2: Incident Investigation and Analysis Process Flowchart



SECTION A: Incident Grading and Identification and Decision to Investigate

Grading of Incident	Level of Investigation	Investigation Team	Investigation Template	Improvement Plan Template	Timescale/Key Performance Indicators
Red Incidents in which severity in terms of actual harm is extreme and/or graded as very high including RIDDOR	Comprehensive investigation. Requires escalation – see Adverse Event Operational Procedure, Appendices 1a & 1b	Senior Management involvement in deciding who investigates the incident	Complete investigation template (see Appendix 2, Investigation Protocol)	Complete improvement plan (see Appendix 2, Investigation Protocol)	Commence formal investigation within 12 working days. Complete within 60 days.
Orange Incidents in which severity is major, e.g. major injury, long-term incapacity requiring medical treatment and/or counselling/ RIDDOR and/or graded as high	Comprehensive investigation. Requires escalation – see Adverse Event Operational Procedure (Appendices 1a & 1b)	Senior Management involvement in deciding who investigates the incident	Complete investigation template. As above	Complete improvement plan. As above	Commence formal investigation within 12 working days. Complete within 60 days.
Yellow Incidents in which severity is moderate, e.g. short-term affects and/or graded as low or medium risk.	Concise investigation.	Person in charge of the department/ area to lead investigation and document on outcome.	Complete investigation template.	Complete improvement plan template.	Commence formal local investigation within 12 working days. Closed within 28 days
Green – no harm or minor injury and/or graded as low risk.	No further action required. Incident clusters should however be investigated for this grade of incident	N/A	N/A	N/A	Incident approved within 10 working days of being reported/closed within 20 days

In certain circumstances the Medical Director or an Executive Director may decide to also commission an independent investigation. They will appoint the members of the investigation team and be responsible for ensuring the operations team are kept fully up to date.

It should also be noted that at any time during the investigation process the investigation team may wish to get the multidisciplinary group together to:-

- To allow the people with inside knowledge to see and discuss your understanding and fill gaps
- To seek their help in identifying problems
- To allow them to take responsibility
- To contribute to workable solutions

SECTION B: Select the People for the Investigation Team

Appropriate experts are essential for investigation of serious incidents. Ideally, an investigation team should consist of 3 or 4 people facilitated by the investigation leader. It is important to identify team members with multiple skills and the time to commit to the process.

An ideal team to investigate a Significant Adverse Event might include:

- Individuals with incident investigation and analysis experience
- Senior management expertise (e.g. Medical Director, Director of Nursing, CH(C)P General Manager/Director of Operations, employee relations, partnership representation)
- Senior clinical expertise/senior consultant
- It is also valuable to have someone with knows the relevant unit or department well, though they should not have been directly involved in the incident

SECTION C: Organisation and Data Gathering

Documenting the Incident

All facts, knowledge and physical items related to the incident should be collected as soon as possible. This may include:

- All medical records (e.g. nursing, medical, community, social workers, general practitioner, etc).
- Documentation and forms related to the incident (e.g. protocols and procedures).
- Immediate statements and observations.
- Conduct interviews with those involved in the incident.
- Physical evidence (e.g. ward layout schematics, etc).
- Secure equipment involved in incident (e.g. shower rail used to commit suicide).
- Information about relevant conditions affecting the event (e.g. staff rota, availability of trained staff, etc).

Statements can be a useful data source, but only if guidance is provided on the type of information needed, otherwise they tend to be just summaries of the medical records. The statement needs to contain the individual's account of the sequence and timing of events, a clear account of their involvement in the case and an account of any difficulties they faced and problems (such as faulty equipment) that may not be detailed in the medical notes. Some issues, such as not being properly supported or supervised, may be best discussed in interviews. Information from statements will be integrated with other data sources such as audit reports, quality initiatives, maintenance logs, medical notes, prescription charts, etc to get a complete picture of the factors likely to have impacted the incident. **Information is best collected as soon after the incident has occurred.**

The purpose for collecting information at this stage is to:

- Secure information to ensure it is available for use during the investigation and later if the case was to go to court.
- Allows an accurate description of the incident, including the sequence of events leading up to the incident.
- Organisation of the information.
- Provides initial direction to the investigation team.
- Identifies relevant policies and procedures.

Conducting Interviews

One of the best means of obtaining information from staff and other persons involved regarding the incident is through interviews. The investigation team will need to determine who needs to be interviewed and arrange for these interviews to take place as early as possible. Interviews lie at the heart of effective investigation.

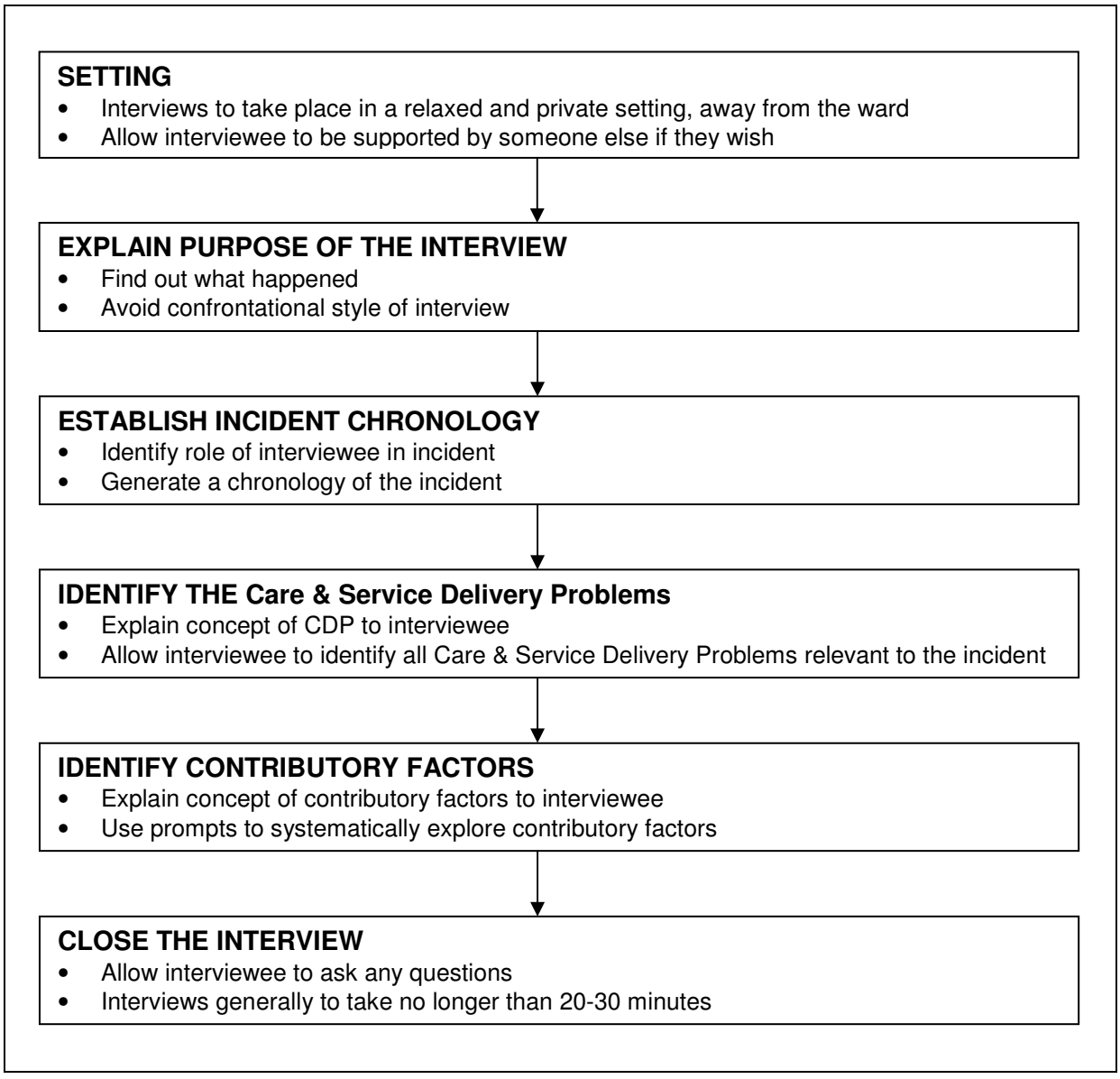
Setting the scene

Interviews should be undertaken in private and, if at all possible, away from the immediate place of work in a relaxed setting. The team will need to decide whether the whole team or just two interviewers will conduct the interview and report back to the wider team. Ask the member of staff if they would like a friend or colleague to be present.

There are several distinct phases to the interview and it is generally most effective to move through these phases in order.

Figure 3 provides a summary of the interview phases and the information to be obtained during the interview.

Figure 3 – Summary of the Protocol's Interview Process



Conducting interviews is resource intensive and it may be that this approach to data gathering can either only be applied to very serious incidents or where only the key persons involved in an incident can be interviewed. If interviews cannot be used fully the protocol investigation process can still be followed, by relying more on other data sources.

All staff interviewed as part of an incident investigation must be made aware of these principles and of the fact that transcripts of any interviews and copies of any statements made by them as part of the investigation will be kept confidential. This may result in interviewees being interviewed/asked for statements more than once. Staff should be advised that the only exception is when it is required by the Police or under a court order.

Although the incident investigation is not in itself a disciplinary process, staff are entitled to request support from their trade union or professional organisation.

SECTION D: Determine Incident Chronology

The next step in the investigation is to establish a clear and reasonably detailed chronology of the incident. Interviews, statements from persons involved in the incident, and a review of the medical records identify what happened and when. The investigation team will need to ensure that this information is integrated and that any disagreements or discrepancies are clearly identified. When a group is working together it is useful to map the chronology on a wall chart, to which Care & Service Delivery Problems and contributory factors can be added once the chronology is complete. There are various ways of doing this.

- **Narrative of chronology** – both interviews and medical records will generate a narrative of events, which allows one to show how events unfolded and the roles and difficulties faced by those involved. A narrative chronology is always necessary in any final report of an incident:

Monday 17th March 2001, 9.15am
Patient A absconded from secure unit. Police informed that Patient A was missing.
Monday 17th March 2011, 10.25am
Patient A had been found by the Police. He was located at home, covered in blood as he had killed his common-law wife.

- **Timeline** – tracks the incident and allows the investigators to discover any parts of the process where problems may have occurred. This approach is particularly useful when a team works together to generate the chronology.

Pre-prepare drugs 12.00noon →	Prepared medications disrupted 12.45pm →	Wrong medication given 1.15pm →	Respiratory Arrest 1.30pm →	Patient dies 1.45pm

- **Time Person Grids** – allows you to track the movements of people before during and after an incident.

	9.02am	9.04am	9.06am	9.08am
SHO	With patient	At Drs station	At Drs station	With patient
Ward Manager	In office	In office	With patient	With patient
Nurse	With patient	With patient	With patient	With patient

- **Flow Charts** – draw a picture of the movement of people, materials, documents or, information within a process. In determining the sequence of events it may be useful to develop separate flow charts that illustrate (a) the sequence of events as documented in the policies and procedures; (b) the sequence of events that occurred during the incident.

SECTION E: Identify Care & Service Delivery Problems

Having identified the sequence of events that led to the incident, the investigation team should now identify the Care & Service Delivery Problems. Some will have emerged from interviews and records but may need to be discussed more widely. It is often useful to organise a meeting with all the people (consultant to porter) involved in the incident to let them tease out the Care & Service Delivery Problems.

Ensure that all Care & Service Delivery Problems are specific actions or omissions on the part of the staff, rather than more general observations on the quality of care. Only explore the Care & Service delivery once you have a full history.

It is easy for example to put down 'poor teamwork' as a Care & Service Delivery Problem which maybe a correct description of the team, but should be recorded as a contributory factor as it was likely that poor teamwork influenced the Care & Service Delivery Problem. Although in practice Care & Service Delivery Problems and contributory factors may engage together, it is best not to explore the contributory factors until the team is sure they have a complete list. A variety of techniques are available to both an individual investigator or team to tease out the Care & Service Delivery Problems, such as brainstorming, brain writing and failure modes and effects analysis.

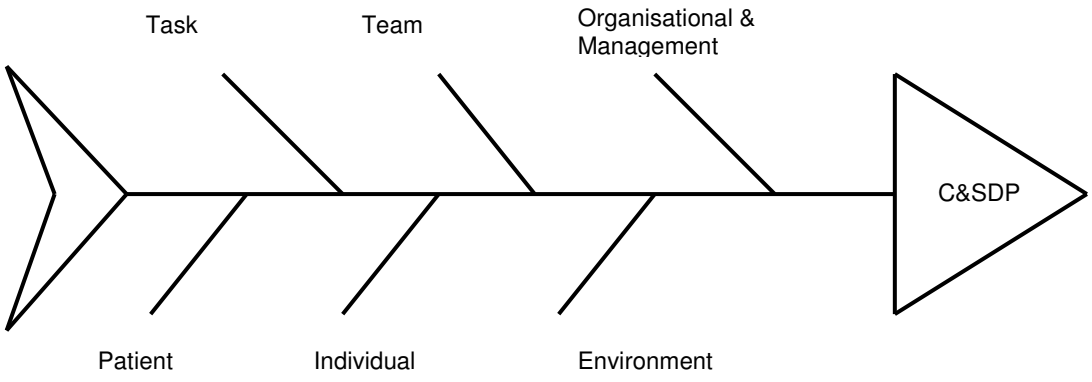
SECTION F: Identify the Contributory Factors

The next step is to specify the conditions associated with each of the Care & Service Delivery Problems. With a large number of Care & Service Delivery Problems, it is best to select a small number of these regarded as most important. Note that each Care & Service Delivery Problems are analysed **one** at a time as each will have their own set of contributory factors.

Each Care & Service Delivery Problem maybe associated with several factors at different levels of the framework

(E.g. poor motivation Individual, lack of supervision Team, inadequate training policy Organisation and Management). The Fishbone diagram as set out in Figure 4 can be used to record the contributory factors associated with a specific Care & Service Delivery Problem. This diagram shows the contribution associated with one Care & Service Delivery Problem.

Figure 4: Fishbone Diagram - Care & Service Delivery Problem



SECTION G: Making Recommendations and Developing an Improvement Plan

Once the Care & Service Delivery Problems and their associated contributory factors have been identified the analysis of the incident is complete. The next step is to generate a set of recommendations/ improvement plans to tackle the system weaknesses that have been revealed.

The implementation plan should include the following information:

- Prioritise the contributory factors in terms of their importance for the safety of future healthcare delivery.
- List the actions to address these contributory factors as determined by the investigation team.
- Identify who is responsible for implementing the actions
- Identify the timeframe for implementation
- Identify any resource requirements
- Evidence of completion. Formal sign-off of actions as they are completed
- Identify the date to evaluate the effectiveness of the Improvement Plan

Many incident investigators focus on very complex, resource intensive solutions or recommendations that are outside their own remit or control. To improve the uptake and implementation of recommendations, they should be categorised as being under the control of the individual/group, local (team), department/directorate or organisation and people from the correct management strata should be tasked with implementing recommendations relevant to their own area. This ensures ownership and appropriate implementation of recommendations, and also promotes a positive safety culture as people see positive actions coming from the accident investigation process.

Appendices 1 and 2 provide templates for investigation and improvement plans for recording to track progress, which maybe useful to ensure implementation has taken place. The organisation can immediately identify where the main emphasis of change management needs to occur. As previously mentioned it is normal to identify more factors that contributed to an incident and the investigation team will need to prioritise the solutions proposed.

Appendix 1
of Investigation Protocol

Please read Incident Investigation Protocol before initiating an investigation
(Available on staff Intranet)

Investigation Template

Summary incident description and outcome		**Datix No:**	
Description of Investigation Team	Time period of investigation:		Reported to
	Start	Finish	

Incident date:	
Incident type:	
Location of incident:	
Actual effect on patient/staff/ please specify:	

Scope and level of investigation
Involvement and support of patient and relatives in response to incident
Detection of incident (who, when & how)
Chronology of incident/events (dates & times of key events/actions, use separate sheet if required.
Care and service delivery problems that led to the incident
Contributory factors, e.g. patient/staff, task/technology, individual/team, environment
Key issues

Lessons learned				
Recommendations				
Improvement plan				
Arrangements for shared learning – where, when & by whom				
Author:	**Date:**	**Was the incident avoidable?**	**Yes**	
			No	
To be signed off by Chief Operating Officer if Significant Adverse Event	**Signed:** **Date:**			

Appendix 2
of Investigation Protocol

Improvement Plan Summary Document – (Datix No)

Contributory Factors	Issues linked to contributing factors	Actions to Address Factors	Level of Recommendation (Individual, Team, Directorate, Organisation)	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off

:

Appendix 6

Table 1 – Incident Management Key Performance Indicators

KPI 1	The Risk Management Team submits incident reports to Healthcare Governance and Risk Management Committees/Groups 4 times per annum for review and action. Compliance Target 100%
KPI 2	Number of all incidents clinical/non-clinical with major harm or death/very high and/or graded as very high or high risk (red and orange), an investigation is **commenced** within 12 working days of being reported, expressed as a percentage of total incidents with major harm or death - Compliance target 100%
KPI 3	Number of all incidents clinical/non-clinical with major harm or death and/or graded as very high or high risk (red/ orange), have been fully closed within 60 working days of being reported and recorded on Datix - Compliance Target 100%
KPI 4	The number of incidents in which severity is moderate and/or graded as medium or low risk with a risk grading of moderate (yellow) a local investigation has been commenced within 12 working days of being reported, expressed as a percentage of total incidents with major harm or death – Compliance target 100%
KPI 5	The number of incidents in which severity is moderate and/or graded as medium or low risk with a risk grading of moderate (yellow) fully closed within 28 working days of being reported, expressed as a percentage of total of incidents reported as moderate - Compliance target 100%
KPI 6	Number of incidents graded as no harm or minor injury and/or is graded as low risk (green) approved within 10 working days of being reported, expressed as a percentage of total of incidents reported as low - Compliance 100%
KPI 7	The number of incidents graded as no harm or minor injury and/or is graded as low risk (green) fully closed within 20 days of being reported, expressed as a percentage of total of incidents reported as low - Compliance target 100%

: