ADVERSE INCIDENT REPORTING & INVESTIGATION POLICY

South Central Ambulance Service NHS Foundation Trust

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ADVERSE INCIDENT REPORTING & INVESTIGATION POLICY

1. POLICY STATEMENT

1.1 South Central Ambulance Service NHS Foundation Trust recognises its statutory, civil, moral and financial responsibility to manage risk. The Trust Board is committed to providing robust risk management strategies and procedures in order to safeguard the organisation, its employees, patients and others who may be affected by its activities.

1.2 The Trust supports the principles of fair blame and promotes a culture where incidents (including complaints and claims) can be reported and investigated in a non-punitive and supportive environment to ensure that investigations identify whether the actions of individuals were due to systems failures or whether the individual knowingly committed a reckless intentional unsafe or criminal act. Disciplinary action will only be taken against an individual(s) where there is a reasonable belief that intent to cause harm, negligence or reckless behavior existed.

1.3 The Trust requires that all adverse incidents, near misses or hazards be reported and documented using the Trust's electronic reporting system (Datix) as part of a proactive approach to risk management. This policy details the action to be taken, which applies equally to both clinical and non-clinical incidents.

1.4 Where adverse incidents are reported they will be investigated, and all reasonable steps taken to implement control measures which will either remove or reduce the level of risk to an acceptable level. The Trust will aim to respond quickly and positively to all risk issues in order to mitigate their consequences in the best interests of the organisation, patients and staff.

1.5 The Trust will ensure that all policies and procedures relating to risk management (including safe working practices) are made widely available to all staff and will ensure that all employees are suitably informed and trained in the Trust procedures for the reporting and management of risk.

1.6 This Policy will be reviewed by the Patient Safety Group and should be read in conjunction with the Trust's Risk Management Strategy which sets out, the:
- Trust's definition of Risk & Risk Management
- Organisational structures and accountability for the management of risk
- Committee Structure for the management of risk
- Strategic Aims and Objectives for the management of risk

1.7 This policy will provide guidance to managers and staff on adverse incident reporting, investigations, Being Open, analysis and improvements and supporting staff through incidents, claims and complaints.

2. DEFINITIONS

2.1 An **'adverse incident'** is any occurrence or set of circumstances, which has the potential or does result in harm/injury, loss, damage or unwanted effect, to the organisation or any individual including staff, patients, customers or members of the public. Such "incidents" may be clinical or non-clinical in nature and include such examples as, an adverse reaction in a patient following treatment, failure of medical

equipment, breach in security, theft or property damage, fire, major failure in plant or machinery, all injuries sustained by a member of staff, patient or third party to whom the Trust owed a duty of care.

2.2   A **'hazard'** is anything that has the potential to cause harm, injury, loss or damage.

2.3   A **'risk'** is the likelihood that the identified hazard will occur resulting in injury, damage or loss.

2.4   A **'near miss'** is defined as any accident or adverse event which did not occur but had the potential to prevent the Trust from delivering on its objectives, notwithstanding the fact that no adverse consequences occurred from the specific incident.

2.5   A **'medical device'** is any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease.

2.6   **'Immediate Cause'** is defined as the factor(s) which triggered the actual incident.

2.7   **'Contributory Cause'** is defined as the circumstance(s) which contributed to the occurrence or incident, which by itself would not have caused the incident to arise.

2.8   **'Root Cause'** is defined as the underlying cause(s) to which the incident could be attributed and if corrected would prevent or minimise the likelihood of recurrence.

2.9   '**MHRA**' stands for Medicines and Healthcare Products Regulatory Agency, The Medicines and Healthcare Products Regulatory Agency is a UK government agency which is responsible for ensuring that medicines and medical devices work and are acceptably safe. Formed in 2003 with the merger of the Medicines Control Agency and the Medical Devices Agency. The agency further merged in 2003 with the National Institute for Biological Standards and Control and was rebranded with the MHRA identity being used for the parent organisation and one of the centres within the group. It is an executive agency of the Department of Health.

2.10   '**NRLS**' stands for the National Reporting and Learning System which is a central database of patient safety incident reports. The NRLS was formulated in 2003 and uses information submitted to analyse and identify hazards, risks creating opportunities to continually improve current safety cultures of patient care.

2.11   '**Moderate Harm**' is a term used to identify a Patient Safety Incident (PSI), that resulted in a moderate increase in treatment and that caused moderate, but not permanent harm to one or more patients. A moderate increase in treatment is defined as a return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an out-patient, cancellation of treatment, or a transfer to another area such as intensive care as a result of the incident.

2.12   **Duty of Candour (Being open)**, The organisation's culture is to be open with our patients, informing them of any moderate or serious patient safety incident in which they have been involved. By 'being open', the Trust will acknowledge the incident has occurred, apologise to the patient/next of kin and explain why the incident

occurred and what actions will be put in place to prevent reoccurrence.

2.13 **RIDDOR** stands for the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations, under which the Trust has to report specific incidents to the Health and Safety Executive (HSE) within specific timeframes.

2.14 **Serious Incident Requiring Investigation (SIRI)** is an incident identified by the Trust that has to be reported on STEIS and investigated within specific timeframes.

2.15 **Other definitions from the Risk Management Strategy**

Risk Assessment
The process by which hazards are identified and the risk rated using tools implemented by the Trust for use by all employees. Assessments can either be general or specific but will be undertaken by competent persons who have received the appropriate degree of information, instruction and training.

Risk Management
The identification, quantification, control, mitigation, review and audit of any risk that threatens the services delivered or assets of the Trust. This shall include such diverse aspects as health & safety, clinical care & patient experience, property, vehicles & equipment and relationships with stakeholders.

Risk Matrix
The tool that is used to "score" each risk and determine its place on the Risk Register, levels of authority are determined through the matrix and this will provide a priority list for managers to use within their respective area of control.

Corporate Risk Register
The register is the recording tool for identified risks and will be held centrally, maintained by the Director of Patient Care. The register will also record risk identified through the Assurance Framework.

Health & Safety Risk Register
The register is the recording tool for risks identified and will be held centrally, maintained by the Head of Risk & Security. The register will be monitored by the Health, Safety and Risk Group and issues escalated for inclusion on the Corporate Risk Register as appropriate.

Acceptable Risk
The Trust Board accepts that no system can be totally risk free and that there are occasions when the Trust will have to accept a degree of risk in the course of its undertakings. Work practices, procedures and equipment will be assessed to identify the significant hazards and risks and ensure that controls are implemented to eliminate or reduce the risks to the lowest reasonably practicable level.

Organisational Risk
Any potential threat or occurrence that could prevent the Trust from delivering its aims, achieving its objectives or developing projects to improve its services within the economic, human, environmental and technological boundaries.

Clinical Risk

Any potential threat or occurrence related to the diagnosis, treatment and/or outcome of patient care where the likelihood is that the identified hazard causes harm or distress to the patient.

Financial Risk

Any potential threat or occurrence that could prevent the Trust from effectively managing its finances, meeting its statutory financial duties.

Information Risk

Any potential threat or occurrence that could prevent the Trust from effectively processing information relating to corporate services or directly relating to patients or staff.

Board Assurance Framework

From 2001/2002 all NHS Chief Executives have been required to sign a Statement on Internal Control (SIC), which forms part of the statutory accounts and annual report. To provide this Statement, Boards need to be able to demonstrate that they have been properly informed through assurances about the totality of their risks, not just financial, and have arrived at their conclusions based on all the evidence presented to them.

The Board need to be confident that the systems, policies and people it has in place are operating in a way that is effective, is focused on key risks and is driving the delivery of objectives. Through the consideration of a formal organisational assurance framework the Board will have full awareness of the strategic risks facing the organisation.

3. DUTIES

3.0 The **Chief Executive** has overall responsibility for having effective and safe systems in place for risk management within the Trust and for meeting all statutory requirements and adhering to guidelines issued by the Department of Health and the Health and Safety Executive (HSE) etc.

3.1 The **Board** is will receive assurances that there are safe systems in place for risk management. They will receive:
- Upward report from the Quality and Safety Committee
- All risk assessments categorised as 'Red' (high scoring risks) monthly reports from the Director of Patient Care and other Directors
- Assurance reports provided by external bodies such as the Care Quality Commission, NHS Protect and the NHS Litigation Authority (NHSLA) etc.
- Monthly Key Result Areas and Key Performance Indicators reports in the Integrated Performance Report (IPR)

3.3 The **Director of Patient Care** has delegated responsibility for ensuring that there are safe systems in place for risk management and incident reporting.

The Director of Patient Care responsibilities include:
- Coordinating and ensuring the implementation and continued development of the

risk management process throughout the Trust

- Communicating the Trust's commitment to the Adverse Incident Reporting & Investigation
- Policy throughout the organisation:
- Identifying & interpreting new legislation and Government guidance in relation to risk
- Advising the Chief Executive, Directors and Board on matters of risk management
- Coordinating and obtaining assurances from each of the Executive Directors in relation to
  o Risks within their directorate
  o Receiving and monitoring risk, adverse incident, claims and complaints reports, identifying trends and producing statistical data for the Trust Board
- Acting as the Trust's designated Board and Executive Level Lead for Risk Acting as the designated Executive lead for Security Management.

3.4   The **Executive Directors** have delegated responsibility for the Adverse Incident Reporting & Investigation Policy and will be responsible for ensuring that the policy is adopted in their respective area.

Responsibilities of the Executive Directors will include:
- Raise staff awareness of the Adverse Incident Reporting & Investigation Policy.
- Championing the risk management policy implementation process within their respective directorates.
- In conjunction with the Risk Department and Director of Patient Care, ensure that the Trust's key risks relating to adverse incident, clams and complaints are identified and addressed.
- Provide the Trust Board with assurance that risk is managed within their directorates.

3.5   **Managers** are responsible for implementing and monitoring the Adverse Incident Reporting & Investigation Policy within their designated areas and scope of responsibility. In situations where significant risks have been identified and where local control measures are considered to be potentially inadequate, managers are responsible for bringing these risks to the attention of their respective Manager. They should also report the issue via the Trust's electronic online (intranet) DATIX reporting system. This effectively replaces the paper based IR1 form. The IR1 form will still be available should the electronic DATIX system not be available due to technical problems which would others wise prevent the reporting of an incident.

All *Managers and Supervisors* have a responsibility to undertake risk assessments as required, to supervise activities within their area of responsibility to ensure that policies and procedures are properly applied and that areas of risks are adequately controlled. In the event that a member of staff identifies a risk or issue to them, they will investigate and implement appropriate control measures to minimise that risk. Where the required action is outside or beyond their area or level or authority, they will document their actions and recommendations before passing the matter to the next level of management for attention.

Trust Managers and Supervisors will:

- Fully support and implement the Adverse Incident Reporting & Investigation Policy within their directorates.

- Ensure that all of their staff report incidents immediately or within 24 hours of the incident occurring.
- Ensure that they inform the Risk Department of any staff who have been off work or incapacitated from doing their normal job of work for over 7 days (not including the date of the incident) following an incident/injury sustained at work.
- Ensure that their department as a whole is effective and efficient in the management of Adverse Incident Reporting & Investigation.
- Ensure that the Adverse Incident Reporting & Investigation Policy is followed by carrying out investigations and risk assessments and monitor the outcome.
- Ensure that following an incident all appropriate risk assessment within their area of responsibility is carried out and/or reviewed.
- Ensure they follow the principles of this policy in an open and transparent manner and support staff through any adverse incident, claim, complaints or court hearing process

3.6 **Company Secretary** will work closely with the Chairman, Chief Executive and other Executive Directors to co-ordinate the Trust Board and other relevant committees' agendas. This will ensure that the Trust meets all legal, corporate and mandatory obligations.

3.7 **Assistant Director of Quality** will be responsible to the Director of Patient Care for the development of effective Trust wide policies and procedures. Specific responsibilities will include monitoring all areas of risk management performance, maintaining and developing the Trust's Risk Register and risk databases, providing reports to the Patient Safety Group and Operational Health, Safety and Risk Group on incident reporting, Serious Incidents Requiring Investigations (SIRIs), claims and complaints and identifying trends and actions. The Assistant Director of Quality will be the point of reference within the Trust for all internal and external contacts in relation to all matters relating to Risk Management, incidents, claims, PALS and complaints.

3.8 **Risk Department** will support the Assistant Director of Quality in managing risks. They will provide specialist advice and support to managers. They will ensure that investigations, safety audits and inspections are carried out. The Head of Risk and Security, the Non-Clinical and Clinical Risk Managers will individually act as the respective designated 'competent person' in relation to Health and Safety as required by the 'Management of Health and Safety at Work Regulations 1999' (Regulation 7) and provide reports to the Operational Health, Safety and Risk Group on incident reporting, identifying trends and actions.

3.9 **Head of Patient Experience** is responsible for coordinating the investigation and responses to all complaints, concerns, comments and compliments received by the Trust. They will provide reports to the Patient Experience Review Group and monitor trends of complaints/compliments to ensure that learning points can be identified and implemented.

3.10 **Investigation Managers** will be responsible for carrying out the investigation of SIRIs, serious incidents and complaints as agreed with the Assistant Director of Quality.

3.11 **Information Governance Manager** will coordinate the annual Information Governance self- assessment and provide specialist advice in relation to Freedom of Information (FOI) requests, Data Protection and Records Management. They will be responsible for the development and delivery of an annual improvement plan for

information governance.

3.12 **All Employees**

All Trust employees will:
- Understand and co-operate with the Adverse Incident Reporting & Investigation Policy.
- Report any identified areas of risk immediately in accordance with the Management of Health and Safety at Work Regulations 1999 (Reg. 14), the Trust's Risk Management Strategy and Adverse Incident Reporting & Investigation Policy;
- Inform their line manager if they anticipate being off work or incapacitated from doing their normal job of work for over 7 days (not including the date of the incident) following an incident/injury sustained at work.
- Co-operate in any investigation relating to an adverse incident, claim or complaint to ensure an appropriate conclusion.
- Use the Adverse Incident, DATIX Reporting Procedure to report any identified risks and near misses, completing the on-line form fully with a completed risk assessment score and sending it to the Risk Department in its electronic format immediately or within 24 hours of the incident and/or near miss and identification of a hazard.
- Inform their line manager and seek support for any concerns around incidents, claims and complaints and any pending court appearance.

3.13 For the Trust's Committee Structure see the Risk Management Strategy.

4. ADVERSE INCIDENT REPORTING PROCEDURE

4.1 It is the responsibility of all staff to report any adverse incidents, potential incidents (i.e., near miss) and all identified hazards and risks. In all cases, reports must be made without delay and an on-line DATIX report completed and electronically sent to the Risk Department by the member of staff within 24 hours of the incident taking place.

4.1.1 On occasions that the staff member(s) involved are unable to submit a DATIX report of an incident due to absence; the member(s) of staff's Line Manager can submit the DATIX report on their behalf after collating factual information relating to the incident.

4.1.2 All Managers, Team Leaders and Clinical Mentors or Secondment Team leaders who have investigation duties within DATIX of all adverse Incidents are required to contact the Risk Department stating if possible, the duration of unavailability/absence along with a name of an alternative Investigator.

4.1.3 'New Starters and Leavers'; to enable all staff with investigating duties to have access to DATIX, It will be the respective Area Manager's responsibility to notify the Risk Department of new staff with that duty, this will enable the Risk Department to assign the investigator a username and password. In line with the Trust's policy of Information Governance it will be both the Human Resources (HR) Department and the respective Area Manager's responsibility to inform the Risk Department of staff leaving with the staff member's final day of work in the Trust within a 30-day notice window enabling the DATIX account to be closed.

4.1.4 Private Ambulance Services used within the South Central Ambulance Service are equally encouraged to report all adverse incidents. To assist with this, the South Central Ambulance Service (SCAS) will provide the Private Ambulance Service staff an IR1 paper pad system for their staff to report all incidents related to SCAS. This is to encourage a fair culture of patient and staff safety. The IR1 will be submitted and sent to the Trust's Risk Department.

4.2 Where serious injury, risk, death, fire or loss occurs, the EOC and Risk Department should be informed immediately with a request for a Senior Manager to attend the incident. The relevant Operational Director and the Director of Patient Care must be notified immediately by telephone, including events that occur outside of normal working hours. In the event of it not being possible to contact the relevant Operational Director, the duty Executive Director must be immediately informed.

4.3 Below are examples of unexpected serious incidents to patients, staff or others, as a result/consequence of our undertaking and or activities:

a) Death of a patient, member of staff or member of the public.
b) Any major fractures as defined by Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR).
c) Dislocations of shoulders and hips of patients or staff.
d) Loss of sight, major burns.
e) Any treatment or incident that leads to a patient or member of staff which results in unconsciousness.
f) Drug administration error.
g) Road Traffic Accident.
h) Violence against staff resulting in injury.
i) Trust property stolen.
j) Major national health scare.
k) Loss of information technology functions.
l) Major incident.

(These are examples of serious incidents which are not exhaustive**)**

4.4 The person reporting the incident must ensure that the DATIX is copied to their Line Manager, by way of inclusion on the DATIX form itself. On receipt of a DATIX the line manager will:

- Check that the DATIX has been completed correctly and the risk rated by the member of staff.
- Any required amendments can be noted within the DATIX report itself with a follow-up email (completed within the DATIX itself) to the respective persons that need to be made aware of the incident or of the amendment/additional information.
- Undertake an initial investigation to ascertain the facts and identify any immediate actions required to eliminate, reduce or control the risk where possible. If appropriate, staff should be alerted verbally, on notice boards or by email.
- Conduct any necessary interviews and obtain statements which can be attached onto the DATIX report itself. This should include any immediate actions taken and, if appropriate, the department/person to whom the DATIX has been forwarded for investigation. This will be dependent upon the type and risk rating of the incident/risk. Investigation guidance is included at Section 8 of this Policy.
- The appointed Investigating Officer/department/person responsible for the

investigation will be advised via the DATIX system in email format.

- Upon completion of the investigation, the DATIX must be completed with actions or recommendations and an updated risk rating. The DATIX system will allow the Investigating Officer to hold all paperwork and allow for progress reports to be placed in the respective sections of the DATIX, allowing review by authorised persons.
- Ensure they or the Investigating Officer provides feedback to the member of staff who submitted the DATIX. Feedback to staff on the actions taken following a reported incident/risk is critical in improving and maintaining staff engagement.
- Ensure all/any statements, reports, photographs etc are uploaded onto the relevant DATIX report – this will allow continuity and provide evidence for any review or referencing to it by other linked managers.

4.5　It is essential in the case of injury or other incident, which may subsequently result in insurance claims or litigation, that a full detailed report is produced and wherever possible, photographs taken for future reference. Again, all such evidence must be attached / uploaded onto the DATIX report itself at the time of completion or subsequently forwarded to the Risk Department for attachment.

4.6　Notifiable and industrial injury/incidents absences exceeding 7 days must be reported on DATIX and this information provided to the Risk Department by the eighth day of absence to allow timely HSE reporting. As in 4.1.1 on occasions that the staff member(s) involved are unable to report an incident due to absence; the member(s) of staff's Line Manager can submit the DATIX report on their behalf after collating factual information relating to the incident.

4.7　It is essential that potential incidents (near misses) are also reported using DATIX in order to maintain the Trust's proactive approach to both clinical and non-clinical risk management.

4.8　On receipt of a DATIX the Risk Department will review the risk rating and actions to ensure they are proportionate to the level of risk and record the incident on the Trust's incident reporting database.

4.9　In the event of further action being required the Risk Department will initiate such action. They will also be responsible for reporting such incidents as are required to be reported to other departments and or external agencies such as the Health and Safety Executive.

4.10　The Trust actively encourages staff to report adverse incidents and has adopted a fair blame culture with regards to reporting risk. The primary purpose of any investigation is to learn why the incident occurred by identifying the root causes of the incident and to prevent reoccurrence and not to apportion blame. The Trust encourages openness and constructive criticism particularly in relation to clinical care.

4.11　Guidance on completion of a DATIX report is undertaken through the Risk team providing training and issuing a Quick Guide to all SCAS personal. The completion of an IR1 (only to be used when completion of the electronic DATIX is not possible) can be found on the inside of the front cover of the pad along with the Easy Guide issued by the Risk Department (see Appendix 3A). All employees will receive formal instruction on DATIX and IR1 completion during corporate induction training and through the Trust's training needs analysis process. Individuals who have yet to

receive training may need guidance in relation to the procedures or assistance in completion of a DATIX report. Assistance is available from the Risk Department or any manager, supervisor or mentor.

4.12   All incidents (any unintended or unexpected incident which could have or did lead to harm) involving patients will be reported by the Clinical Risk Manager to the National Reporting and Learning System (NRLS). Incidents that are regarded within the moderate harm to serious incident requiring investigation (SIRI) category should be reported immediately after the event as these types of incidents have to be reported to the NRLS. The process of contacting the relevant Director/Manager and Risk department should be followed as in 4.2 either immediately after or before the DATIX is/has been submitted.

4.13   All patients within the moderate harm/SIRI category will be contacted by telephone or visited by the Investigating Officer in line with the Trust's requirement under the "Duty of Candour"; where upon the Trust's requirements and reasons for contact will be explained to the patient/relatives. The Investigating Officer will also offer contact details and regular welfare checks.

4.14   It is the line manager's responsibility to ensure that a copy of this policy, and for when DATIX cannot be accessed, an IR1 pad is kept within the department/station, is up to date, and is readily available to staff for the reporting of incidents.

4.15   The DATIX reporting system must be highlighted to all staff as the method / route to use in the first instance when reporting any incident, and that the IR1 is only to be used as a fall back when the DATIX system is not available. The IR1 pad should be displayed at all times and made available to staff. It should not be removed from the department/station until all forms are used at which point it should be returned to the Risk Department.

5.   INCIDENT GRADING

5.1   All reported incidents will be initially graded by the member of staff according to their perception of the impact and the likelihood of recurrence as soon as possible after the event. A matrix is included within the DATIX report itself for this purpose.

The level of investigation and management action required for each report should be dependent upon the incident grading.

5.2   The 'Impact' and 'Likelihood' scores when plotted on the chart (See Appendix 3A) will provide a colour coded risk level.

- Red   =   High Risk
- Amber   =   Significant Risk
- Yellow   =   Moderate Risk
- Green   =   Low Risk

5.3   Examples are given in Appendix 3 as to the qualitative measures which might be considered under each of the heading's consequence or impact.

5.4   The following grid provides example descriptions in relation to the Likelihood axis

Descriptor	Example description (Likelihood)
Rare	Not expected to occur annually <1% Will only occur in exceptional circumstances
Unlikely	Expected to occur at least annually 1-5% Unlikely to occur
Possible	Expected to occur at least every 6 months 6-25% Reasonable chance of occurring
Likely	Expected to occur at least monthly 26-60% Likely to occur
Almost Certain	Expected to occur at least weekly >60% More likely to occur than not

5.5 The initial incident grading will be reviewed and adjusted if necessary following the completion of any in depth investigation by the Manager or following review by the Risk Department.

6. REPORTING SERIOUS INCIDENTS REQUIRING INVESTIGATION (SIRIs) or NEVER EVENTS TO THE CLINICAL COMMISSIONING GROUPS

6.1 SIRI/Never Events will be reported and investigated in accordance with the Trust Serious Incident Requiring Investigation Policy.

6.2 A SIRI may be defined as:

Any event which: Involves a patient, service user, member of the public, contractor, NHS staff, locum staff and out of hours providers, children, young people, prisoners and young offenders, or other providers of healthcare involved in the process of treatment, care or consultation on NHS premises, or in the course of treatment or care that is commissioned by the NHS but may be delivered by a private provider on non NHS premises which results in (or could have resulted in) one or more of the following:

- Serious Injury
- Unexpected death
- Permanent harm
- Significant public concern
- Significant media concern
- Significant disruption to health care services.

The process for reporting and investigation of a 'Never Event' as defined by the Department of Health is the same as for a SIRI.

6.3 For further guidance on reporting SIRIs see the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation which can be found at:
https://www.england.nhs.uk/patientsafety/serious-incident/

7. REPORTING OF INJURIES, DISEASES AND DANGEROUS OCCURRENCES TO THE HEALTH AND SAFETY EXECUTIVE (HSE)

7.1 Under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995, the Trust has a statutory duty to report certain types of major injuries, diseases and dangerous occurrences which occur at work to the Health and Safety Executive (HSE).

7.2 There are five broad categories of incident arising 'out of or in connection with' work or work activities, these are:

- **Fatalities**.
- **Major Injuries** such as certain physical injuries (e.g., breaking an arm/leg).
- Incidents which incapacitate an employee **for over seven days** (such as spraining an ankle and/or physical violence).
- **Diseases** (such as occupational asthma, allergy to latex).
- **Dangerous occurrences** (such as electrical fault which causes a fire or explosion).

7.3 Following receipt of an incident report which involves one of the above, the Risk Department will notify the Health and Safety Executive (HSE) of the incident.

8. INVESTIGATION OF ADVERSE INCIDENTS, CLAIMS AND COMPLAINTS

For Duties see section 3.0 to 3.12.

8.1 The primary purpose of an investigation is to establish the facts and sequence of events leading up to the adverse incident (whether an incident, complaint or claim) to determine what happened, how it happened, why it happened, who was involved and to determine the impact on patients and/or staff.

8.2 Human error is frequently seen as the direct or a contributory cause of incidents. However, the root cause is often a more complex series of factors which have been lying dormant or have been tolerated and have come together to allow the incident to occur. Unless incidents are investigated to identify the underlying, tolerated or dormant factors and these are addressed, improvement strategies aimed solely at individual practice are unlikely to be successful in preventing a recurrence.

8.3 The structured and systematic approach to the review of all events leading up to an adverse incident facilitates the identification of the direct, contributory and root causes of adverse incidents.

Direct Cause is defined as the immediate cause which triggered the incident.

Contributory Cause is defined as a cause which contributes to an incident but which by itself would not have caused the incident.

Root Cause is defined as the underlying cause to which the incident could be ultimately attributed and which, if corrected, would prevent a recurrence.

8.4 The analysis of the information gained from the investigation allows the

determination of recommendations that will help to prevent another incident of the same kind or one caused by similar issues. The lessons learned through the investigation process will be used to ensure learning takes place either by individuals, teams or the organisation.

8.5   Not all incidents need to be investigated to the same extent or depth. Having assessed each incident against the risk grading matrix the level of investigation and analysis effort should be expended in relation to the risk level and whether the incident has resulted in harm.

Risk Rating of Incidents Explained

a. Green incidents –low/no harm

These incidents generally do not have ongoing serious consequences and can be managed promptly on the spot. The department manager would undertake any review which may identify learning points or safety improvements. Any identified control measures should be implemented immediately.

b. Yellow incidents – Moderate harm or low risk

These incidents should be reviewed in the department where the event occurred. The department manager would undertake any review but the nature of the incident and possible implications may require a more senior manager to be informed. Any identified control measures should be implemented promptly.

c. Amber incidents – Significant harm or moderate risk

These should be subject to a root cause analysis investigation led by a suitably trained manager. It will be the responsibility of the investigating manager to ensure all learning points and safety improvements are appropriately identified and implemented.

Any controls identified which are not within the control of the local management team should be included on the appropriate risk register for consideration/action by a more senior manager or director.

Details of all reported incidents are recorded on the Trust's risk management database to allow monitoring of trends. It may be appropriate to establish any causes or contributory factors where trends are identified and for this information to be shared with other departments, locations or other stakeholders to share safety lessons.

d. Red incidents – High Major/Catastrophic harm or high/very high risk

Where major (i.e. permanent injury) or catastrophic harm (avoidable death or significant shortening of life expectancy) has occurred, an investigation team led by a suitably trained manager will be identified and a full root cause analysis carried out. The recommendations from the investigation report will be included on the corporate risk register if appropriate. Any identified actions to reduce or eliminate the risk of the incident recurring will be monitored by the Patient Safety Group or Serious Incident Review Group as appropriate.

8.6 A full and detailed explanation of root cause analysis techniques and how they should be applied can be found at:
www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/
There is also further guidance for managers on investigation and root cause analysis at Appendix 4 within this policy.

8.7 The investigation must be undertaken by more than one person. However, depending on the severity of the incident, individuals may conduct all, or part, of the investigation. The lead investigator should be trained in incident investigation and root cause analysis techniques and should be chosen from a cadre of expert/specialist, trained members. For example:

- Someone with specialist knowledge about an aspect of the incident e.g., a member of the clinical team, risk department, fleet engineer
- Someone with no specialist knowledge to provide an objective view
- Someone from the training department peer group support

8.8 For major incidents i.e., where death or serious injury has occurred, where a criminal investigation may result or where there has been a serious failure of a piece of equipment, external agencies such as the Health and Safety Executive, Medicines and Healthcare Regulatory Agency (MHRA), relevant CCG, NRLS or Police should be communicated with, to either form part of the investigation team or to share lessons learnt.

8.9 The Investigating Officer may be able to take remedial action immediately for any immediate and/or underlying causes but will more usually make recommendations for possible solutions to prevent a recurrence. If the recommendations fall within the remit and level of authority of the Investigating Officer they should be implemented without delay and recorded in the DATIX report. If they are of a wider scope, require additional resources or have implications across the Trust they will be referred to the appropriate Director and included on the Corporate Risk Register and forwarded for approval, via the Health, Safety and Risk Group, to the Quality and Safety Committee.

8.10 SIRIs or 'Never Events' reported to the relevant CCG will be investigated by an Investigation Manager supported by relevant experts depending on the nature of the incident.

8.11 The Serious Incident Review Group will monitor and follow up all relevant action plans developed from SIRIs/Never Events reported to the lead CCG. The lead manager or departmental director will monitor and follow up action plans developed from a green or yellow risk investigation.

9. SUPPORTING STAFF INVOLVED IN ADVERSE INCIDENTS, CLAIMS AND COMPLAINTS

For Duties see section 3.0 to 3.12.

9.1 If any member of staff is experiencing difficulties following an adverse incident, complaint or claim the line manager should offer immediate support.

9.2 Managers are responsible for ensuring that staff are given the opportunity to debrief

following an adverse incident (whether an incident, complaint or claim) and that staff are informed of how to access counselling services and additional support. This list of actions is available for managers or individuals to take if the staff member is experiencing difficulties associated with the event:

- Occupational Health Services
- Employee Assistance Scheme (Optum – www.livewell.optum.com – password SCAS)
- Leave of absences
- Trust's solicitors approved by the NHSLA
- Counselling
- Staff Union Representatives
- Clinical Educators

(This list is not definitive)

9.3   No member of staff should attend a court hearing or an internal investigation on their own. If a member of staff receives notification of court proceeding, they should contact their line manager immediately.

9.4   The Trust will provide support to staff identified as a witness in any investigation or court proceedings, in the preparation of statements, the court appearance and a debriefing following the court appearance. This will be assessed by the line manager and the Risk Department and the appropriate level of internal and external support provided.

9.5   Managers are to maintain regular contact with all staff involved in any adverse incident, claim or complaint until such time as the members of staff are satisfied and the proceedings or concerns are completed.

10.   DUTY of CANDOUR and BEING OPEN (PATIENT SAFETY INCIDENTS)

10.1   These guidelines describe how the Trust meets it's obligations to healthcare organisations/teams and patients and/or their carers by being open and honest about any mistakes that are made in the way patients are cared for and treated.

10.2   Details are provided on how and when staff should communicate with healthcare organisations/teams, patients and/or carers following a patient safety incident. It is based on recommendations made by the National Patient Safety Agency (NPSA) document 'Being Open: Communicating patient safety incidents with patients and their carers'. The document is available at: http://www.nrls.npsa.nhs.uk

10.3   A patient safety incident is defined as '*any unintended or unexpected incident that could have, or did, lead to harm for one or more patients receiving NHS funded healthcare'.*

10.4   Duty of Candour and 'Being Open' simply means apologising and explaining what happened to patients and/or their carers who have been involved in a patient safety incident. This process only applies to those incidents where a patient has been harmed; (moderate or severe). Currently the Health Act 2009 requires all NHS

organisations (including independent organisations providing NHS services) to have regard to the NHS Constitution which already provides, that: "The NHS also commits … when mistakes happen to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively." From this perspective, it looks as though the "change/impact" may be minimal. However, the 2009 Act only requires NHS organisations to have regard to the NHS Constitution, not to mandatorily follow it. In contrast, the new duty of candour is contractual and, therefore, will create a contractual obligation.

This policy should be read in conjunction with the Duty of Candour policy.

10.5 Apologising to a healthcare organisations/teams, patient and/or carers does not constitute an admission of liability. Ref NPSA/2009PSA003.

10.6 **Key Principles**

Communicating effectively with healthcare organisations/teams, patients and/or their carers is a vital part of the process of dealing with errors or problems with their care or treatment. Not only does effective communication reduce the distress caused by the incident, but it has also been shown that the likelihood of legal action is reduced as the majority of patients involved in a patient safety incident want an apology and explanation of what happened rather than financial compensation or disciplinary action. Patients are less likely to forgive medical errors for which they have not received an apology, or which have not been fully explained and as a result are more likely to press for compensation.

Throughout the whole process healthcare organisations/teams, patients and/or carers should be treated with sympathy, respect and consideration. Confidentiality should be maintained at all times by anyone involved in the incident.

The NPSA 'Being Open' document details ten key principles that should be adhered to when communicating with patients and/or carers about an incident. These are:

1. Acknowledgement of the incident.
2. Truthfulness, timeliness and clarity of communication.
3. Apology, verbal and written.
4. Recognition of patient and carer expectation.
5. Professional support.
6. Risk management and systems improvement.
7. Multidisciplinary responsibility.
8. Clinical governance.
9. Confidentiality.
10. Continuity of care.

These principles have been considered in developing this policy.

10.7 The incident may be identified by the healthcare organisations/teams, patient, carer or member of staff through a patient experience inquiry, claim, complaint or DATIX. All concerns must be taken seriously, patient concerns should never be dismissed without further investigation.

10.8 Following the occurrence of a patient safety incident staff involved in the patient's

care must explain to the patient and/or carer that an incident has occurred and that this will be investigated. A verbal apology should be offered as soon as the incident is identified and a record on the patient report form made.

10.9 The initial information given must be truthful, unambiguous and based solely on the facts known at the time. No speculation as to possible causes, no attribution of blame or comments or criticisms should be made. The patient should be informed that they will be updated through face-to-face meetings, verbal and or written communication as new information emerges. Further explanations and apologies may be necessary as the patient and/or carer begins to comprehend the situation. The patient and/or carer may require additional support and staff should facilitate this by providing repeated opportunities for further questioning and a single point of contact for any additional questions.

10.10 A DATIX must be completed and brought to the attention of the line manager. Staff as well as patients can be affected by their involvement in an incident. The line manager must ensure that the staff involved are fully supported after the patient safety incident and throughout any subsequent investigation. See Supporting Staff section 8.0.

NOTE: When establishing contact with the patient / family / carers, it is important to offer a variety of contact methods. A face-to-face meeting is seen as the optimum, and when making the offer to meet in a mutually acceptable place, home address or at a SCAS building, emotions, location and family wishes need to be considered. The initial contact by investigators will no doubt be via a telephone call, and it is at this point that the patient, complainant, family or carer preferences in respect of being contacted can be established. With patient choice being important, this decision should be noted and adhered to, but also offering other choices throughout the investigation process should be offered and again noted.

10.11 A face-to-face meeting should be set up as soon as possible to discuss the incident and establish the level of detail required by the healthcare organisations/teams, patient and/or carers, as they may not wish to know the details, this may be especially relevant if there has been a severe injury or a death. Clarity around the identity and role of the staff must be explained to the patient and/or carer as they may have some preference regarding who is present.

10.12 All communication should be documented, and a copy provided to the patient and/or carers. The documentation should include the time, place and date of the meeting along with the name and role of all meeting attendees; and include the patient and/or carers account of the events, which will further inform the investigation of the incident, and any concerns raised. Medical jargon and acronyms should be avoided. The documentation should be securely filed along with any correspondence notes, incident report forms and any statements taken.

10.13 Only clear, unambiguous and accurate information should be given. If all the facts are not known at the time of the meeting this should be explained to the patients and/or carers. Information of any support that can be accessed and information on the Patient Experience service and complaints procedure should be provided.

10.14 Details of how this information will be shared must be given to the patient and an opportunity for them to object given the proviso that information may not be shared for legal or public interest reasons.

10.15 During these meetings the patient and/or carers may express feelings of anger, confusion or anxiety and these should be dealt with appropriately.

10.16 An investigation into the cause of the incident must be conducted, the level of which will depend on the seriousness of the incident. The Patients and/or carers should be kept updated on progress with the investigation by further meetings, or verbal and /or written correspondence. Information should only be provided to the patient (s) and/or carers once the facts have been confirmed and the outcome report reviewed by the Risk Department. If this is not to be for some time, then regular contact with the patient and/or carers must be maintained to reassure them that the investigation is still underway.

10.17 At all points during the contact, the patient and/or carers should be asked if they require any contact details such as Patient Experience or external support agencies. These may have been declined at an earlier stage but may be required subsequently.

10.18 When the investigation is complete a written apology on behalf of the Chief Executive should be sent to the patient and/or carer. This should include an explanation of why the incident occurred i.e., the results of the investigation, any actions that have been put in place to prevent recurrence and a clear statement that the Trust is sorry for any harm or distress caused. Any concerns expressed by the patient and/or carer throughout the process should be summarised and addressed in this letter. The patient and/or carer should be offered an opportunity to provide feedback on both the outcome of the investigation and the Being Open process.

10.19 Throughout the process it is important that the patient is reassured that any dispute will not detract from future care.

10.20 Where patients and/or carers are not satisfied with the process, a mutually acceptable mediator should be arranged to help identify the issues where there is disagreement. The patient and/or carer should always be made aware of how to make a formal complaint.

10.21 The Head of Patient Experience is available to provide advice and work with the managers throughout the investigation process.

10.22 The Trust has a duty to provide a safe environment for patients and to learn from mistakes when they occur. The Trust will report all patient safety incidents to the National Reporting and Learning System (NRLS) in line with National Guidance.

Significant incidents will be subjected to full Root Cause Analysis as recommended by the NRLS – still available through the NPSA site. The Trust has made available to all managers the NRLS Incident Decision Tree which will be used for all significant incidents.

10.23 The Trust is committed to increasing the reporting of patient safety incidents and provides an open reporting culture for staff to report incidents and provide feedback to staff. This in turn will encourage reporting from staff and will enable them to feel able to admit errors. The Trust reviews patient safety incidents to improve the patient's experience and the care provided by the Organisation. The Trust has appointed a Non-Executive Director to the role of Patient Safety Champion who is

a member of the Quality and Safety Committee.

11. ANALYSIS AND IMPROVEMENT

For Duties see section 3.0 to 3.12.

11.1 The DH publication 'An organisation with a memory' (2000) emphasises the need to learn from adverse events. Whilst the occurrence of adverse incidents, claims and complaints almost automatically leads to reactive risk management (damage limitation and immediate remedial action) they can also be seen as an opportunity for proactive risk management (learning from what has happened) and looking ahead to see how the same things or worse can be prevented from happening again.

11.2 The Risk Team, using DATIX, will collate all adverse incidents, claims, compliments and complaints and produce aggregated reports to include qualitative and quantitative analysis, trends, actions and recommendations at every meeting held by the Operational Health, Safety and Risk Group (non clinical) and Patient Safety Group (clinical).

11.3 Reports for claims, incident, compliments and complaints should include the following:

- The numbers by month through the year compared to last month's/years data to identify variations in numbers in form of graphs
- The numbers by category by month and through the year and a comparison made between last month's/year's data to identify variations in numbers in the form of graphs
- Narrative should include, within each report, an overview of previous reports and current situation. Include all high-risk areas within the report in detail. Identify any trends either high or low and make recommendations and action plan with named individuals for approval.

The system is able to identify trend and locator analysis which contributes to the above reports.

11.4 Each of the Groups/Committees will receive and review the reports as follows:

a. Serious incidents will be reviewed, and actions/recommendations monitored by the SIRI review group and Trust Board.

b. A claims report will be reviewed, and actions/recommendations monitored by the Executive Management Committee.

c. Adverse incidents will be reviewed, and actions/recommendations monitored by the Operational Health, Safety and Risk Group and the Patient Safety Group.

d. All compliments and complaints will be reviewed, and actions/recommendations monitored by the Patient Experience Review Group and Executive Management Committee.

11.5 All of the Groups and Committees have agreed Terms of Reference and meet four

or six times a year and report to the next Quality and Safety Committee through upward reports. Throughout the committee structure there is representation from all directorates and groups to ensure good communication. See Committee Structure in the Risk Management Strategy and the Terms of References.

11.6   The relevant group/committee will be the primary reviewer of the relevant reports and will identify any underlying causes within the report. The group/committee or panel will use the report to produce an improvement strategy with prioritised actions designed to eliminate root causes, responsibilities, timescales and indicators to measure the effectiveness of the actions taken. Residual risk that cannot easily or immediately be resolved by the implementation of the improvement strategy will be incorporated into the corporate risk register and reported to the Quality and Safety Committee.

11.7   It is vital that changes from incidents locally and organisationally are communicated across the Trust in order to demonstrate continuous learning. Outcomes will be shared with appropriate groups or committees and where appropriate internal and external stakeholders will also be informed to share safety lessons. Where follow up action has involved a change of practice or there are lessons to be learnt this will be communicated through Trust newsletter, training programmes and training needs analysis, risk/safety bulletins, risk alerts, safety notices and staff briefings. We will also communicate with our stakeholders in writing, sharing lessons learnt and providing regular updates where appropriate. A log demonstrating implemented change will be maintained by the Serious Incident Review Group.

11.8   Progress on implementing recommendations to reduce the risk and measure the effectiveness of actions taken will be monitored by Executive Management Committee through regular reports until such time as the risk has been managed to an agreed level.

12.   ADVERSE INCIDENTS RELATING TO MEDICAL EQUIPMENT

12.1   All adverse incidents will be reported through the completion of a DATIX report.

(Note: Examples of medical devices include resuscitators, wheelchairs, defibrillators, syringes and needles, dressings, lifting equipment including stretchers, etc.)

12.2   Following the failure of a medical device the item of equipment must be immediately withdrawn from service and held securely for inspection.

12.3   The local manager will investigate and document the background to the incident. All associated documents, e.g., statements, service records, etc. are to be attached to the DATIX report and submitted to the Risk Department.

12.4   The Assistant Director of Support Services will via the Clinical Risk Manager advise the Medicines and Healthcare Products Regulatory Agency (MHRA) of any reported incidents, the manufacturer/supplier, and will notify other Ambulance Trusts as necessary.

13. INCIDENTS RELATING TO MEDICINES MANAGEMENT

13.1 All incidents regarding medicines should be reported immediately on the Trust's electronic incident reporting system (DATIX) and the Medicines and Research Manager contacted, who will advise on MHRA notification.

13.2 In the event of a defect or suspected defect, the medicine must be labelled and stored separately from other medicines to prevent inadvertent use. The line manager must be notified and will decide (in consultation with the Medicines and Research Manager or a Medical Director) if it is appropriate to withdraw from use all medicine of the same batch pending further investigation.

13.3 All other departments (including the *Make Ready* service, a contracted service) holding stock of the faulty medicines should be informed immediately by telephone. If appropriate, Emergency Operations Centres should be informed and instructed to notify all vehicles to prevent further administration.

13.4 All Medicines incidents must be reported to the Risk Department and have a DATIX report completed.

14. ACCIDENTS AND INJURIES

14.1 All accidents including those which involve injury to employees, patients, contractors and third parties affected by the Trust's operation must be reported to the Risk Department using a DATIX report.

15. EXTERNAL AGENCIES

15.1 RIDDOR reportable injuries and incidents must be notified immediately to the Risk Department in order that the Health and Safety Executive (HSE) may be informed at the earliest possible opportunity.
(Note: Further information may be found in the Trust RIDDOR Policy).

15.2 All incidents involving violence and aggression towards SCAS staff will be reported to the Head of Risk & Security. Line managers are required to encourage and support all staff that have been subject to violence or abuse, in reporting all such incidents to the Police and recording them as a crime.
(Note: Further information may be found in the Trust Violence and Aggression Policy)

15.3 All relevant adverse incidents involving medical products will be reported by the Clinical Risk Manager to the MHRA.

15.4 The National Learning and Reporting System (NRLS) will be advised by the Clinical Risk Manager of all incidents involving injury or 'near miss' to patients.

15.5 The relevant commissioners, local and the Care Quality Commission will be advised

of all Serious Incidents Requiring investigation (SIRIs).

In the event of a SIRI/Never Event involving a death, the relevant Coroner should be informed of the circumstances and that an investigation is taking place.

15.6 The Trust will share cross border risks with other Health and Local Authority partners and will work collaboratively in any investigation and subsequent implementation of control measures and or lesson learned ensuring feedback to the teams concerned.

16. SECURITY

16.1 All incidents (either actual or potential) regarding security matters shall be reported using the DATIX report. Such incidents may include theft, criminal damage, unlawful entry to Trust premises, etc.

16.2 The Police are to be informed immediately about all incidents involving theft, criminal damage or suspicious behaviour. Copies of any statements and details of the Police action and crime report number are to be forwarded to the Head of Risk & Security.

17. FIRE INCIDENTS

17.1 In all cases of fire the Trust Fire Policy and local premises fire procedures must be strictly adhered to.

17.2 The Duty Executive Director must be notified immediately by the Emergency Operations Centres of any confirmed fire involving Trust property.

17.3 The senior manager present or attending the fire shall complete DATIX report. All false alarms should be similarly recorded.

18. DEFECTS IN ENGINEERING PLANT, INSTALLED SERVICES, BUILDINGS AND BUILDING FABRIC.

18.1 Normal day-to-day failure of equipment and plant need not be reported under the guidelines of this policy. Only major, repeated or potentially serious failures and those involving actual or potential injury or harm should be reported on DATIX report. In all other cases the Trust Defect Reporting Procedures will apply.

19. VEHICLE ACCIDENTS AND DEFECTS.

19.1 All traffic accidents involving Trust vehicles shall be reported and investigated in accordance with the Driving and Care of Trust Vehicles Policy.

19.2 Where personal injury occurs as a result of a road traffic accident involving a Trust vehicle then a DATIX report must be completed.

19.3 Normal day-to-day vehicle defects should be reported in accordance with the Trust's vehicle defect reporting procedure. A DATIX report should however be submitted where there are concerns about safety, or welfare of staff, patients or others.

19.4 The Driving Standards Manager will review and investigate all vehicle accidents and recommend the appropriate actions.

20. WHISTLEBLOWING POLICY

20.1 The Trust believes that any member of staff wishing to express their concerns regarding any issue within the Trust will be able to do so freely, without fear of blame or retribution, and will have their voice heard.

20.2 In the unlikely event that issues are not resolved through other Trust Procedures, and the member of staff has genuine and serious concerns that the risk has not been adequately addressed the individual may recourse to the Trust's Whistle Blowing Policy.

21. MONITORING

21.1 Key performance indicators will be monitored by the Patient Safety Group these will include:
- Number and Percentage of staff completing mandatory and induction training in year Number of incidents reported through the Whistle Blowing Policy
- Number of Adverse Incidents, Serious Incidents, Complaints and Claims reported, and the time taken to complete along with the outcome and learning of these incidents and the pathway in which a claim arose from
- Number of Root Cause Analysis performed on Adverse Incidents, Complaints, Claims, Serious Incidents and reported outcome
- Number of reported incidents to external agencies (NPSA/NRLS, STEIS)
- Proportion of identified potential control measures that have been actioned against risks identified through incident investigation (monitored through risk register review).

21.2 All of the KPI's are monitored at the Patient Safety Group. Specific ones are also monitored at the following:

- Patient Safety Group monitor all of the above and in particular the Trust Monitoring of Action Plans which includes high level investigations
- Patient Safety group will monitor progress and outcomes of clinical investigations, patient involvement and subsequent action plans
- A review on achievements against objectives set in Committee Terms of Reference will be escalated through the committee structure.

21.3 Effectiveness of managerial investigation will be monitored by the Quality and Safety Committee and risks identified will be entered onto the Corporate Risk Register.

22. TRAINING

22.1 The Education Review Group reviews the training needs analysis annually taking into consideration risk assessments and the trends analysis of key performance indicators (KPIs) that it receives at each meeting.

22.2 The results of the training needs analysis are used to inform the SCAS Training Programme.

22.3 The Trust recognises the importance of training and education in increasing awareness of risk and safety issues. All staff will receive information, instruction, training and supervision in relation to Health and Safety, Risk Management, Complaints, Claims, Patient Experience, Being Open and Adverse Incident Reporting as provided through the Trust's Training Needs Analysis.

22.4 Managers will provide advice at a local level; in particular they will emphasise the need for open communication and seek further professional advice when required.

23. EQUALITY IMPACT STATEMENT

The Trust is committed to promoting positive measures that eliminate all forms of unlawful or unfair discrimination on the grounds of age, marriage and civil partnership, disability, race, gender, religion/belief, sexual orientation, gender reassignment and pregnancy/maternity or any other basis not justified by law or relevant to the requirements of the post. The Trust will therefore take every possible step to ensure that this procedure is applied fairly to all employees regardless of the aforementioned protected characteristics, whether full or part-time or employed under a permanent or a fixed-term contract or any other irrelevant factor.

By committing to a policy encouraging equality of opportunity and diversity, The Trust values differences between members of the community and within its existing workforce, and actively seeks to benefit from their differing skills, knowledge, and experiences in order to provide an exemplary healthcare service. The Trust is committed to promoting equality and diversity best practice both within the workforce and in any other area where it has influence.

Where there are barriers to understanding; for example, an employee has difficulty in reading or writing, or where English is not their first language, additional support will be put in place wherever necessary to ensure that the process to be followed is understood and that the employee is not disadvantaged at any stage in the procedure. Further information on the support available can be sought from the HR Department.

Employees exercising their rights and entitlements under these regulations will suffer no detriment as a result.

24. OTHER REFERENCE & RELATED DOCUMENTS

Risk Management Strategy
Health and Safety Policy & Procedures
Control of Infection Policy & Procedures
Patient Experience Policy
Duty of Candour policy
Serious Incidents policy
Risk Register and Associated Risk Assessments and Action Plans
Board Assurance Framework
Whistle blowing Policy
Capability Policy
Disciplinary Policy
Driving Standards Policy
Security Policy
Counter Fraud Policy
Safeguarding policy

For further guidance on reporting SIRIs see the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation which can be found at: https://www.england.nhs.uk/patientsafety/serious-incident/

NPSA Website: www.npsa.nhs.uk
RCA Forms and Toolkit

APPENDIX 1: PROCESS FOR THE REPORTING OF RISK/ADVERSE INCIDENTS

Adverse Incident occurs or risk identified
Member of Staff

↓

Incident reported by DATIX completed and sent electronically to Risk Department within 24 hours
Member of Staff

Column 1:

DATIX received by Risk Department, reviewed and entered onto Risk Management Database
Risk Assistant

↓

Incidents reviewed and reports produced for Health, Safety & Risk Group Meeting. Operational Risk Register updated where necessary
Risk Managers

↓

Quality & Safety Committee review trends and serious incidents
Assistant Director of Quality (ADQ)

↓

Trust Board review trends, serious incidents and processes including recommendations
Director of Patient Care (DOPC)

Column 2:

Line Manager reviews DATIX, begins investigation and implements any immediate actions
Line Manager

↓

Depending on type of incident and risk score, DATIX may be allocated to Department Head, Area Manager etc for investigation and feedback
Investigating/Line Manager

↓

Investigation to be completed with 29 days, feedback provided to originator and DATIX completed - Risk Department process and close on database
Investigating/Line Manager

↓

Risk formally assessed and assurance sought that appropriate actions are taken
Risk Managers

Column 3:

External Agencies such as: HSE, CCG, NRLS, MHRA, NHS Protect informed as required
Risk Department

↓

Significant risks identified and staff informed via Risk Information Notices
Risk Department

↓

Incident trends and performance reported to staff via Hot News and Staff Matters
Risk Department

APPENDIX 2: EASY GUIDE – ADVERSE INCIDENTS

This guide is an 'aide memoire' to assist staff and managers in DATIX reporting procedure detailed in the **Trust Adverse Incident and Reporting Policy**. All staff and managers must read this policy before using this guidance.

Why Report?

The Trust actively encourages staff to report adverse incidents and has adopted a fair blame culture with regards to reporting risk. The primary purpose of reporting and investigating is to learn why the incident occurred by identifying the root causes of the incident and to prevent reoccurrence and not to apportion blame. The Trust encourages openness and constructive criticism particularly in relation to clinical care.

Successful risk management depends upon both pro-active and reactive risk identification and reporting. The Trust's DATIX reporting system should be used to report all risks irrespective of their type or origin and where the incident may result in a complaint or litigation being brought against the Trust. If in doubt, report the incident or contact the Risk Department for advice. The following list provides examples but is not exhaustive.

- All incidents involving injury to patients, staff or third parties
- All violence and aggression incidents irrespective of whether physical assault occurred
- All security incidents, such as theft, vandalism, intruders on Trust premises or breaches in Information Technology
- All clinical incidents such as equipment failure, medication errors, drug reactions or inappropriate procedures
- Any hazard or risk which if left unattended might result in loss or harm to the Trust, patients, staff or others
- Any near miss
- Any breach of patient confidentiality.

Guidance for Staff

The DATIX report is in electronic format, and available to all staff via the SCAS Intranet. When the information has been entered on the DATIX report, by clicking "Save" and "Submit" the system automatically sends the report to the Risk Department for review. If DATIX is not available due to technical difficulties, then the provided IR1s should be completed and then faxed to the Risk Department on **01869 365215** by the reporting member of staff within 24 hours of the incident taking place.

- When using the IR1 Forms these should be completed neatly and legibly using a

black or blue pen
- Complete the form (DATIX or IR1) as fully as possible, if using an IR1 form and, if it is necessary, continue on a separate sheet which must include the original IR1 serial number
- When using the IR1 form, tick all the appropriate boxes
- Ensure all comments are accurate, relevant and factual. Do not make subjective comments, or hearsay as the form may need to be produced in a court of law
- If concerned over the potential seriousness of the incident contact the Risk Department by telephone for advice
- All cases of crime must also be reported to the Police and the crime unique reference number (URN) recorded on the form
- In the case of injury to staff, clearly indicate the anticipated period of absence from work as there may be a need for the Trust to inform the HSE under RIDDOR
- If you have had to utilise an IR1 form, once faxed, forward the IR1 to your line manager.

Where serious injury, risk, death, fire or loss occurs, the EOC and Risk Department should be informed immediately with a request for a Senior Manager to attend the incident. The relevant Operational Director and the Director of Patient Care must be notified immediately by telephone, including events that occur outside of normal working hours. In the event of it not being possible to contact the relevant Operational Director, the duty Executive Director must be immediately informed.

Guidance for Managers

When an incident report form on DATIX is completed, within the system there is the facility for the reporter's line manager to be emailed and informed of the incident. When the manager receives this email, it should be opened as soon as possible and responded to accordingly.

If an IR1 has had to be utilised and faxed to the Risk Department, the IR1s must be forwarded to the member of staff's line manager. Line managers must ensure they have a process in place within their team/department to receive notification of submitted IR1s from their staff such as a phone call, email or collection point. On receipt of a DATIX or IR1 the line manager will:

- Check that the content of the DATIX report, if it is an IR1, ensure that it has been completed correctly and the risk rated by the member of staff. If not, the form should be updated and re- faxed to the Risk Department
- If an IR1 has been completed, ensure that a copy of the IR1 has already been faxed to the Risk Department. This should be indicated in the box on the top right-hand corner of the form.
- Undertake an initial investigation to ascertain the facts and identify any immediate actions required to eliminate, reduce or control the risk where possible. If appropriate, staff should be alerted verbally, on notice boards or by email
- Conduct any necessary interviews and obtain statements to accompany the DATIX or IR1 where appropriate.
- Enter all outcome information or comments onto the DATIX report itself, or complete the Line Manager's Comments section of the IR1 if that has been

used. This should include any immediate actions taken and, if appropriate, the department/person to whom the DATIX / IR1 has been forwarded for investigation.

- If an IR1 has been used, send it to the department/person responsible for the investigation. A copy of the form should be retained by the line manager
- Upon completion of the investigation check the DATIX report for any outstanding issues and if an IR1 has been utilised, ensure the Actions section of the form has been completed with actions or recommendations and an updated risk rating. If they are not satisfied with the outcome of the investigation, they should redress the issue with the investigating officer or raise their concerns with the Risk Department or a Senior Manager within their Directorate
- Ensure they or the Investigating Officer provides feedback to the member of staff who submitted the DATIX or IR1. On the IR1, this should be recorded on the Staff Sign Off section of the form. Feedback to staff on the actions taken following a reported risk is critical in improving and maintaining staff engagement
- With regard to an IR1 having been completed, fax or post the completed IR1 including any statements, reports, photographs etc to the Risk Department.

Guidance for Investigations

The level of investigation will be dependent upon the risk rating and the type of incident/risk. General guidelines are as follows:

Risk Rating:

- Low Risk (Green, 1-3) – Local line manager should investigate and identify learning points or safety improvements

- Moderate Risk (Yellow, 4-6) – Local line manager should investigate; however, the nature of the incident and possible implications may require input from another department and the involvement of a more senior manager

- Significant Risk (Amber, 8-12) – Requires root cause analysis investigation led by a suitably trained manager. It will be the responsibility of the investigating manager to ensure all learning points and safety improvements are identified and implemented

- High Risk (Red, 16-25) – Requires full root cause analysis investigation by a suitably trained manager, or one of the dedicated Trust Investigation Managers in the event of a SIRI. The recommendations from the investigation report may be included on the corporate risk register and any identified actions monitored by the Quality and Safety Committee.

APPENDIX 3: TRUST RISK SCORING SYSTEM CONSEQUENCE/IMPACT SCORE

	1	2	3	4	5
Descriptor	**Insignificant**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Injury (Physical & Mental) to anyone	Minor injury (not requiring first aid)	Minor injury or illness (first aid treatment needed)	Reportable to external agencies/statutory bodies (e.g. RIDDOR, HSE, NRLS Police, MHRA, CCGs)	Major injuries, or long term incapacity / disability (loss of limb)	Death or major permanent incapacity
Patient Experience	Unsatisfactory patient experience no injury	Unsatisfactory patient experience and or involving first aid treatment – readily resolvable	Mismanagement of patient care requiring more than first aid treatment and is likely to take more than one month to recover (breach of working practices)	Serious mismanagement of patient care (major permanent harm) (breach of working practices)	Totally unsatisfactory patient care (breach of working practices)
Complaint / Claim Potential	Locally resolved complaint	Justifiable complaint peripheral to clinical care / management	Justifiable complaint involving lack of appropriate care / management Claim below excess	Multiple justifiable complaints. Claim above excess	Multiple claims or single major claim
Objectives / Projects	Insignificant cost increase / schedule slippage Barely noticeable reduction in scope or quality	< 5% over budget / schedule slippage Minor reduction in quality or scope	5 – 10% over budget / schedule slippage Reduction in scope or quality requiring client approval	10 – 25% over budget / schedule slippage Does not meet secondary objective(s)	> 25% over budget / schedule slippage Does not meet primary objective(s)
Service / Business Interruption	Loss / interruption < 1 hour	Loss / interruption >1 hour and < 8 hours	Loss / interruption > 8 hours and < 24 hours	Loss / interruption > 24 hours and < 1 week	Loss / interruption > 1 week
Human Resources / Organisational Development	Short term low staffing level temporarily reduces service quality < 1 day	Ongoing low staffing level reduces service quality	Late delivery of key objective / service due to lack of staff (recruitment, retention or sickness). Minor error due to insufficient training. Ongoing unsafe staffing level(s)	Uncertain delivery of key objective / service due to lack of staff (recruitment, retention or sickness). Serious error due to insufficient training	Non delivery of key objective / service due to lack of staff. Very high turnover. Critical error due to insufficient training
Financial	Small loss < £100	Loss > 0.1% of budget or > £100 and < £1,000	Loss > 0.25% of budget or > £1,000 and < £5,000	Loss > 0.5% of budget or > £5,000 and < £10,000	Loss > 1% of budget or > £10,000
Inspection / Audit	Minor recommendations Minor non-compliance with standards	Recommendations given Non-compliance with standards	Reduced rating Challenging recommendations. Non-compliance with core standards Reportable to associated external / statutory agencies	Enforcement action Low rating. Critical report. Multiple challenging recommendations. Major non-compliance with standards	Prosecution Zero rating. Severely critical reports.
Adverse Publicity / Reputation	Rumours	Local Media interest (short term)	Local Media interest (long term)	National Media interest < 3 days. Local MP concern	National Media interest > 3 days. National MP concern (questions in the House)

Risk Scoring System Likelihood Score

	1	2	3	4	5
Descriptor	**Rare**	**Unlikely**	**Possible**	**Likely**	**Almost Certain**
Frequency	Not expected to occur annually	Expected to occur at least annually	Expected to occur at least every 6 months	Expected to occur at least monthly	Expected to occur at least weekly
Probability	< 1%	1 – 5%	6 – 25%	26 – 60%	> 60%
	Will only occur in exceptional circumstances	Unlikely to occur	Reasonable chance of occurring	Likely to occur	More likely to occur than not

Governance & Risk Management

Successful risk management depends upon both pro-active and reactive risk identification and reporting, the Consequence/Impact & Likelihood **Descriptors** can be used by any part of the organisation to help determine any eventuality whether it be Financial, Human Resources or Training etc and for scoring items being placed on the Trust Risk Register.

Incident Reporting / Investigation - Datix

DATIX user guide can be found on the SCAS intranet site by entering DATIX within the search bar, once on the new page scroll down to the documents section and select DATIX user guide which is in PDF format.

Incident Reporting/Investigation (Ir1)

The IR1 form will also be available on the Trust intranet as a backup if DATIX was to go off-line. The user guide will also be available via the Trust's Intranet site.

PROCEDURE Person reporting

1. Identify a heading from the **Descriptor** column in Table 1;
2. Consider and match to as near as possible the Consequence – Impact of the incident / occurrence from the definitions under, a. **Insignificant, Minor, Moderate, Major, Catastrophic.**
3. Tick the box on the IR1 form that corresponds to this figure under **Impact** heading in 'Incident Details'.
4. Identify a heading from the **Descriptor** column in Table 2;
5. Consider and match to as near as possible the Frequency and or Probability from the definitions under. **a. Rare, Unlikely, Possible, Likely, Almost Certain.**
6. Tick the box on the IR1 form that corresponds to this figure under **Likelihood** heading in 'Incident Details'.
7. Multiply the figures together from the **Impact & Likelihood** boxes and place this number in the 'Total Risk Score' box.

PROCEDURE Person Investigating

Following your investigation of the incident/occurrence follow the steps outlined above in 1 – 7.
The scores identified from the **Descriptors** column in Table 1 & 2 are decided upon following any remedial action identified/taken.

APPENDIX 3A: TRUST RISK ASSESSMENT MATRIX

Likelihood / Consequence	Rare (1)	Unlikely (2)	Possible (3)	Likely (4)	Almost Certain (5)
Insignificant (1)	1	2	3	4	5
Minor (2)	2	4	6	8	10
Moderate (3)	3	6	9	12	15
Major (4)	4	8	12	16	20
Catastrophic (5)	5	10	15	20	25

It is important that all recorded incidents are immediately and appropriately investigated, and feedback provided to the submitting member of staff by the investigating officer/line manager as early as possible, however not all incidents require investigation to the same extent and depth.

Category	Investigation	Analysis	Outcome
Red (High)	- Full investigation by local/duty manager - Executive Director notified by telephone	- Full Root Cause Analysis - Refer to Ex Team - Refer to QSC - Board informed	- Immediate control measures implemented - Long term improvement strategy developed
Amber (Significant)	- Full investigation by local/duty manager - Executive Director notified within 24 hours or by telephone if appropriate	- Consider Root Cause Analysis - Refer to Ex Team - Refer to QSC	- Planned implementation of control measures
Yellow (Moderate)	- Investigation by local manager	- Trends monitored	- Where possible risk reduction measures introduced
Green (Low)	- Minimal investigation	- Trends monitored	- Minimal action

APPENDIX 4: GUIDANCE FOR MANAGERS ON INVESTIGATION AND ROOT CAUSE ANALYSIS

Introduction

The following guidance notes have been produced as an 'aide memoire' to assist managers in investigating reported risks, adverse incidents and near misses.

When do I need to investigate?

All risk reports require some degree of investigation and action, however in many cases incidents are relatively minor in nature and can be resolved quickly at a local level without the need for a formal investigation. In order to ascertain where the boundary is it is first necessary to risk score the incident report using the grid provided on the inside cover of the Risk/Adverse Incident Report Pad.

All significant and high risks (i.e. those involving injuries to patients, staff or others) should be fully investigated and recorded using full root cause analysis where appropriate.

Medium risks generally require full investigation but do not usually require root cause analysis unless re- occurring on a high frequency.

Incident Reporting Investigation Procedures

All incidents are to be investigated thoroughly by the appropriate line managers and the findings recorded on the South Central Ambulance Service NHS Foundation Trust DATIX reporting system.

Purpose of Investigation

- To fulfil legal duty
- To protect and gather evidence immediately following the incident
- To ensure appropriate lessons are learnt

The investigation must include full details of the circumstances of the incident to include:

a. Any equipment involved, recording type and serial number.
b. Any medication, recording batch number and date of drug.
c. Persons involved including staff and others.
d. Vehicles involved including make and registration.
e. Staff absences recording the length of time with an estimated return to work. Treatments received or follow up treatment planned.
f. Statements taken from third parties.
g. Police involvement recording incident number and PC identity.
h. Record facts which lead to the incidents, time, date, location, position of staff and where incident occurred.
i. Root Cause Analysis outcome.
j. Utilising tape recording within the call centre.
k. Utilising information from support databases.

Incident investigations should:

- Learn from the incident and make recommendations to help prevent or minimise recurrences, thus reducing future risk of harm
- Identify underlying failures in infrastructure
- Identify reasons for substandard performance
- Satisfy mandatory and other reporting requirements

Investigations will be led by a manager with the relevant knowledge and experience to make authoritative recommendations. In most instances within SCAS, the Investigating Officer will either be a Team Leader, PTS Manager or a nominated Senior Manager, other managers with specific areas of expertise e.g., Risk Managers, Assistant Director of Quality, Human Resources Department, Operational Directors or Ergonomics Adviser, may need to be involved or advise on certain cases. Other external stakeholders may also need to be involved, e.g., manufacturers of equipment, Health & Safety Executive. SIRIs and Never Events will be investigated by Investigation Managers.

A good investigation is prompt and thorough, to the necessary level and where possible remedial action or solutions will be recommended. If the investigation is not done as soon as practicable after the event, conditions and memories fade. The Investigating Officer is required to compile their report, basic analysis, action plan and recommendations.

There are five components of any investigation:

1. **Collect evidence** about what happened.
2. **Assemble and consider** the evidence.
3. **Compare the** findings with relevant standards, protocols or guidelines, whether these are particular to SCAS or national, to establish the facts, draw conclusions about causation.
4. **Make recommendations** for action to minimise risk of recurrence. *
5. **Implement the** recommendations, seeking collaboration with staff where possible and track progress.

(* when a full Root Cause Analysis is undertaken this may result in an Improvement Strategy being drawn up with prioritised actions, responsibilities, timescales and indicators to measure the effectiveness of actions taken)

1. **Collecting Evidence**
   The sources of information and methods that can be used in investigation typically fall into the three following categories:

Direct observation which is crucial to avoid losing important evidence about the scene, equipment involved, relationships between parts, etc.

Documentation, which identifies what has been recorded as happening at the time, helps establish what should have happened, as well as providing evidence of prior risk assessment, inspections, tests, etc.,

Interviews, which, conducted sensitively, provide both direct testimony as well as

an opportunity to check back on any issues arising from examination of the physical and documentary evidence.

Although these are distinct and important elements of a thorough investigation, they complement each other. They provide an opportunity to 'read across' from one part of the process to another to check reliability and accuracy as well as resolve differences and gaps in evidence.

Adverse incidents seldom arise from a single cause; there are usually underlying failures in management systems, which have contributed to the circumstances leading to the incident.

2. **Assembling and Considering the Evidence**
Good investigations identify both immediate and underlying causes, including human factors. Immediate causes include the patient, the task, the work environment and the people involved, either individually or as part of a multi-disciplinary team. Underlying causes are the management, organisational, cultural and contextual factors that explain why the event occurred. Getting to the root of the problem by identifying the key underlying, or root causes, will help ensure development of an effective improvement strategy later on in the process that, if properly implemented, should prevent or significantly reduce the risk of recurrence.

3. **Comparing Findings with Relevant Standards & Protocols**
The next stage of the investigation is to compare the conditions and sequence of events with relevant standards, guidelines, protocols etc. This helps to minimise the subjective nature of investigations and to generate recommendations which have the maximum impact and relevance. The objectives are to decide:

- If suitable standards/procedures etc have been set to control all the factors influencing the incident
- If standards/procedures etc exist, are they appropriate and sufficient?
- If the standards/procedures were good enough, were they applied or implemented appropriately?
- Why any failures occurred?

4. **Make Recommendations**
Where the investigation identifies immediate or underlying causes involved, the Investigating Officer may be able to either take remedial action immediately or make recommendations for possible solutions to prevent recurrence within the Action Plan.

5. **Implement Recommendations**
If recommendations fall within the remit and level of authority of the Investigating Officer, they should be implemented without delay. If however, they are of a wider scope, require additional resources or have implications across the Trust, the risk and recommendations should be placed on the appropriate risk register and discussed with their line manager or Director, in accordance with the Trust Procedure for the Maintenance of Risk Registers.

Red incidents (and some Amber) will be followed up by the SIRI Review Group who will instruct that a full root cause analysis of the incident be undertaken. This

will usually result in an Improvement Strategy being drawn up with prioritised actions, responsibilities, timescales and indicators to measure the effectiveness of actions taken.

It is important that progress on implementing recommendations or improvement strategies is tracked and that the effectiveness of actions taken is monitored. Effective actions result in demonstrable improvements in safety and, where appropriate, quality of care.

For advice and guidance on completing the incident report forms contact the Risk Department.

Further Guidance on carrying out a Risk Assessment

Introduction
South Central Ambulance Service NHS Foundation Trust has produced this document to provide a generic guide for the establishment and implementation of the risk management process involving establishing the context and the identification, analysis, evaluation, treatment communication and ongoing monitoring of risk. Risk Management is recognised as an integral part of good management practice. The Organisation is committed to expanding its knowledge of risk management and the intention is for a fully comprehensive risk management programme to be conducted throughout the services provided. To ensure adequate Healthcare Standards and clinical governance processes are followed. This document has been prepared using the joint Australia/New Zealand Standard on Risk Management, revision AS/NZ 4360:1999, which has been adapted to meet the needs of the Organisation to assess risks associated to Health and Safety incidents, Clinical Incidents and Complaints. This document is accepted as an International best practice document.

Aim

The principal aims of the risk assessment procedure are:

a. Reduce the exposure of risk to the lowest possible level.
b. Provide the Organisation with an acceptable level of risk, which can be managed throughout the Organisation.
c. Provide an early warning system for managing risk events.
d. Provide data and information to monitor and manage risk within the Organisation.

Objective

To control the risk for the Organisation across all directorates by identifying and managing risk and at the same time heightening the awareness and importance of risk management.

Operational Use

Risk management can be applied at strategic and operational levels within the organisation. It may be applied to specific projects to enhance the decisions

process and manage specific recognised risk areas. Risk management is an interactive process that can contribute to organisational improvement. With each cycle, risk criteria can be strengthened to achieve progressively better levels of risk management. For each stage of the process adequate records should be kept, sufficient to satisfy independent audit.

Management of risk is a multifaceted process, appropriate aspects of which are often best carried out by a multi-disciplinary team. A risk assessment should be carried out using members of staff, from all levels, with relevant experience in the area being assessed. The line manager, along with the Risk Department, will be responsible for co-ordinating the risk assessment and provide the appropriate members of staff. The assessment team should be kept to a minimum and be able to communicate the findings and influence the outcome.

The risk assessment tool should be applied for the following reasons or function:

a. For grading all incidents and complaints reported through the Organisation's incident reporting system by senior managers, line managers and supervisors.
b. Introduction of equipment, vehicles or premises.
c. For any new initiative introduce by the Organisation i.e., SRV and First Responders, new IT software.
d. Any major risk which has been identified by the Organisation.
e. To manage and risk assess corporate management issues, policies and procedures.
f. Identify risk within each operational directorate.
g. When changing clinical and non-clinical practice (change management).
h. Re-evaluate existing risk treatment plans on a continuous basis.

Methodology

The main elements of the risk management process are as follows:

a. Establish the context: establish the strategic, organisational and management context in which the rest of the process will take place. Criteria against which risk will be evaluated should be established and the structure of the analysis defined.

b. Identify risks: identify what, why and how things can arise as the basis for further analysis.

c. Analysis risk: determine the existing controls and analyse risks in terms of consequence and likelihood in the contexts of those controls. The analysis should consider the range of potential consequences and how likely those consequences are to occur. The consequence and likelihood scores should be multiplied to produce an estimated level of risk.

d. Evaluate risks: compare estimated levels of risk against the pre-established criteria. These enable risks to be ranked so as to identify management priorities. If the levels of risk established are low, then risks may fall into an acceptable category and treatment may not be required.

e. Treat risks: accept and monitor low-priority risks. For other risks, develop and implement a specific management plan, which includes consideration of funding.

f. Monitor and review: monitor and review the performance of the risk management system and changes which might affect it.

h. Communicate and consult: communicate and consult with internal and external stakeholders as appropriate at each stage of the risk management process and concerning the process as a whole.

Risk Documentation

Each stage of the risk management process should be documented. Documentation should include assumption, methods, data sources and results. The reasons for documentation are as follows:

a. To demonstrate the process is conducted properly.
b. To provide evidence of a systematic approach to risk identification and analysis.
c. To provide a record of risks and to develop the organisation's knowledge database.
d. To provide the relevant decision makers with a risk management plan for approval and subsequent implementations.
e. To provide an accountability mechanism tool.
f. To facilitate continuing monitoring and review.
g. To provide an audit trail; and
h. To share and communicate information.

The Organisation will maintain a risk register using IT software Risk Management System, providing regular reports to the Trust's Quality and Safety Committee and Board. The following documents are provided for the record and assessment of identifying risk within the organisation:

1. SCAS Risk Consequence (Impact) Score (Appendix 3).
2. SCAS Risk Matrix Scores (Appendix 3A).
3. SCAS Risk Assessment Record (CEO1) (Appendix 6).
4. SCAS Risk Register.

Risk Assessment Evaluation and Risk Rating

Risk assessments should be re-evaluated using SCAS Risk Consequence (Impact) Score. With an agreed end date to ensure that the risk has been effectively managed. When analysing the risk, the following guidelines should be adhered to:

Green Level of Risk:
Low risk: managed by routine procedures*, so review timescale is one to two years.
Yellow Level of Risk:
Moderate risk: management responsibility must be specified, and review is six months to a year.
Amber Level of Risk:
Significant risk: senior management attention needed, and review is three to six months.
Red Level of Risk:
High risk; immediate action required and reviewed in one to three months.

* Defined as replacement/repair of equipment or local training at Departmental level. This would include Health and Safety issues relating to the premises and working practice in the workplace.

Using the Risk Consequence/Impact Score to identify the severity and likelihood of reoccurrence provides the Trust with information to quantify the level of acceptable risk. The colour coding within the risk assessment tool provides the Trust with four levels of risk. This is achieved by assessing the likelihood of reoccurrence on the column down the left-hand side, and the consequences or impact on the Trust using the top horizontal row. Identifying the colour in the square at the horizontal and the vertical juncture will give you the risk evaluation. The colour corresponds to the four levels of risk, Green and Yellow to be dealt with at local level by operational and line manager responsibility and the Amber and Red to be reported to the SIRI Review Group via the Quality and Safety Committee and Trust Board. The Trust Board has the authority and may choose to accept risks that are identified high scoring risks.

Review timescales should be applied to all levels of risk as in the above chart. This would involve re- evaluation of the Risk.

ROOT CAUSE ANALYSIS

Unless the fundamental, or root causes of adverse events or complaints are properly understood, lessons will not be learned, and suitable improvements will not be made to secure a reduction in risks. Adverse incidents rarely arise from a single cause; there are usually underlying failures in management systems, which have helped to create the circumstances leading to the incident.

Full Root Cause Analysis (RCA) will, in the majority of circumstances, be undertaken by the Investigation Panel (IP) often with the assistance of the relevant Investigating Officer or other managers with expertise in specific areas. Where necessary, this panel will also seek advice from external experts.

The purpose of the analysis exercise is to identify the Immediate, Contributory and Root causes of the incident or complaint and recommend remedial actions through an Improvement Strategy. It is not proposed, in this guidance, to include a detailed explanation of RCA, however RCA would normally include the following steps:

3.	Chart the event with current knowledge	Staff involved
4.	Gather documentary and other evidence	
5.	Revise the chart	
6.	Arrange and carry out interviews	Investigating Officer
7.	Revise the chart	
8.	Identify causal factors	
9.	Analyse causal factors	IP
10.	Decide on and cost the options for improvement	
11.	Provide a report	
12.	Ensure implementation of improvement strategy, phased if necessary	IP/ Line Mgr or Director

The Investigation Panel would initially review the investigation report for the incident and confirm the identified causal factors from the Investigating Officer's DATIX and complete a RCA Checklist and then analyse all the factors to identify possible risk treatments. The ultimate focus for the Investigation Panel will be on the underlying causes, as described earlier, the management, organisational, cultural and contextual factors. The Investigation Panel will use the Root Cause Analysis Report to summarise their findings and produce an Improvement Strategy.

Improvement strategies should be designed to eliminate the root cause(s). This may involve changes in training, policies, procedures, equipment etc.

Where it is not practicable to implement risk, treatments identified within the Improvement Strategy, the risk(s) should be logged on the appropriate Risk Register (in accordance with the Trust Procedure for the Maintenance of Risk Registers) to enable monitoring and review.

Membership of the Investigation Panel will be subject to the type of incident and which specialist manager is qualified to inform and take action on the identified Root Cause. The Investigation Panel will have a core membership of:
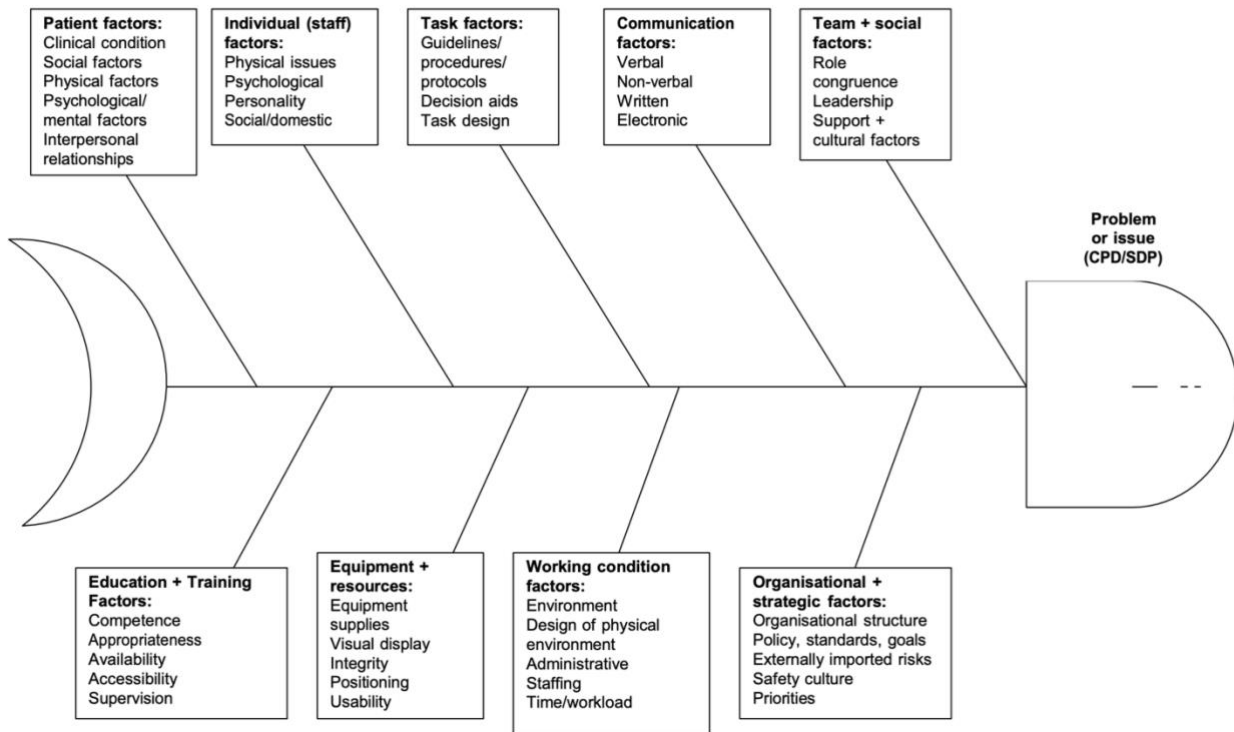
- Director of Patient Quality
- Assistant Director of Quality
- Risk Managers
- Investigating Officer
- Other managers as appropriate

Other members will be called at an ad hoc basis as they are required. This will always include the investigating officer who investigated the incident(s) to be reviewed.

APPENDIX 5: ROOT CAUSE ANALYSIS TOOLS

A root cause analysis form is available for Internal use by SCAS Staff. It can be accessed internally via our Staff Intranet.

RCA Tools – SCAS
Fishbone

Patient factors:
Clinical condition
Social factors
Physical factors
Psychological/
mental factors
Interpersonal
relationships

Individual (staff) factors:
Physical issues
Psychological
Personality
Social/domestic

Task factors:
Guidelines/
procedures/
protocols
Decision aids
Task design

Communication factors:
Verbal
Non-verbal
Written
Electronic

Team + social factors:
Role
congruence
Leadership
Support +
cultural factors

Problem or issue (CPD/SDP)

Education + Training Factors:
Competence
Appropriateness
Availability
Accessibility
Supervision

Equipment + resources:
Equipment
supplies
Visual display
Integrity
Positioning
Usability

Working condition factors:
Environment
Design of physical
environment
Administrative
Staffing
Time/workload

Organisational + strategic factors:
Organisational structure
Policy, standards, goals
Externally imported risks
Safety culture
Priorities

APPENDIX 6: RISK ASSESSMENT RECORD (CE01)

A risk assessment form (CE01) and a health, safety & risk group decision form is available for Internal use by SCAS Staff. It can be accessed internally via our Staff Intranet.