Golden Jubilee Foundation

Adverse Event Management Policy

Name	**Adverse Event Management Policy**
Summary	Guidance on the reporting and management of adverse events
Associated Documents	Adverse Event Toolkit
Target Audience	All staff
Version number	2.2
Date of this version	April 2018
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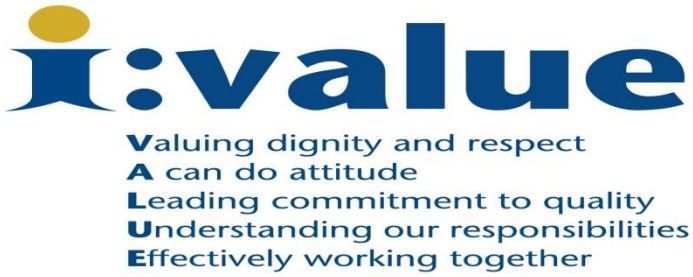
Approving committee/group	Clinical Governance Committee
Document Lead	Laura Langan Riach, Head of Clinical Governance
Document Author (if different)	

Golden Jubilee Foundation Values Statement

What we do or deliver in our roles within the Golden Jubilee Foundation is important, but the way we behave is equally important to our patients, customers, visitors and colleagues. We know this from feedback we get from patients and customers, for example in “thank you” letters and the complaints we receive.

Recognising this, the Golden Jubilee Foundation have worked with a range of staff, patient representatives and managers to discuss and promote our shared values which help us all to deliver the highest quality of care and service across the organisation. These values are closely linked to our responsibilities around Equality.



Our values are that we will:

- Take responsibility for doing our own job well
- Treat everyone we meet in the course of our work with dignity and respect
- Demonstrate through our actions our commitment to quality
- Communicate effectively, working with others as part of a team
- Display a “can do” attitude at every opportunity.

Our policies are intended to support the delivery of these values which support employee experience

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Background

"The best way to reduce harm ... is to embrace wholeheartedly a culture of learning."

A promise to learn – a commitment to act, The National Advisory Group on the Safety of Patients in England, chaired by Don Berwick, August 2013

Golden Jubilee Foundation (GJF) aims to provide high quality care which is safe, effective and person centred. Healthcare is complex and high risk and it is inevitable that on occasion things will go wrong and adverse events will occur which may or may not cause harm. We are committed to continually reviewing our systems and processes to prevent or reduce the risk of harm. We recognise the learning potential within adverse events and support a culture and system that enables reporting and management of them to inform improvement and safer care and quality services.

GJF has a statutory duty, under Health & Safety at Work Act 1974 to protect employees and non employees (e.g. patient, visitors etc) from risks to their health and/ or safety that arise out of, or in connection with, the activities of our work.

In 2013 Healthcare Improvement Scotland (HIS) issued a National Framework for NHSScotland titled Learning from adverse events through reporting and review, an updated version of was published in 2015. In addition the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 received Royal Assent on 6 April 2016 and introduced a new organisational duty of candour on health, care and social work services. The implementation date for the duty of candour provisions to come into effect is 1 April 2018. The overall purpose of the new duty is to ensure that orginisations are open, honest and supportive when there is an unexpected or unintended incident resulting in death or harm, as defined by the act. **(Appendix 8)**

Scope

This policy applies to all areas of service within the GJF, and includes staff, patients, visitors, contractors and all others interacting with GJF regardless of age, disability, gender, race/ethnicity, religion/belief or sexual orientation, in alignment with the GJF's Embracing Equality, Diversity and Human Rights policy.

The policy applies to all adverse events and near misses, including significant adverse events.

Operational management of infection control outbreaks will be in line with specific Infection Control policy and guidance; these will still be logged as events via the reporting system.

Operational aspects of adverse event management such as the conduct of debriefings are not considered in detail here. Whenever an adverse event has occurred consideration must be given to mitigating any immediate safety concerns. For serious adverse events consideration should also be given to supporting staff members involved as potential "second victims". **(Appendix 6).**

Key definitions and requirements are outlined in this policy with detail in the appendices and supporting guidance.

Policy Aim and Purpose

This policy and supporting guidance aims to provide a framework to support the identification; reporting and management of adverse events and in doing so create practices which value openness, continuous learning and improvement.

Specifically this includes ensuring:

- Staff awareness of adverse event reporting, i.e. what and how to report
- An electronic incident management system to facilitate reporting of adverse events
- All staff have access to report incidents including those who cannot access the electronic system
- That immediate corrective action is taken in response to an event
- That events are appropriately reported and escalated within the organisation
- That a high standard of investigation is consistently carried out for all significant adverse events including appropriate staff and patient/ carer/ family involvement
- That all feasible improvements are appropriately implemented with a system to monitor progress
- That learning from events is shared locally within GJF and nationally as appropriate to support wider learning and improvement
- That requirements of the HIS National Framework are met
- That legal requirements in line with the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013 to the Health & Safety Executive and Duty of Candour are met
- Reporting of events in line with other statutory requirements e.g. MHRA, Procurator Fiscal, please see appendix 2 for more examples
- Robust governance to support implementation and monitoring of this policy

Basic Principles

To support the policies aim and purpose, the GJF will promote and embed a positive safety culture in all organisational activity and uphold the following principles:

- Be open and transparent in relation to the identification, reporting and managing of adverse events, including with patients, families, relatives and carers in line with the principles of the NPSA Being Open guidance and Duty of Candour.
- Be consistent in the response when adverse events occur.
- Investigations are about establishing causality not about apportioning blame
- Staff members involved in events should have the opportunity to contribute to an investigation but should not be directly involved in the investigation team/ panel
- Investigation teams may be part of the same service in which the event occurred. For some investigations it may be more appropriate to have an investigation team from out with the service.
- Significant Adverse Events investigations are appropriately supported by robust processes.
- Seek to identify areas of good practice as part of the investigation process.

Definition of Key Terms

Adverse Event
An adverse event is defined as any event (act or omission) that could have, or did, lead to unintended or unexpected harm, loss or damage to patients, staff, visitors, premises, property other assets and/ or may adversely affect the organisation.

Harm is an outcome with a negative impact which may affect an individual, groups or people or the organisation. It can include worsening of a medical condition, inherent risk of further investigation/ treatment, system failure, service disruption, financial loss or unfavourable publicity.

Not all harm is avoidable and at times investigation is required to determine this and any learning. See appendix 1 for examples of types of events.

Near Miss
A Near Miss is described as event that could have resulted in harm but did not, either due to chance or intervention.

RIDDOR Events
The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013 require certain categories of such events to be reported to the Health & Safety Executive. This includes any injury at work which results in an employee being unable to do their normal work for more than 7 days. Health & Safety should be notified of any events, see appendix 2 for full details.

Severity
The severity of events considers the event impact, and is graded in line with the Healthcare Improvement Scotland (HIS) definitions **(Appendix 3)** with five levels:

- *Severity 1 Events*: Those with no harm or minor levels of harm where no further action is required
- *Severity 2 Events*: Those with events with minor harm requiring intervention at local level
- *Severity 3 Events*: Those with moderate harm e.g. reportable to external agency, short term effect on patient condition/ outcome, significant injury requiring medical treatment
- *Severity 4 Events*: Those with major harm associated including long term incapacity or disability, or a sustained loss of service
- *Severity 5 events*: Those with catastrophic harm such as death or major permanent harm to an individual, severe financial loss, major adverse publicity

Never Event
Never Events are serious, largely avoidable patient safety incidents that should not occur if the available preventative measures have been implemented by the organisation. Some events are always classified as Never Events due to the potentially high risk of significant harm, even though the event may not necessarily have led to any harm, however, some events are only classified as Never Events if the actual outcome is death or severe harm.

Significant Adverse Event (SAE)
Significant Adverse Events (SAEs) are events or circumstances that could, or did, have significant or catastrophic impact on patients, staff, visitors and may negatively affect the organisation and have potential for wider learning (i.e. learning that can inform future service delivery).

SAEs will generally be associated with a high severity rating though this is not always the case. Some near misses and some lower impact events, particularly those associated with significant potential for learning (and consequent system change) can be considered as an SAE. In some cases the complexity of an event requires a full level 1 review in order to gain a deep understanding of what has occurred and why. An event being declared an SAE should thus be driven by a need to investigate thoroughly as much as by the actual event impact.

All events graded with a severity of 4 or 5 are considered SAE and must have an SAE review tool completed within 2 weeks to inform the level of investigation required. SAE events can be reviewed at Level 1 with a full Root Cause Analysis or at Level 2. The SAE tool must clearly record the rationale for the level of review agreed.

Regardless of severity, the following events should also be considered a potential SAE and a review tool completed:

- Any unexpected patient deaths (i.e. death was not reasonably considered in the preceding 24 hours, including death within 24 hours of discharge)
- Any patient deaths post transplant
- Any wrong procedures (i.e. wrong patient or wrong site)
- Any retained swab or surgical item
- Re-use of a non-sterile instrument
- Wrong patient blood transfusion
- Any falls resulting in a major fracture or head injury requiring intervention
- Significant near misses
- Any H&S events with major injuries
- Any significant medication errors
- Readmission within 24 hours of discharge
- Any events that trigger Duty of Candour

Duty of Candour Event
By law a Duty of Candour event is defined as any unintended or unexpected adverse event that has resulted in, or could result in:

- death of the person
- a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions
- an increase in the person's treatment
- changes to the structure of the person's body
- the shortening of the life expectancy of the person
- an impairment of the sensory, motor or intellectual functions of the person which has lasted, or is likely to last, for a continuous period of at least 28 days
- the person experiencing pain or psychological harm which has been, or is likely to be, experienced by the person for a continuous period of at least 28 days

- the person requiring treatment by a registered health professional in order to prevent:
    - the death of the person, or
    - any injury to the person which, if left untreated, would lead to one or more of the outcomes mentioned above.

The Duty of Candour legislation places a legal requirement on organisations to inform patients if they are involved in an event and involve them in the investigation. It is important to stress that Being Open principles apply to all types of events; the Duty of Candour legislation formalises that process for those that meet the criteria.

In majority of cases these will be obvious significant adverse events; if in any doubt please contact Clinical Governance for advice. All Duty of Candour events will be managed via the SAE process if not already.

Reporting and Review of Events

All events should be reported using the Datix DIF1 form and will be reviewed by the line manager (or nominated deputy) of the area in which the event occurred. Line managers should consider sources of further expertise and support where there is any difficulty or uncertainty **(Appendix 1)**

The purpose of this review is to consider the impact of the event and to assign an impact rating using knowledge of what has occurred and understanding of local systems. The impact rating is then used, in conjunction with a specific consideration of whether the event should be treated as a SAE, to determine the level of investigation. See Table below. A triage tool for SAEs is given in appendix 5.

A second designated manager is then responsible for confirming that the event has been appropriately classified and is being correctly managed. The second reviewer is also responsible for ensuring that the Datix record is fully completed and updated, including that the incident is closed when the review is completed and any learning recorded and reported.

For events escalated as SAE, a second reviewer should confirm the SAE status and attach the completed review tool but should not close the event.

An overview of the process is shown in Appendix 4.

Level of Investigation	Review Process	Reporting of findings and learning	Guidance Timescale
Level 1	RCA Investigation	CGRMG, development and implementation of improvement plan to sit with Division/ Function where event occurred.	Reviews commence within 2 weeks and complete within 3 months.

Level 2	Division Management Review	Via Divisional forums with evidence of improvement plans as required.	Reviews commence within 2 weeks and complete within 6 weeks.
Level 3	Local review	Via aggregate incident reports	Event approved and closed within 2 weeks of report.

Significant Adverse Event Review (Level 1)
When an SAE occurs/ is identified it should be immediately reported to the Senior Manager for the department/ service who will communicate to Executives and support the response.

All SAEs will be considered for a Level 1 investigation using the SAE Review tool; the process is outlined in appendix 4.

Specific tools are provided to support the review of the following events:

- Any deaths associated with severe Clostridium Difficile Infection (CDI) or Staph Aureus Bacteraemias (SAB)
- Grade 3 and 4 Pressure Ulcers which develop during their stay
- Falls with harm

If an SAE does not progress to Level 1 investigation the rationale and decision making should be clearly recorded. The event should then be subject to a Level 2 investigation and the appropriate template completed and uploaded to Datix in line with timescales.

For all SAE events the patient/ family must be advised a review will take place and the remit of this to allow them opportunity to raise any concerns. A point and frequency of contact must be agreed at the outset for all Level 1reviews regardless of Duty of Candour status.

Local Management Review (Level 2)
The Division management and Clinical Governance Leads should agree a plan to investigate these events within 6 weeks seeking input and support from CG and internal advisors as required. The Division Management Team will sign off the investigation and the findings recorded on the Datix system to evidence the lessons learned and any improvements generated. The final outputs will be reported and discussed at the next available Clinical Governance Forum.

Divisional/ Functional Forums will monitor these events to ensure reviews are completed and will review learning to consider any shared learning and wider action.

Local Review
These events should be managed locally with details of local action taken recorded on Datix, the event will be closed by the manager who has agreed approval responsibility on Datix. These events will be reported to Divisional/ Functional forums on aggregate basis to support trend identification.

Some clinical areas are developing a model of continuous clinical governance for minor adverse events and learning opportunities. Where appropriate links are made to Datix but the process currently sits aside this formal policy process.

Duty of Candour Events
These will be managed as Level 1 SAE and following the SAE process will ensure requirements are met. The Clinical Governance department will ensure the Duty of Candour procedure is appropriately triggered and support maintenance of Datix to meet reporting requirements.

Organisational Roles and Responsibilities

The **Medical Director** is the named Executive lead for this policy supported by the **Head of Clinical Governance**.

All Staff have a responsibility to:
- Take care of their own safety and that of others,
- Report adverse events to their line manager,
- Complete a Datix form for any adverse events,
- Support investigation of such events in line with the policy and procedures,
- Raise any concerns with a senior member of staff,
- Support implementation of improvement actions following investigation.
- Notify the person affected by the event and provide an apology

Managers have a responsibility to:
- Ensure as a priority immediate action is taken to safe guard the situation and ensure any persons affected receive appropriate treatment/ support.
- Equipment involved must be made safe, removed from use and retained for inspection. Ensure that reporting procedures are complied with and events escalated appropriately Support debrief of staff involved in events, ensuring staff involved in events have appropriate support.
- Identify and escalate RIDDOR events to Health & Safety as soon as possible to meet the regulatory reporting requirement to the HSE.
- Undertake reviews of adverse events and near misses, liaising with others as appropriate, recording on the electronic system.
- Monitor trends within their area of responsibility.
- Contribute to dissemination of lessons learned and implantation of improvement actions.

Heads of Operations/ Functions have a responsibility to:
- Ensure implementation and management of the Policy within their service areas, supported by the senior leads and the Clinical Governance team.
- Ensure the delivery of, and compliance with the policy, for example, actively promoting attendance and allowing staff time to attend training courses, ensuring localised systems are in place to investigate adverse events, generate and deliver on recommendations and action plans and share learning outcomes.

Associate Medical Directors/ Divisional Nurse Leads/ AHP Lead/ Healthcare Scientist Lead - have a responsibility to:

- Work with, and support, Operational Managers in the implementation of the policy within their Divisions
- Provide leadership and support to Clinical Governance Leads, Nurse Managers, AHPs and HSC in their implementation and responsibilities
- Support investigation of SAE as required

Clinical Governance (CG) Leads

Each speciality has an appointed medical CG Lead with a responsibility and dedicated time to support Clinical Governance activity. This will include support to SAE investigations as directed by the Senior Management Team and support to implementation of improvement actions and dissemination of learning amongst medical colleagues.

Specialist Advisors
(e.g. Clinical Governance, H&S, Medical Physics, Information Governance, Pharmacy, Infection Control)

- Provide general advice, guidance and support to managers and employees
- Advise on any mandatory/ regulatory reporting requirements relevant to the event and support completion as required
- Assist in adverse event investigation, providing expert advice to SAE as necessary
- Support analysis of adverse events and recommendations to reduce risk

If the event is an SAE, contact **Clinical Governance** for advice and support.

To support **RIDDOR** reporting contact **Health & Safety.** The Health and Safety Advisor must notify the enforcing authority without delay of:

- accidents resulting in the death of any person
- accidents resulting in specified injuries to workers
- non-fatal accidents requiring hospital treatment to non-workers and
- dangerous occurrences

For accidents resulting in the over-seven-day incapacitation of a worker, the Health and Safety Advisor must notify the enforcing authority within 15 days of the incident, using the appropriate online form. Cases of occupational disease, including those associated with exposure to carcinogens, mutagens or biological agents must be reported as soon as the responsible person receives a diagnosis.

To support reporting in line with **IRMER** of events involving unintended exposure or overexposure of patients to radiation the ***Radiation Protection Supervisor*** will ensure events are managed in line with GJF Radiation policy and properly investigated and recorded.

Events involving **medical equipment** must be reported to **Medical Physics** immediately to ensure prompt investigation. All external reporting must be channeled via the Equipment Co-ordinator (Head of Medical Physics).

Key Groups and Committees

The **Clinical Governance Committee (CGC)** and **Person Centred Committee (PCC)** have a responsibility to:

- Ensure development of a fair, open culture that embraces reporting and learning from adverse events
- Receive regular reports on trends and outcomes of adverse events and near misses from Clinical Governance and Health & Safety
- Receive regular reports on significant adverse events
- Monitor that appropriate action and learning has taken place from events

The **Clinical Governance and Risk Management Group (CGRMG)** reports to the CGC and in supporting the CGC has specific responsibility to:

- Be assured of policy implementation within Divisions
- Receive regular reports from Divisions on trends and outcomes of adverse events and near misses
- Receive regular reports from Clinical Governance and Health & Safety of Board wide incidents to support identification and discussion of cross divisional trends and actions
- Review reports from all Significant Adverse Event (SAEs) and approve improvement action plans considering any cross Divisional issues
- Monitor progress against action plans arising from SAEs and cross divisional trends

The **Divisional Clinical Governance Groups** are responsible for working with the Divisional Management Teams to:

- Support implementation of the policy
- Monitor incident numbers and trends, act on these as appropriate, and report to the CGRMG
- Review recommendations from final investigation reports and develop improvement plans for approval by the CGRMG
- Ensure implementation of agreed actions and, where relevant, monitor subsequent outcomes.

Specialist Groups & Committees (e.g. Health & Safety, Infusion Devices, Drug & Therapeutics, and Transfusion) have responsibility to review incident trends and outcomes specific to their remit and report to the CGRMG as required.

Training and Education

Clinical Governance will provide training to staff across the organisation to support the implementation of the policy as required, specifically to ensure:

- All new staff will be made aware of the reporting process via Corporate Induction
- Datix training for those responsible for review and approval of events
- Investigation training for staff in root cause analysis to support SAE investigation
- Information and awareness of Duty of Candour legislation
- Links to Learning & Development to support clinical staff in communicating with patients/ relatives if involved in an event

Ongoing Analysis and Reporting of Events

Clinical Governance will support development of a reporting framework to support reporting at relevant committees and also feedback to departments to support dissemination of learning; this may include newsletters/ urgent communications in addition to formal reports.

Monitoring Implementation

Committees have a role in supporting implementation and monitoring of actions as outlined; to support this, the Clinical Governance department will:

- Maintain the central system that records all adverse events and associated key documents
- Provide regular reports on performance to provide assurance of policy and procedure implementation

Glossary

- **AHP – Allied Health Professionals**
  This includes diagnostic medical sonographers, dietitians, medical technologists, occupational therapists, physical therapists, radiographers, respiratory therapists, and speech language pathologists.
- **Clostridium Difficile Infection (CDI)**
  A Clostridium difficile infection is a type of bacterial infection that can affect the digestive
  system.
- **Datix**
  The risk management software that is used to support electronic reporting. This is a database in which all adverse events are reported and reviewed.
- **Healthcare Improvement Scotland (HIS)**
  The national healthcare improvement organisation for Scotland and part of NHSScotland;
  published the National Framework 'Learning from Adverse Events'.
- **HFS – Health Facilities Scotland**
  Provides procurement and technical services primarily to the NHS in **Scotland**
- **IRMER** – Ionising Radiation (Medical Exposure) Regulations 2000
  These Regulations implement basic measures for the health protection of individuals against dangers of ionising radiation in relation to medical exposure"
- **MHRA – Medicines and Healthcare products Regulatory Agency**
  The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. MHRA is an executive agency, sponsored by the Department of Health.
- **NPSA – National Patient Safety Agency**
  Based in NHS England the NPSA lead and contribute to improved, safe patient care by informing**,** supporting and influencing organisations and people working in the health sector. The issue guidance on areas of patient safety and also alerts on risk issues; although not mandatory in NHS Scotland this is considered best practice.
- **RIDDOR** – Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 These Regulations require employers, the self-employed and those in control of premises to report specified workplace incidents.
- **Staph Aureus Bacteraemias (SAB)**
  SAB has long been recognised as one of the most important bacteria that cause disease in humans. It is the leading cause of skin and soft tissue infections such as abscesses (boils), furuncles, and cellulitis. Although most staph infections are not serious, it can cause serious infections such as bloodstream infections, pneumonia, or bone and joint infections.

Appendix 1 – Specific Categories of Events
Sources of Advice

Types of Events

Health & Safety events, for example accidents where injuries are sustained from an event, these may affect anyone on the campus e,g. slip, trip or fall. Some events may be specific to certain areas/ types of people e.g. sharps injuries to clinical staff.

Any instances of violence/ abuse against any person should be reported.

Security events are those where a breach or lapse of security is the dominating factor e.g. theft, vandalism, data security e.g. missing case record, theft of a PC.

Clinical/ Patient Safety events are those events which cause harm to patients; this may include medication errors, treatment delays, treatment errors, events involving medical device malfunction/ misuse.

Unintended over exposure to radiology is a reportable event under the Ionising Radiation (Medical Exposure) Regulations 2000 and must be reported on Datix and to the Radiation Protection Supervisor, separate guidance exists to support this.

Incidents involving medical equipment must be reported to Medical Physics immediately to ensure prompt investigation. Where possible, all material evidence relating to adverse events must be preserved, labelled and kept secure. This includes the medical device, consumables, packaging and any other means of batch identification. Equipment involved in serious events must not be tampered with and if necessary will be quarantined by Medical Physics. Events requiring external reporting to HFS or MHRA will be managed in line with the Hazards and Safety Action Notice Policy. All external reporting must be channelled via the Equipment Co-ordinator (Head of Medical Physics).

Internal Advisors

The following people may be contacted for advice when reviewing incidents and investigation support:

Clinical Governance
Health & Safety
Medical Physics
Pharmacy
Infection Control
Information Governance
Radiation Protection Supervisor

Appendix 2 – RIDDOR Reporting

What is RIDDOR?
RIDDOR is the law that requires employers, and other people in control of work premises, to report and keep records of:

- work-related accidents which cause death;
- work-related accidents which cause certain serious injuries (reportable injuries);
- diagnosed cases of certain industrial diseases; and
- certain 'dangerous occurrences' (incidents with the potential to cause harm).

Why report?
Reporting certain incidents is a legal requirement.

The **report** informs the enforcing authorities (HSE, local authorities and the Office for Rail Regulation (ORR)) about deaths, injuries, occupational diseases and dangerous occurrences, so they can identify where and how risks arise, and whether they need to be investigated. This allows the enforcing authorities to target their work and provide advice about how to avoid work-related deaths, injuries, ill health and accidental loss.

What must be reported?

Work-related accidents
For the purposes of RIDDOR, an accident is a separate, identifiable, unintended incident that causes physical injury. This specifically includes acts of non-consensual violence to people at work.
Not all accidents need to be reported, a RIDDOR report is required only when:
the accident is **work-related**; and it results in an injury of a type which is **reportable** (as listed under 'Types of reportable injuries'). When deciding if the accident that led to the death or injury is work-related, the key issues to consider are whether the accident was related to:

- the way the work was organised, carried out or supervised;
- any machinery, plant, substances or equipment used for work; and
- the condition of the site or premises where the accident happened.

If none of these factors are relevant to the incident, it is likely that a report will not be required.

Types of reportable injury

Deaths
All deaths to workers and non-workers must be reported if they arise from a work-related accident, including an act of physical violence to a worker. Suicides are not reportable, as the death does not result from a work-related accident.

Specified injuries to workers
The list of 'specified injuries' in RIDDOR 2013 (regulation 4) includes:

- a fracture, other than to fingers, thumbs and toes;
- amputation of an arm, hand, finger, thumb, leg, foot or toe;

- permanent loss of sight or reduction of sight;
- crush injuries leading to internal organ damage;
- serious burns (covering more than 10% of the body, or damaging the eyes, respiratory system or other vital organs);
- scalpings (separation of skin from the head) which require hospital treatment;
- unconsciousness caused by head injury or asphyxia;
- any other injury arising from working in an enclosed space, which leads to hypothermia, heat-induced illness or requires resuscitation or admittance to hospital for more than 24 hours.

Over-seven-day injuries to workers
This is where an **employee, or self-employed person, is away from work or unable to perform their normal work duties for more than seven consecutive days** (not counting the day of the accident).

Injuries to non-workers
Work-related accidents involving members of the public or people who are not at work must be reported if a person is injured, and is taken from the scene of the accident to hospital for treatment to that injury. There is no requirement to establish what hospital treatment was actually provided, and no need to report incidents where people are taken to hospital purely as a precaution when no injury is apparent.
If the accident occurred at a hospital, the report only needs to be made if the injury is a 'specified injury' (see above).

Reportable occupational diseases
Employers and self-employed people must report diagnoses of certain occupational diseases, where these are likely to have been caused or made worse by their work. These diseases include (regulations 8 and 9):
carpal tunnel syndrome;
severe cramp of the hand or forearm
occupational dermatitis
hand-arm vibration syndrome;
occupational asthma;
tendonitis or tenosynovitis of the hand or forearm;
any occupational cancer;
any disease attributed to an occupational exposure to a biological agent.

Reportable dangerous occurrences
Dangerous occurrences certain, specified 'near-miss' events (incidents with the potential to cause harm.) Not all such events require reporting. There are 27 categories of dangerous occurrences that are relevant to most workplaces. For example:
the collapse, overturning or failure of load-bearing parts of lifts and lifting equipment;
plant or equipment coming into contact with overhead power lines;
explosions or fires causing work to be stopped for more than 24 hours

Any incident falling within the above must be reported immediately to allow Health and Safety to report these incidents to the Health and Safety Executive Incident Contact Centre. A copy of the RIDDOR report should be attached to Datix

Appendix 3 — Severity Grading Tool

Consequence/Impact Definitions

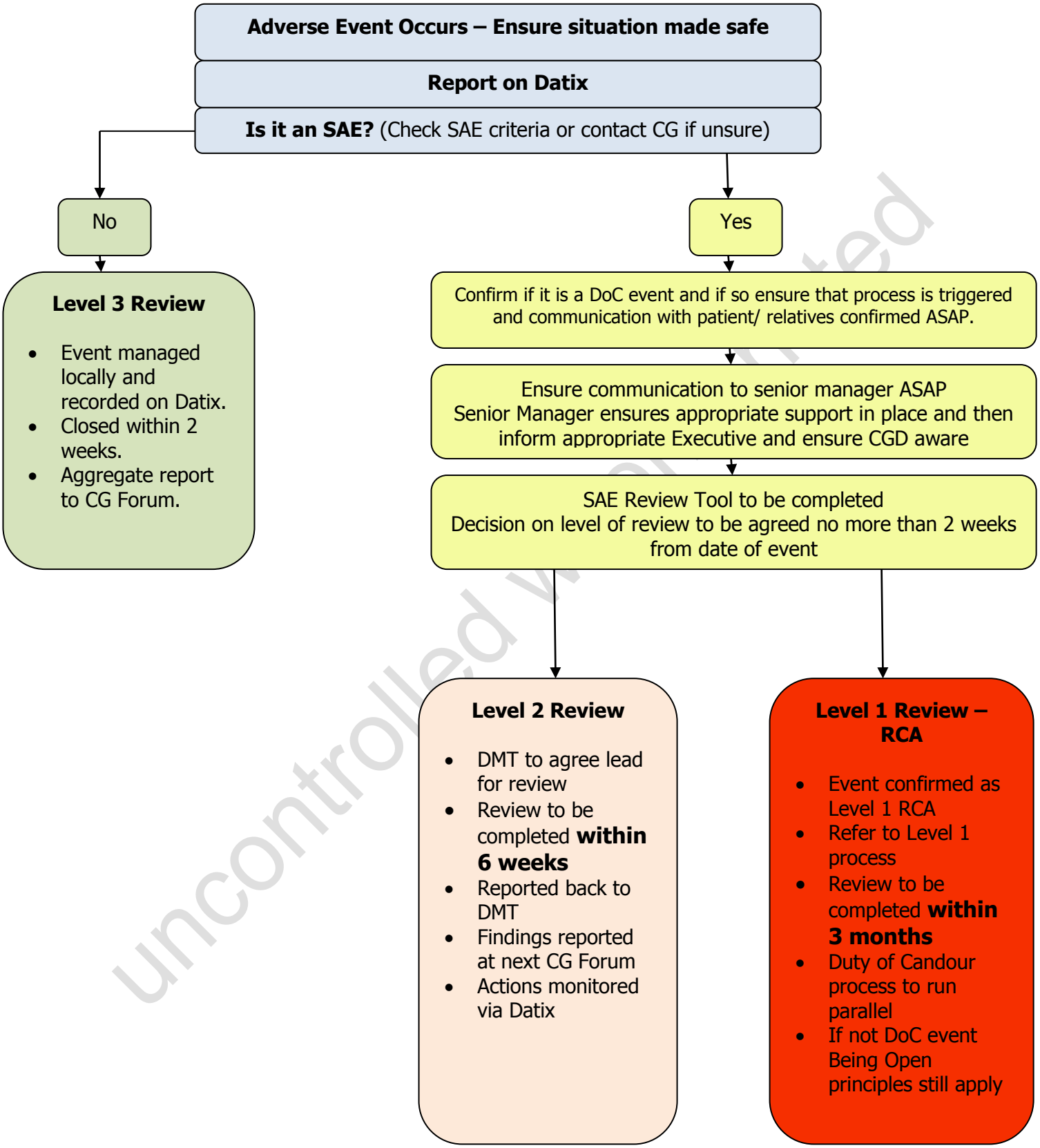
Descriptor	Negligible	Minor	Moderate	Major	Extreme
Patient//Guest Experience	-Reduced quality patient/guest experience/clinical outcome not directly related to delivery of clinical care	-Unsatisfactory patient/guest/ experience/clinical outcome directly related to care provision – readily resolvable	- Unsatisfactory patient/guest experience/ clinical outcome, short term effects – expect recovery less than 1wk -Increased level of care/stay less than 7 days	-Unsatisfactory patient/guest experience /clinical outcome, long term effects - expect recovery over more than 1week - Increased level of care/stay more than 7 -15 days	-Unsatisfactory patient/guest experience/clin i cal outcome, continued ongoing long term effects
Objectives/ Project	-Barely noticeable reduction in scope/quality/schedule	- Minor reduction in scope/quality/ schedule	- Reduction in scope/quality/project objectives or schedule	-Significant project over-run	-Inability to meet project/corporat e objectives, reputation of the organisation seriously damaged
Injury /illness (physical and psychological) to patient/guest/visitor / Staff	-Adverse event leading to minor injury not requiring first aid -No staff absence	- Minor injury or illness, first aid treatment required - Up to 7 days staff absence	- Agency reportable, e.g. Police (violent and aggressive acts) -Significant injury requiring medical treatment and/or counselling -RIDDOR over 7-day absence due to injury	-Major injuries/long term incapacity /disability (e.g. loss of limb), requiring, medical treatment and/or counselling -RIDDOR over 7-day absence due to major injury/dangerous occurrences	-Incident leading to death(s) 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/guest care or the ability to continue to provide service	- Short term disruption to service with minor impact on patient/guest care/service provision	- Some disruption in service with unacceptable impact on patient /guest care -Temporary loss of ability to provide service - Resources stretched - Potentially impaired operating capability -Pressure on service provision	-Sustained loss of service which has serious impact on delivery of patient/guest care resulting in major contingency plans being invoked -Potentially impaired operating capability -Temp service closure	- Permanent loss of core service/ facility - Disruption to facility leading to significant "knock on" effect -- Inability to function
Descriptor	**Negligible**	**Minor**	**Moderate**	**Major**	**Extreme**

Staffing and Competence	- Short term low staffing level temporarily reduces service quality (less than 1 day) - Short term low staffing level (>1 day), where there is no disruption to patient/guest care	- Ongoing low staffing level reduces service quality - Minor error due to lack of/ ineffective training/ implementation of training	- Late delivery of key objective/service /care due to lack of staff - Moderate error due to lack of/ ineffective training/implementation of training - Ongoing problems with staffing levels	- Uncertain delivery of key objective/service/care due to lack of staff - Major error due to lack of/ ineffective training/implementation of training	- Non-delivery of key objective/ service/care due to lack of staff. - Loss of key staff -Critical error due to lack of/ ineffective training/ implementatio
Financial (including Damage/Loss/Theft/ Fraud	- Negligible organisational/ personal financial loss up to £100k Hotel up to £1k	- Minor organisational/ personal financial loss of £100k - £250K Hotel £1k - £5k	- Significant organisational/personal financial loss of £250k - £500k Hotel £5k - £10k	- Major organisational/personal financial loss of £500k - £1m - Hotel £10k - £50k	-Severe organisational financial loss of more than £1m Hotel greater than £50k
Inspection/ Audit	- 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 - Improvement Notice	-Enforcement/prohibition 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/public perception of the organisation Local MSP/SEHD interest	- 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/SEHD concern (Questions in Parliament) - Court Enforcement/FAI

Appendix 4 – Process Overview



Appendix 5 – Significant Adverse Event Process Guidance

To support this process each Division/ Function should agree who within the service will support the roles of:

- Local/ Divisional Management Team – senior managers (i.e. Heads of Operations, Associate Medical Director, Clinical Nurse Manager, AHP lead) that will consider escalated events and agree SAE status and investigation team
- Local/ Divisional Management Leads – Clinical/ Service leads that can support the initial review of events using the review tool, to advise on need for SAE investigation including Clinical Governance Leads

Key steps:

1. If an SAE, or likely SAE, occurs then it should be communicated to the senior manager for the service/ department immediately. The department/ service senior manager will ensure that the Duty Manager for the day is alerted to the event and consider wider communication as appropriate.
2. A DIF1 should be completed as soon as possible.
3. The Divisional/ Function leads should review the Datix within 72 hours and complete the SAE review tool and submit to the Divisional/ Functional manager.
4. Review confirms Level 1 review is required – this will trigger an e-mail alert to agreed list to confirm Level 1review is taking place
5. Level 1 Investigation takes place using Root Cause Analysis methodology.
    a. Divisional/ Functional Management team agree core investigation team and remit. Core team consists of no more than 5 individuals relevant to the incident. CG department will generate a timeline base d on information available.
    b. Core Team meets within 1 week. Review timeline, agree areas of focus, and identify information required e.g. statements, identify any interviews (more may be required after statements reviewed). Set provisional panel date, and in consultation with Divisional / Functional management teams agree any additional members required to support a panel review.
    c. Evidence gathering and further core team meetings as required. Full panel meeting within 6 weeks of event being declared an SAE.
    d. Follow on actions and further panel meeting(s) if required (a second panel meeting would be unusual)
6. Draft report available for chair within 5 working days of final panel meeting
7. Draft report shared with all members of the panel for a factual accuracy check and final comments within 10 working days. Any staff involved whose written statements or interviews have influenced the findings/ report should also have the opportunity at this stage to check the report for factual accuracy only. All comments must be returned within 2 weeks of draft being issued. The panel Chair will be the final arbiter.
8. Preparation of a final draft for submission to the Divisional / Functional Management Team within five working days of comment deadline.
9. Final draft presented to CGRMG; where required an Extra-Ordinary meeting will be called to support timely sign off. Any revisions to report from review must be discussed ad agreed with the panel, the panel Chair will be the final arbiter.
10. The final report stored on Datix and shared with staff via local managers.
11. Report discussed at next Divisional/ Functional forum to agree improvement plan which is then shared with CGRMG.
12. Actions monitored via Divisional CG Forum and CGRMG.

Notes

Involvement of Patients and Family

Patients, patients' family members and patients' representatives should be involved as closely as possible with all stages of the process. They should be informed that the event is being investigated as an SAE and kept abreast of progress. Where appropriate their specific input should be sought e.g. in helping determine areas of focus for the investigation or particular questions to be answered. They should be offered a copy of the final report in the context of appropriate support and follow up. See the separate guidance on Communicating with Patients/ Families.

Staff Participation and Rules of Evidence

An investigation into an SAE is not a disciplinary investigation or an investigation into the conduct of any one individual. It is a systems analysis of an event with a view to learning lessons for improving safety and quality of care. The Golden Jubilee Foundation aims to foster an open and fair culture and all staff are required to engage with the processes of adverse event analysis. Staff will not be blamed for systems failures or their consequences. With certain qualifications, as described below, information is given in confidence and in good faith to the panel. If they wish, interviewees should be allowed to be accompanied by a person of their choosing. Interviewees should be given the opportunity to check transcripts and accounts of their own evidence for factual accuracy. Those interviewed and / or submitting statements do not have a right to access material provided by others involved in the investigation.

Links with disciplinary and other procedures including Professional regulatory processes

If it becomes apparent at any point in an adverse event investigation, as a result of evidence gathered through the investigation, that it is appropriate to commence a disciplinary investigation into the conduct of an individual, or make a referral to a professional body such as the GMC or NMC, this will be set in motion as a separate procedure. This may run subsequent to or in parallel with the adverse event analysis. This might occur if there is clear evidence of, for example, professional misconduct, criminality, maliciousness or clear deviation from expected standards of care. If there are parallel processes then the chairs of both should discuss and ensure clarity on remit and that all relevant information is shared.

Confidentiality

Individuals will not be named in public reports resulting directly from the incident investigation process. Nevertheless individuals should be aware that they may be identified from the unique circumstances of the incident. Additionally staff should be fully aware that investigation of adverse events may link with other investigative proceedings, for example, Procurator Fiscal reviews, and Fatal Accident Inquiries (FAIs). Information gathered as part of the investigation process may be shared with such external investigations, and this is inclusive of witness statements and interview transcripts. When an internal disciplinary enquiry or referral to a professional regulatory body commences as a result of findings that come to light in an adverse event investigation, evidence leading to the decision, including witness statements and interview transcripts may be shared with the relevant body or investigatory team. The individual in these cases will have the usual rights of access and challenge to the evidence under the new procedures.

SAE Process Overview (April 18)

Stage	Action	Templates/ Guidance
Escalation Immediate	• Local manager alert senior manager and duty manager for the day • Ensure all notified who need to be aware including patient/ relative • Ensure incident reported on Datix and SAE trigger selected to trigger alert • Ensure local debrief taken place and staff support offered	Datix Switchboard for Duty Manager Staff Support guidance
Commissioning Within 2 weeks of escalation	• Review tool to be undertaken by Divisional/ Functional Lead(s) with input from others as required and submitted to the Divisional/ Functional Management team for review. Initial review to be undertaken within 5 days. • Divisional/ Functional Management team to confirm SAE status including if Duty of Candour event **within 2 weeks** • Lead Investigator, (LI) Core team (including CG link) and remit confirmed • Agree communication with patient/ family at this time – initial contact needs to take place within 10 days of event confirmation and no morethan one month after the event. • CG commence draft timeline as soon as SAE confirmed	Guidance on Communication with patients and families Staff support guidance Decision Tree SAE review tool SAE Checklist
Investigation Iweek 2 – week 8	• Lead investigator and CG link meet within 1 week and confirm plan for review, CG update to Division/ Function Management Team. • Invites sent for panel meeting (date must be within 6 weeks) along with requests for information from panel members – additional meetings can be held before or after the RCA panel date and are encouraged where possible • Information requested, shared and reviewed • Plan reviewed and updated every 2 weeks to ensure progress maintained, prompted by CG. • Any issues in progressing reported back to Division/ Function Management Team as soon as possible	Guidance on Writing Statements Reflective exercise for staff SHEEP sheet Timeline templates Cause Effect Model Barrier Analysis HF in SAE SAE Checklist
Report Final draft agreed within 11 weeks	• Draft report available within 5 working days, shared with panel and staff who have contributed for factual accuracy check (2 weeks to review). • Consider patient/ family engagement at this stage • Report reviewed and signed off via CGRMG – any comments go back to panel for consideration, Lead Investigator agrees final draft • Final report can be shared with patient/ family/ staff	SAE Report template SAE Checklist
Review of Recommendations & Actions	• Final report to be reviewed at Cross Divisional CG Forum at the next available meeting • If on review of final report there are significant issues with findings and/ or progression of recommendations, an addendum to the report may be considered • Improvement plans for recommendations to be agreed including arrangements for monitoring • Action plan shared with CGRMG • 3 and 6 month check on progress of action after plan agreed undertaken by CG	SAE Checklist Datix (for actions)

SAE Review Tool

Incident Review Tool

To be used for review of:

- Severity 4/5
- SAE listed events
- Those events with potential for significant harm

Division:

Report prepared by:

Input from:

Approved by:

Approved date:

Event Details			
Ward/ Department event occurred in:			
Date of Event		**Time of Event**	
CHI/ Hospital number if applicable		**Outcome/ Condition of patient/ person affected**	
If a clinical event, is the patient outcome a known complication of a disease / treatment?			
Datix Web reference number: WEB-			
Brief summary of event (include actions taken in response)			

SAE Assessment Questions	**Yes**	**No**
Was there a problem with any equipment involved in this case?		
Has there been a breach of policy or procedure?		
Is there something you think should have been done differently in this case?		
Do you feel there is any learning to be gained from investigating this event? (Would something be done differently next time?)		
Are there any patient / family concerns regarding the treatment / care / outcome?		
Are there any management concerns related to the event or individuals involved?		
Is there currently any interest from the Procurator Fiscal?		

Is this a Duty of Candour event?		
Do you believe this event was avoidable?		
If you have answered 'yes' to any of the questions above or there are a significant number of unknowns about the case, consider escalating to SAE review.		
Do you believe this event should progress to a RCA Investigation? Yes / No (delete as appropriate)		

If **Yes** commence the SAE process in line with policy and guidance.

For events **not progressing to SAE Investigation** a **Level 2 review** must be completed within 6 weeks. Findings should be recorded below and approved by the DMT then reported to the CGF:

Comment on decision not to progress to SAE Please indicate below the main reason for your decision this does not require RCA investigation:

Outcome and Learning from Level 2 Review

Additional Background identified via review
Assessment of Issues
Recommendations/Learning/Outcome

Remember to attach this document to Datix when completed and approved for both SAE 'yes' and 'no' as a record of the decision making.

Appendix 6 – Action Plan Process

Immediate Actions	• Immediate actions taken to ensure safety, RCA investigation completed
RCA Report Approval	• RCA findings and report presented at CGRMG for approval – report will include detail of actions already taken and recommend additional actions
Draft Action Plan	• Report distributed to Division DMT • Draft action plan developed by Division DMT with support from CG including proposed leads and timescales
Assignment of Actions	• Proposed action owners contacted by appropriate DMT lead with support from CG to discuss action and agree ownership and timescales
Action Plan Approval	• Draft action plan presented and discussed at cross divisional CG Forum for agreement • Final copy of action plan shared with CGRMG for noting
Actions recorded and monitored	• Actions confirmed on Datix and tracked at Division CG Forums • CGD to repro to CGRMG on status of actions highlighting any overdue or when due dates extended

Appendix 7 – The 2nd Victim

An adverse event can lead to multiple victims:
1. The patient/ family if a clinical event or the person injured/ affected in a non clinical event
2. The staff members directly and indirectly involved in the event
3. The organisation and management team

Second victim definitions:

"A healthcare provider involved in an unanticipated adverse event or medical error who is traumatised by the event."
"A healthcare provider who is involved in a patient adverse event who subsequently has difficulty coping with emotions."
"Frequently second victims feel personally responsible for the unexpected patient outcomes and feel as though they have failed their patient, second guessing their clinical skills and knowledge base."
Scott et al, Quality & Safety in Healthcare, 2009

Although the definition refers to healthcare providers, GJF recognise that any staff member, directly or indirectly involved, in an adverse event can become a second victim. The impact is influenced by:
- The outcome of the error/ event
- The degree of personal responsibility
- Legal/ fiscal interest, media/ external attention, reaction of colleagues, patient/ family response should also be considered; other factors may also be relevant

Support to the second victim is on multiple levels and involves immediate support, peer support and ongoing support, including professional support.

GJF is committed to developing a framework to support the second victim. The policy toolkit contains guidance on debrief and staff support which will be developed further as part of this work.

Support for staff is also available via Human Resources, Occupational Health, Confidential Contacts and Spiritual Care.

Appendix 8 - Duty of Candour

We share a common purpose that we provide a high quality care to our patients and ensure the best possible outcomes for people using our services. Promoting improvement is very much at the heart of what we do. We know that we deliver exceptional care on a daily basis but sometimes things go wrong and it's how we deal with important incidents. The Duty of Candour provisions in legislation set out for us a range of things that need to happen when unexpected or unintended harm has occurred.

Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016

The Duty of Candour provisions in the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill were given Royal Assent on 6 April 2016. The implementation date for the duty of candour provisions is 1 April 2018. The principles of Candour exist in our organisation and within professional codes of conduct and adherence to is expected from all healthcare staff. What the Act does is introduces a statutory organisational Duty of Candour on us as healthcare staff and services.

Purpose

The overall purpose of the duty is to ensure that organisations are open, honest and supportive when there is an **unexpected or unintended incident resulting in harm or death**, as defined by the Act. Organisations are required to follow a duty of candour procedure which includes notifying the person affected, apologising and offering a meeting to give an account of what happened.

The duty will also require the organisation to review each incident and consider the support available to those affected (both those who deliver and receive care and support services). Organisations have a requirement to publish an annual report on when the duty has been applied. This will include the number of incidents, how the organisation has implemented the duty and what learning and improvements have been put in place.

Key principles

Providing healthcare is associated with risk and from time to time there are unintended or unexpected events resulting in death or harm. When this happens people want to be told honestly:-

- what happened,
- what will be done in response,
- and to know what improvements will be made to stop this happening again to someone else in the future

There is a need to improve the focus on support, training and transparent disclosure of learning to influence improvement and support the development of a learning culture across services.

Being candid promotes accountability for safer systems, better engages staff in improvement efforts and engenders greater trust from patients and people who use services.

Implementation of the procedure will support:

- Cultural change across organisations
- Consistency of response to an event or incident that has resulted in unexpected or unintended harm or death
- Individuals affected remaining at the centre of the process
- Emphasis on learning, change and improvement to, where possible, avoid the incident happening to someone else.

Appendix 9 – Duty of Candour Procedure

Summary of the Duty of Candour Procedure
The Duty of Candour procedure applies to incidents that the responsible person becomes aware of after 1 April 2018. For example, after 1 April 2018, if the responsible person becomes aware of unexpected psychological harm that occurred because of care provided to the relevant person in 2015, the Duty of Candour procedure should be activated. The overall purpose of the duty of candour is to ensure that organisations are open, honest and supportive when there is an unexpected or unintended incident resulting in death or harm, as defined in the Act.

The responsible person
The new Duty applies to organisations and not individuals and is placed upon health, care and social work organisations with the "responsible person" defined as the Health Board.

The responsible person has responsibility for:
- carrying out the procedure;
- undertaking any training required by regulations;
- providing training, supervision and support to any person carrying out any part of the procedure as required by regulations;
- reporting annually on the duty.

Incident which activates the duty
The duty of candour procedure must be carried out by the responsible person as soon as reasonably practicable after becoming aware that an individual who has received a health, care, or social work service has been the subject of an unintended or unexpected incident, and in the reasonable opinion of a registered health professional has resulted in, or could result in:

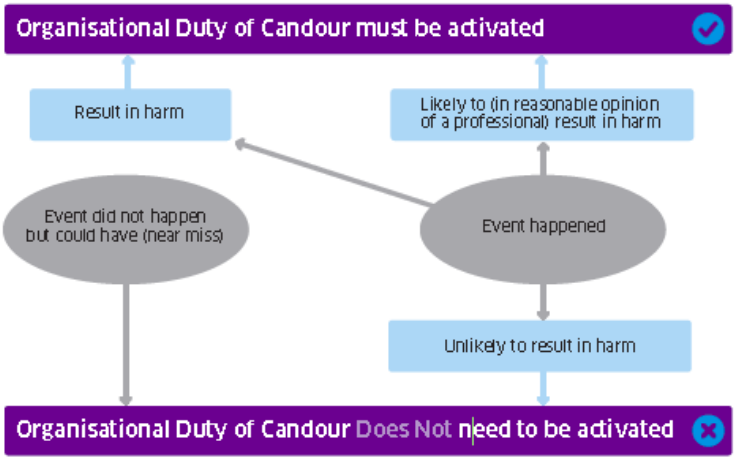
- the death of the person;
- a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions;
- an increase in the person's treatment;
- changes to the structure of the person's body;
- the shortening of the life expectancy of the person;
- an impairment of the sensory, motor or intellectual functions of the person which has lasted, or is likely to last, for a continuous period of at least 28 days;
- the person experiencing pain or psychological harm which has been, or is likely to be, experienced by the person for a continuous period of at least 28 days;
- the person requiring treatment by a registered health professional in order to prevent:
    - the death of the person; or
    - any injury to the person which, if left untreated, would lead to one or more of the outcomes mentioned above.

The view of the registered health professional
A registered health professional must give their view on the incident and its relationship to the occurrence of death or harm and pre-existing illnesses or underlying conditions. Organisations must ensure that the registered health professional who gives the opinion mentioned above, following an unintended or unexpected incident, is not someone who was involved in the incident.

When a registered health professional has agreed to provide the responsible person with their view, this should cover the following:
- Based on the background information available, does it appear that this incident resulted in or could result in the death or harm described?
- Does the natural course of the person's illness or underlying condition directly relate to the death or harm described?

Although it is likely that the organisation will already have a view on whether the procedure should be activated, the views of the registered health professional not involved with the incident form an important further step in the duty of candour procedure.

What does 'could result' mean and how is that decision to be made?
If the registered health professional thinks that it is unlikely that harm will occur, then the duty of candour procedure need not be activated for that incident. The diagram below sets out the decision making process in more detail:



The Procedure
The 'duty of candour procedure' means the actions to be taken by the responsible person in accordance with regulations made by the Scottish Ministers. The regulations detail the specific actions and recording of information required by the responsible person when carrying out each stage of the procedure.

The key stages of the procedure include:
(a) to notify the person affected (or family/relative where appropriate);
(b) to provide an apology;
(c) to carry out a review into the circumstances leading to the incident;
(d) to offer and arrange a meeting with the person affected and/or their family, where appropriate;
(e) to provide the person affected with an account of the incident;
(f) to provide information about further steps taken;
(g) to make available, or provide information about, support to persons affected by the incident;
(h) to prepare and publish an annual report on the duty of candour.

GJNH Process
All Duty of Candour events will be managed via the Significant Adverse Events process which will support all aspects of the legislation.

The SAE review involves relevant clinicians who will undertake the role of the registered health professional in confirming if the Duty of Candour procedure is triggered.

The Clinical Governance Department will support the identification of events via Complaints, Claim and adverse events to ensure process is followed and timescales managed.

Clinical Governance will maintain a Duty of Candour file within Datix for all events and will support development of the annual report.

Clinical Governance will support education and awareness raising of the Duty of Candour and responsibilities within and will link to Clinical Education in supporting staff in meetings those responsibilities.

Appendix 10 – Guidance to Support Communication with Patients/ Relatives

Introduction
This document provides guidance on the communication that must be maintained with patients/ relatives involved in a Significant Adverse Event. Whilst the principles of Being Open apply to all Significant Adverse Events, it is important in meeting the legal requirements of Duty of Candour that the stages and timelines in this guidance are strictly adhered to. Any problems in achieving this should be highlighted to the DMT and Head of Clinical Governance as soon as possible.

Informing the patient of an event
- The patient/ relative must be informed of the event as soon as possible.
- Where possible this should be undertaken by the patient consultant and senior nurse.
- At this time an apology should be offered to the patient/ family for the event that has occurred (see additional guidance on apology).
- The focus of the discussion will likely be on any clinical impact but details of the SAE process should be offered and open for discussion if questions later arise. Leaflets on the process are available that can be provided to patients/ relatives.
- Details of clinical team discussion should be reflected in the family communication within the patient record.

Confirmation of SAE
When an SAE is agreed it should be confirmed by the Divisional Management Team that the patient/ family is aware of the event and discussions undertaken as to contact to be made and ensuring the Lead Investigator for the SAE is fully briefed on this. It is generally advisable for the lead investigator to discuss with the patient consultant in the first instance and establish the status of patient/ family relationship and agree a plan for further contact.

The DMT will ensure that a lead contact for the patient/ family has been confirmed and a plan agreed for communication. The plan should ensure any staff members involved in discussions are adequately supported. The Clinical Governance Department wil support the Lead Investigator in patient contact and can be offered as an additional point of contact.

For Duty of Candour (DoC) events the SAE confirmation date is Day 1 of the procedure.

Initial contact
The initial contact must take place no later than 10 working days of the SAE confirmation (legal requirement for DoC events). If this is more then one month since the date of the event a reason for the delay must be given.

The initial contact with a patient/ family should aim to:
- Convey an apology for the event that has occurred and effects this has had (see additional guidance on apology).
- Inform that an investigation will take place and the process for this (if event triggers Duty of Candour this should be specified)
- Establish if the patient/ family would wish to be involved and if so level of involvement i.e. be kept informed or express concerns they wish considered
- Confirm how they would prefer to be contacted and who will be the point of contact (for them and for us)
- Make them aware of the timescales involved (including frequency of contact)

It is always recommended that the initial contact in respect of an investigation is made in person. Where face to face communication is not possible, it should be agreed with the Divisional Management Team and patients consultant the best way to progress communication including who should undertake this. In these instances a meeting should be offered to further discuss.

It is important that the remit of an investigation is clearly communicated to a patient/ family. They should be offered the chance to express any concerns they have and any information relevant to the review. Where it is possible to address any concerns immediately this should be done. If a patient/ family member expresses concerns outwith this remit (which is often the case) these should be referred to the DMT to progress via the appropriate process.

A letter must be sent to the patient/ relative summarising the discussions. This letter should include a written apology for the event and distress caused and outline the investigation process, any key points discussed and communications going forward as agreed. Clinical Governance will support the drafting of the letter for sign off by the Lead Investigator (and person undertaking contact if different).

Contact during investigation
Contact should be maintained with the patient/ relative as agreed and recorded in Datix.
If there is any delay to the planned timescales Clinical Governance will prompt for an updae to the patient/ relative of the delay and reason(s) why.
Clinical Governance will monitor the patient/ relative contact for SAE events and prompt as required.

Sharing the Investigation Findings
All patients/ families will receive a copy of the final report from the investigation. They should be offered a face to face meeting to allow apology and full explanation of the findings with the option to read the full report before or after such a meeting. You should ask the patient/ family member in advance for any specific questions/ issues they wish to discuss.

You should try to establish early on if a meeting is likely and if the patient/ relative wishes to review the report prior to the meeting. In some cases people may wish to review the report before making a decision on meeting. If someone declines a meeting and then reconsider this should be accommodated where possible.

The Lead Investigator should agree who will support the feedback meeting; ideally the patient consultant would be involved along with an appropriate member of the review panel.

Appropriate notice should be given of a time and date and of the nature of the meeting to allow all invited to prepare. An appropriate venue should be sought and consideration given in selection (if the patient/ family have expressed a desire not to attend any particular areas/ sites). If possible it is useful to have a separate area available as a waiting area.

The meeting should aim to:
- Apologise for the events
- Outline the investigation undertaken
- Fully explain what happened based on the findings of the investigation
- Outline what actions have been / are being taken in response
- Allow the patient/ family an opportunity to ask questions
- Agree any follow up actions and communication

The patient/ family can be kept informed of the actions resulting from an investigation; this can be in the form of a follow up meeting or via letter in agreement with the patient/ family. A letter will be sent summarising the meeting, patients/ families should be offered the opportunity to respond with any comments.