


SERIOUS INCIDENTS AND SIGNIFICANT EVENTS POLICY & PROCEDURE

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CHANGE RECORD

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V1	18/05/2015	Updated to ensure compliance with Serious Incident Framework (NHS ENGLAND) and respond to comments by CCG and introduction of Significant Event Analysis
V1.01	January 2016	Minor amendments
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1. INTRODUCTION

Humber NHS Foundation Trust is committed to providing the best possible service to its patients, service users and staff. The Trust recognises that, on occasions, serious incidents (SI), significant events (SE) or near misses will occur and that it is important to identify causes and to ensure that lessons are learnt to prevent recurrence. Learning from incidents is an important function of the Trust's commitment to the safety of its patients, staff and the general public.

This policy outlines the way in which SI and SE and/or near misses will be managed to ensure immediate actions are taken to ensure patient safety, provide support for staff, and ensure learning is embedded across the organisation; with changes to practice and or systems and processes to prevent reoccurrence.

2. BACKGROUND

This policy is based upon the guidance from NHS England (2015) and endorses 7 key principles in the management of **serious incidents** which are:

1. **Being open and transparent:** with both people affected and their family and staff involved in the incident,
2. **Preventative:** investigations are undertaken to ensure that weaknesses in a system or process are identified and analysed to understand what went wrong, how it went wrong and what can be done to prevent similar incidents occurring again
3. **Objective:** staff leading the investigation must not be involved in the direct care of those people affected or work directly with those involved in the delivery of the care.
4. **Timely and responsive:** reported within 2 days of occurrence, with an appropriate level of investigation undertaken within the timescales outlined.
5. **Systems based:** to understand the problem (the what), the contributory factors (the how), taking into account the human and environmental factors and the fundamental issues/root cause (the why) that need to be addressed.
6. **Proportionate:** the scale and scope of the investigation should be proportionate to the incident to ensure resources are effectively used. Please see levels of investigations in section 9.
7. **Collaborative:** serious incidents often involve a number of teams and or organisations. The Trust will ensure that the Care Group Triumvirates (CGT's) work together and or with other organisations to ensure that incidents are effectively investigated and learning disseminated across the organisation.

Whilst the above relates to Serious Incidents, the principles apply to the reviews undertaken within the Trusts approach to undertake Significant Event Analysis (SEA).

3. DEFINITIONS

3.1 Serious Incident (SI)

In health care these are events where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant that they warrant our particular attention to ensure these incidents are identified correctly, investigated thoroughly and, most importantly, trigger actions that will prevent them from happening again.

Serious Incidents in the NHS include acts and or omissions that result in:

- Unexpected or avoidable death. This includes suicide/self-inflicted death and homicide by a person subject to a care programme approach, or is under the care of specialist mental health services, in the past six months prior to the event.
- Unexpected or avoidable injury to one or more people that has resulted in serious harm
- Unexpected or avoidable injury that requires further treatment in order to prevent the death or the person or serious harm
- Actual or alleged abuse; sexual, physical or psychological ill-treatment or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative or organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery, female genital mutilation where health care did not take appropriate action/intervention to safeguard such abuse occurring or where this abuse occurred during the provision of the NHS funded care.
- A Never Event – <http://www.england.nhs.uk/ourwork/patientsafety/never-events/>

All never events are defined as serious incidents, although not all never events may result in serious harm or death. The link above regularly updates never events.

- An incident or series of incidents that prevents, or threatens to prevent, the Trust's ability to deliver an acceptable quality of health care including but not limited to data loss or information governance issues, property damage, security breach or concern, incidents in screening,
- Inappropriate enforcement/care under the Mental Health Act, the Mental Capacity Act and Deprivation of Liberty Safeguards.
- Systematic failure to provide an acceptable standard of care
- Activation of major incident plan
- Major loss of confidence in the service - including prolonged adverse media coverage or public concern about the quality of health care.

The Director of Nursing or the Medical Director are the two individuals in the Trust who can confirm an incident as an SI. This duty is delegated from the Chief Executive who has overall accountability for declaring a serious incident.

3.2 Significant Event (SE)

A significant event is any event that is thought to be of concern to anyone in the team. This could be in the care of patients or in the systems and processes within a service. This could be any issue, which may impact upon patient safety or affect the quality of care delivered to people who use services.

A SE is reviewed using Significant Event Analysis (SEA); a qualitative method of clinical audit which offers a structured way of highlighting and reviewing events in a non-threatening meaningful way; involving a range of people to review the issues, to gain a collective understanding of what happened, why it happened and identify areas for learning and or areas for change or improvement to reduce the likelihood or prevent recurrence. The SEA utilises the Human Factors Framework (see Appendix 12) to gain an understanding of the issues.

3.3 Near Miss

A near miss is defined as an unplanned event that did not result in injury, illness or harm but had the potential to do so. Only a fortunate break in the chain of events prevented an injury or fatality. These could be classed as a serious incident near miss if there is the likelihood of the incident occurring again if the current systems or processes remain unchanged and there is potential for harm to patients, staff and the organisation should the incident occur again. This does not mean however that every near miss should be reported as a serious incident but where there is a significant existing risk of system failure and serious harm the SI process should be used to understand and mitigate the risk. It is important that near misses are reported and appropriately investigated as the learning may prevent actual harm occurring to future patients, their families or staff.

3.4 Single Point of Contact with those involved

This is an identified individual who is independent from the investigation team. This person who is agreed as the point of contact for the patient/families and or carers' who are affected by the serious incident. The single point of contact will be available to offer support, clarify the process of the investigation, be available to develop the terms of reference and or respond to queries raised by the patient or the family. The single point of contact will usually be the assigned senior manager support (the buddy) as defined in section 6.11. This person who will form the link for the Trust will be identified to the patient, families and or carers in the initial Duty of Candour letter sent by the Trust.

3.5 Deaths in Custody

People in custody who are detained under the Mental Health Act (1983), Deprivation of Liberty Safeguards, or those detained within the police and justice system are owed a particular duty of care by authorities. In prison and police custody any death will be referred to the Prison and Probation Ombudsman (PPO) or the Independent Police Complaints Commission (IPCC) who are responsible for carrying out the relevant investigations.

It is the responsibility of the Trust to ensure that any death of a detained patient under the Mental Health Act (1983) or Deprivation of Liberty Safeguards (DoLS) is reported to the CQC without delay. In circumstances where the death may have been avoidable or unexpected i.e. not caused by the natural course of the patients illness, or underlying medical condition when managed in accordance with best practice – including suicide and self-inflicted death, then the death must be reported as a serious incident and investigated accordingly. The Trust Mortality Review Guidelines outline the consistent approach expected by the Trust in response to any death.

3.6 Homicides by patients in receipt of mental health care

Where patients in receipt of mental health services, or have been in the previous six months, commit a homicide, the Trust will complete an initial briefing report within 72 hours of the event and an investigation will commence, for conclusion within 60 days (8 weeks). The Trust will liaise closely with the police during this process. NHS England will consider and, if appropriate, commission an independent investigation. NHS England's Regional investigation teams oversee this process. Please see appendix 5.

3.7 Safeguarding – Children and Safeguarding Adult reviews

The local authority via the local safeguarding children board (LSCB) or local safeguarding adult board (LSAB) has a statutory duty to investigate certain types of safeguarding incidents/concerns.

Section 11 of the Children Act 2004 places a duty on a range of organisations and individuals (this includes NHS Trusts, CCG's and NHS England) to ensure that their functions, and any services that they contract out to others, are discharged having regard to the need to safeguard and promote the welfare of children.

As part of that duty they must have arrangements in place to identify, report, investigate and implement/manage any remedial action required, in situations where it is believed that an incident has occurred that could adversely affected the health or welfare of a child. In circumstances set out in *Working Together to Safeguard Children (2015)*, the LSCB will commission serious case reviews. (See Appendix 3)

All Safeguarding children serious incidents child deaths must be initially reported as a Serious Incident. The safeguarding team will always review the reporting of the child death with the CCG prior to reporting on the Strategic Executive Information System (StEIS) to determine which organisation will declare the incident as a serious incident.

3.8 Safeguarding – Adult

In circumstances set out in guidance for adult's safeguarding concerns the Local Safeguarding Adult Board (LSAB) will commission safeguarding adult reviews. The Local authority will also initiate safeguarding adult enquires or ask others to do so if they suspect that an adult is at risk of abuse or neglect.

3.9 Admission of a young person onto an adult mental health ward

A briefing report must be submitted for all admissions of a person under the age of 18 onto an adult mental health ward and each admission will be reviewed in line with what would constitute a SE. It is not an SI unless harm occurred which warrants escalation to an SI. The admission of a young person will always be reviewed and discussed within the weekly Clinical Risk Management Group (CRMG). The admission of a young person will be referred to the Humber Safeguarding Team and will be reported to the CQC and the Commissioner.

The admission of a young person will follow the agreed protocol within the Trust and the briefing paper will include details of the support provided by CAMHS, providing assurance as to the adherence to the protocol to ensure the safety and welfare of

the child and support for the family. The briefing paper submitted will be shared with the CCG to provide assurance of safeguarding the child

3.10 Pressure Ulcers

All pressure ulcers reported via DATIX are reviewed by the lead Tissue Viability Nurse and those that are graded as 3, 4, ungradable or unstageable which have occurred in our care are reviewed using a structured judgement methodology where the phases of care are reviewed. The phases of care are initial assessment, detection of the pressure ulcer, care planning and review, assessment of care overall and avoidability. The phases of care are scored followed the judgements made with an overall avoidability score. All reviews are peer reviewed in the pressure ulcer quality forum. If care is scored at 1 or 2 where poor or very poor care is found within any of the phases of care or where the avoidability of the pressure ulcer is scored at 1 or 2 (definitely avoidable or there is a strong evidence of avoidability), this is escalated for consideration of a serious incident.

3.11 HealthCare Acquired Infections - MRSA Blood stream infections

A Post Infection Review (PIR) for all MRSA bloodstream infection (BSI) cases from April 2013 forms part of the government strategy for achieving a “zero tolerance” to HCAI. A PIR must be undertaken on all MRSA BSI cases, please use link <http://www.england.nhs.uk/wp-content/uploads/2014/04/mrsa-pir-guid-april14.pdf> to support this activity. The PIR replaces the previous requirement to undertake Root Cause Analysis (RCA) for MRSA BSIs.

The PIR process will:

- assist in the identification of factors that may have contributed to a MRSA BSI case;
- assist in the identification of any part of the patient’s care pathway which may have contributed to the infection, in order to prevent a similar occurrence;
- assist in identifying any areas of sub-optimal practice that may have contributed to the MRSA BSI;
- help to identify promptly the lessons learned from the case, thereby improving practice for the future;

A root cause analysis (RCA) will be undertaken for any other HCAs (currently MSSA and *E. coli* BSIs and *Clostridium difficile* infections). All the RCA’s are reviewed to identify any areas of learning.

All the RCA’s are reviewed by the Director of Nursing, with consideration of reporting of SI where there are significant areas for learning or the infection has contributed to a patient’s death. All HCAI acquired in our care undergo a RCA.

3.12 STEIS - Strategic Executive Information System

This is the where all the NHS Serious Incidents are reported and monitored. It is an NHS England web based SI management performance system.

4. SCOPE

This policy applies to all permanent (clinical and non-clinical staff), locum, agency, bank and voluntary staff and students working within the Trust.

5. POLICY STATEMENT

This policy outlines the reporting arrangements for Serious Incidents (SI) and Significant Events (SE), actions to be taken at the time and by whom to ensure that all SI's and SE's are reported internally and externally as required in the timescales agreed.

The policy provides a framework to ensure that the lead investigator for SI's and their team as appropriate are able to undertake a thorough and detailed investigation which involves gathering and mapping information, analysing the information and generating solutions in order to prevent another or similar incident occurring again.

The policy provides a framework to ensure that reviewers undertaking SE's are able to lead quality conversations within the teams to understand what has happened, why, what has been learnt and what has been changed in order to prevent reoccurrence.

6. DUTIES & RESPONSIBILITIES

6.1 Chief Executive and Trust Board

The Chief Executive and the Trust Board has ultimate accountability for ensuring the provision of high quality, safe and effective services within the Trust, ensuring robust systems and processes are in place when serious incidents, serious near miss and or significant events occur. The Chief Executive and Trust board are also accountable for ensuring compliance with duty of candour and to ensure learning to prevent re-occurrence.

The Trust board will receive a monthly report of the all SI's and SEA's, identifying the themes and trends quarterly.

6.2 Executive Director of Nursing, Quality & Patient Experience

The Director of Nursing has responsibility for the strategic implementation and monitoring of this policy and evaluation of organisational learning, holding the responsibility for decision making of reporting SI's to the Clinical Commissioning Groups (CCG) or NHS England (NHSE) within 2 days of occurrence.

The Director of Nursing reviews and signs off all SI investigation reports prior to release to the patient and or family and submission to the CCG/NHSE/Coroner.

6.3 Medical Director

The Medical Director works together with the Director of Nursing, holding joint responsibility for the decision making of what is reportable as an SI. In the absence of the Nursing Director, the Medical Director will be responsible for the decision of reporting SI's and formally signing off all SI investigation reports prior to release to the patient and or family and submission to the CCG/NHSE/Coroner.

6.4 Chief Operating Officer (COO) has the responsibility for:

- Commissioning an independent investigation (Please see 9.1 for definition of when an independent investigation would be commissioned)

- Agreeing were required and for ensuring:
 - The allocation of lead investigators/review team at the Senior Operations Meeting
 - Timely investigations or analysis are undertaken
 - Reports are produced using appropriate methodology
 - Learning from all SI's and SEA's is shared via the Operational Management Group to ensure learning is embedded across the Care Group Triumvirates.
 - The commissioning of the communication and media handling strategy where needed.

6.5 Care Group Directors (CGD) have responsibility for the operational implementation of this policy across the respective Care Groups and will ensure:

- All incidents where there is severe harm or an unexpected death, or serious near miss or never event are reported via a briefing paper and sent to briefing reports email.
- Agreeing who will make the initial contact with those involved, or their family/carers in complex situations to ensure compliance with the requirements for duty of candour, if the serious incident is not the death of a patient.
- The briefing report is written and shared with the Clinical Risk Management Group (CRMG) to assist with the decision making of the level of investigation required
- There are appropriate numbers of people from within the Care Groups trained in Root Cause Analysis (RCA)
- Confirm the people undertaking the lead for a Serious Incident, are allocated taking into account the person with the most appropriate skills, alongside allocation on a rota basis from the list of those trained in RCA.
- Staff within their sphere of responsibility are aware when an incident has been reported as an SI or when an SEA has been commissioned from a briefing report by CRMG
- All staff follow the principles of openness and honesty as outlined within Duty of Candour Policy
- Staff are supported following the occurrence of an Serious Incident or Significant Event

6.6 Clinical Care Directors (CCD) have the responsibility for the operational implementation of this policy across the Respective Care Groups and will ensure:

- Action plans from the SI's and SEA's are developed jointly by staff within the Care Group with budgetary responsibility and an understanding of the wider issues/competing priorities and the investigator of Serious Incidents or reviewers of Significant Events
- Reports for SI's and SEA's are reviewed and agreed prior to sharing with CRMG
- Action plans are monitored on a monthly basis within the CGT's to ensure that they are completed in the timescales agreed.

- Updates and evidence of achievement to be submitted to Governance 2 weeks prior to submission to the Clinical Commissioning Groups (CCGs) monthly SI Panel to enable the SI to be fully closed.
- Learning and or changes needed to practice as identified from an SEA are led from within the Care group Triumvirates and shared within CRMG and across the Trust.

6.7 Nursing & Quality Directorate Senior Team

- Responsible for ensuring that all external legal processes are in place and for coordinating information to external bodies e.g. police, CQC, monitor, local authority to meet the Trusts statutory duties
- Assuring systems and processes are established and reviewed following feedback from the lead investigators/reviewers/ Care Group Triumvirates (CGT's), to ensure continuous quality improvement.
- Attending the SI panel with the CCG providing feedback on queries raised from the panel and or of assurance and evidence of completed actions by the CGT's
- Coordinate the quarterly learning from serious incidents events to ensure learning from all SI's are shared with staff corporately and across the Care Groups

6.8 All Service Managers/Matrons/Team Leaders/Charge Nurses/Ward Sisters are responsible for ensuring:

- All staff within their sphere of responsibility are aware of the contents of this policy and follow the guidance.
- Staff are fully supported in the reporting of a SI, SEA or serious near miss or never event.
- Staff complete a briefing report as soon as possible following any event that has caused severe harm, a serious near miss, never event or where there has been an unexpected death within services
- Staff are open and honest with the person and or their family when harm has occurred. Staff should acknowledge and offer a sincere expression of sorrow or regret for the harm that has occurred, explaining the facts, as they know at the time of sharing the incident.
- Staff are fully aware of the statutory duty of candour where severe harm and above has occurred, informing the person and or their family and providing feedback on the outcome of the investigation or review.
- Contact with the family to offer condolences where a patient has died expectantly whilst using services.
- The offer of the document 'Help is at Hand' is available from the patient safety team to provide to family members when a relative has un-expectantly died.
- Staff within their sphere of responsibility are aware when an incident has been reported as an SI or when a SEA has been commissioned from a briefing report discussed at CRMG
- Receive feedback on the outcome of any investigation or SEA.
- Support for staff during and following an SI, SEA, serious near miss or never event. Where staff experience particular difficulties associated with a SI, SEA or serious near miss and or never event, that referrals are made to the

Occupational Health Department in a timely manner in order to support staff or in the case of junior doctors, referrals are made to the medical director.

- Managers revisit the health and wellbeing of individuals or all staff members when there has been more than one SI and or SEA in any one area in any quarter or consecutive quarters.
- Staff are supported with writing statements for coroner's court.
- Staff are made aware that they may be called to provide evidence to the coroners court.

6.9 Other HFT Staff

- All staff, both clinical and non-clinical are responsible to raise and escalate concerns of any incident which may be reportable of any serious incident, near miss and or significant event to the person in charge on a unit or within a team.

6.10 Assurance Systems Officer is responsible for:

- Informing the Chair, Chief Executive, Chief Operating Officer and Executive Directors and appropriate Care Group Directors when an SI has been declared. Maintaining a log of incidents indicating date reports are due.
- Ensuring the CCG and external agencies are informed as required.
- Reporting serious incidents onto StEIS
- Maintaining hard copy documentation of all SI's and SEA's, for reporting SI's onto StEIS, and liaising with the CCG and Area Team as directed by the Executive Directors, responding to any queries made by CCGs on the outcome and reports of SI's.
- Ensuring that Datix-web is updated and for providing relevant statistics from the database, as required to the Trust board.
- Updates StEIS with the root cause and lessons learnt following the completion of all SI investigations to enable the CCG to close the SI when all actions have been completed.
- Maintain the tracker of all SI's and SEA's, providing a weekly update to CRMG on the progress of all.
- A condolence letter in line with Duty of Candour requirements from the Director of Nursing or Medical Director is sent to the relative when there has been an unexpected death reported as an SI or where an SEA will be undertaken.
- Ensures that the draft reports are received from the care groups by week 9 for review by CRMG, and monitored thereafter until submitted to the CCG within 12 weeks.
- Provide advice and support to all clinical and operational staff in the SI and SEA process ensuring that the reports are anonymous, contains no patient and or staff identifiable information within
- Raise and escalate any concerns with regard to the progress of all SI's and SEA's to the CRMG

6.11 SI Buddy Role

This is a role taken on by senior staff in the nursing and quality directorate.

The buddy is responsible for ensuring that:

- Advice and support is given to investigators/teams with regards the process of their investigations/reviews and the content of their reports
- Provide on-going support to the investigators to ensure that the investigation is progressing well and that the draft report will be completed within 9 weeks and final report submitted to the CCG within 12 weeks
- Updates are provided to CRMG

Please see appendix 9 for details of the buddy role.

6.12 Serious Incident Investigators

- Will either be clinical and or managerial staff from across the Care Groups or corporate services depending upon the nature of the serious incident. They will have undertaken root cause analysis training and have an understanding of use of the fishbone technique and 5 Whys.
- They are responsible for ensuring that they:
 - Meet with the person and or family member to agree additional terms of reference for the investigation
 - Liaise with the person and or their family where possible, throughout the investigation to provide feedback on the interim findings
 - Liaise with Complaints to gain an understanding of any previous PALS and Complaints in the team/unit and or relating to this person.
 - Provide updates as detailed on the progress of the investigation, raising and escalating concerns to the SI buddy as required
 - Review the care delivered against statute, national (NICE) and local guidance (Policies and Procedures)
 - Liaise with others as needed in order to undertake a thorough investigation to identify areas for learning
 - Write a report using the report templates
 - Provide a verbal update to the Care Group Triumvirate on the findings prior to the completion of the report and subsequent action plan
 - Make recommendations for SMART action plans in partnership with the operational staff who hold budgetary responsibility
 - Complete the investigation within the timescales agreed
 - Meet with the family following completion of the investigation and share the final approved report
 - Attend coroners court as the lead investigator

7. INTERNAL GOVERNANCE ARRANGEMENTS

7.1 Clinical Risk Management Group (CRMG)

This is a weekly forum for the senior teams within Quality and Governance to meet with the Care Group Triumvirate (CGT) representatives to review and confirm all incidents reported as SI's and or to commission an SEA where it is felt that learning could be gained from undertaking Significant Event Analysis.

CRMG will monitor the progress of all SI's and SEA's to ensure the progress in the agreed timescales. The group will agree the level of the investigation for an SI, the terms of reference for the SI or SEA and identify investigators for SI's/reviewers for SEA's.

The chair of the group will identify a nominated person from the quality team as support for the SI investigator (buddy role).

7.2 Monitoring of Action Plans

CRMG will monitor the progress of all actions for each SI & SEA. Evidence of assurance will be received from the Care Groups prior to submission to the SI panel with the CCG/NHSE.

Evidence will be provided to the CCG/NHSE, one week following the completion of the final action plan to enable the CCG/NHSE to review at the SI Panel with the CCG/NHSE and close the SI.

7.3 Quality & Patient Safety Group

The Quality & Patient Safety Committee is accountable to the Quality Committee. It has been established to oversee and coordinate all aspects of quality improvement (patient experience/patient safety & clinical effectiveness), assurance and clinical governance activity and delivery. The group has responsibility to escalate any issues that may have a potential impact on the delivery of the organisational objectives to the Executive Management Team.

The group will direct and influence the Trust quality improvement and clinical governance strategies in accordance with the Trusts overall vision values and business strategy. The group reports to the Quality Committee for assurance purposes which is a sub-committee of the Trust Board.

7.4 Deaths

A death review will be completed for anyone who dies whilst in receipt of care from the Trust, as per the Mortality Guidelines and Framework <https://www.england.nhs.uk/ourwork/patientsafety2/rcr-rev/>. Learning from all deaths will be disseminated across the organisation through the mortality review steering group, CRMG and the Trust Board. The key aim of which is to share and learn. Learning will be shared wider through Trust wide events

8. DUTY OF CANDOUR

Every day people are treated safely within the Trust, however occasionally things go wrong and people are harmed within the organisation or people harm themselves, which can result in moderate, severe harm or death. It is important that when incidents occur that healthcare staff communicate openly with the patient and or relatives/carers.

Every healthcare professional must be open and honest with the patient when something goes wrong with their treatment, where care causes or has the potential to cause harm or distress or with relatives/carers when a person has harmed themselves causing moderate, severe harm or death. For further information please see the Trust Duty of Candour Policy which can be accessed via the following link: <https://intranet.humber.nhs.uk/duty-of-candor-policy.htm>

9. SERIOUS INCIDENT INVESTIGATIONS

9.1 Levels of the investigation required for a Serious Incident

The Clinical Risk Management Group will agree the level of investigation and the Terms of Reference.

Concise SI investigations are for less complex serious incidents, which only involve Trust services. This investigation is completed by two members of staff, one of whom must be trained in Root Cause Analysis. This investigation is required to be completed within 12 weeks. Please see appendix 2.

Comprehensive SI investigations are for incidents, which involve other agencies in addition to those of the Trust. This investigation is completed by two members of staff, one of whom must be trained in Root Cause Analysis. This investigation should be completed within 12 weeks. Please see appendix 3.

External SI investigations. External investigations are required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally. This is due to the size of the investigation or the capacity/capability of the available individuals and or number of organisations involved. These should be completed within 6 months from the date the investigation was commissioned and will have an independent neutral investigator lead the investigation. Approval for a 6 month investigation will need confirming with the CCG/NHSE. An investigation buddy from the Trust will be allocated to support the investigation process and act as a liaison for the external investigator. Please see appendix 4.

Homicide SI investigations. These are required for anyone who has been in receipt of mental health services in the 6 months prior to a homicide being committed. When the briefing report has been completed, (within 3 days of the homicide); the investigation will be completed by an independent neutral investigator. Close liaison will be undertaken with the police who are involved in the homicide case. This investigation will be completed within 60 days (8 weeks) and must communicate with individuals and organisations including the families of victims and perpetrators. The report will be shared with the NHS England investigation team who will review the report and consider if an independent investigation is required. Please see appendix 5.

Significant Event Analysis (SEA)

Some incidents reported to CRMG may not reach the SI threshold but the view of the group is that a further review to determine what happened, why did it happen and to identify any learning is needed. CRMG will declare incidents such as these as significant events.

Significant events are any events that are thought to be of concern to anyone in the team, which could be in the care of patients or in the systems and processes within a

service, which may impact upon patient safety or affect the quality of care delivered to people who use services. These do not only need to be commissioned from CRMG, these can be initiated within the care groups by the charge nurse/team leader, Modern Matron/Service Manager or Care Group Directors with learning fed back directly to the team and Care Group.

Levels of review when undertaking a Significant Event Analysis:

SEA Concise – These are for any event which is of concern to a member of the team. The concise SEA is a facilitated discussion, bringing together the people involved in the incident to review the incident. This can include anyone involved in the incident including the clinical team, admin staff, domestic/support staff, patients and families/carers. The personal impact on the event and a review of the human factors framework (People, Activity and Environment) are considered with this analysis process. An SEA Concise will be completed within 4 weeks. Please see appendix 6.

SEA Comprehensive – An SEA Comprehensive will only be undertaken following an incident to a person who was receiving care from the Trust that has not met the criteria for a serious incident and therefore not been reported as an SI, but where the Trust feels there is an area for learning. The coroner will require this report, if involved. This will be completed within 9 weeks. Please see appendix 6.

In these cases the following are the responsibilities of staff:

- The senior clinical leaders where the incident occurred will review the incident. The reviewers will lead quality conversations within the clinical teams to understand what happened, why, what has been learnt, what has been changed to prevent reoccurrence. Staff will utilise the Human Factors Framework and 5 Why's in order to understand what happened and why.
- An action plan will be developed and agreed with the Care Group prior to submission to CRMG.
- If the SEA has been initiated from within a team or unit, the report will be shared and agreed within the Care Group to ensure lessons are learnt from the review and that changes occur within the care group and or across the wider organisation if needed. The report will then be shared with CRMG.
- Ensure that any outstanding actions are developed into an action plan that will be monitored by the Care Group, supported by the Governance team.

10. EQUALITY & DIVERSITY

An Equality and Diversity Impact Assessment has been carried out on this document using the Trust approved EIA.

This has been completed and does not highlight any concerns

11. MENTAL CAPACITY

The Trust supports the following principles, as set out in the Mental Capacity Act and has applied them in the development of this policy:

1. A person must be assumed to have capacity unless it is established that they lack capacity.

2. A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.
3. A person is not to be treated as unable to make a decision merely because he makes an unwise decision.
4. An act completed, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests.
5. Before the act is completed, or the decision made, regard must be had as to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.

12. BRIBERY ACT

The Bribery Act 2010 makes it a criminal offence to bribe or be bribed by another person by offering or requesting a financial or other advantage as a reward or incentive to perform a relevant function or activity improperly performed.

The penalties for any breaches of the Act are potentially severe. There is no upper limit on the level of fines that can be imposed and an individual convicted of an offence can face a prison sentence of up to 10 years.

For further information see <http://www.justice.gov.uk/guidance/docs/bribery-act-2010-quick-start-guide.pdf>.

If you require assistance in determining the implications of the Bribery Act please read the Trust Bribery prevention policy available on the intranet at

<http://intranet.humber.nhs.uk/bribery-prevention-policy-p183.htm>

or contact the Trust Secretary on 01482 389194 or the Local Counter Fraud Specialist on telephone 01482 866800 or fraud@humber.nhs.uk

It is the decision of the author as to whether the Bribery Act applies to this policy or not:

The Bribery Act applies to this policy.

13. IMPLEMENTATION

This policy will be disseminated by the method described in the Policy and Procedural Documents Development and Management Policy.

14. MONITORING & AUDIT

Key elements to be monitored

What	How	Who	Where	When
All SI's are reported in 2 working days of incident occurring	Quality Dashboard	Performance	CRMG CMB	Weekly Monthly
All staff who are RCA trained undertake SI's on rotation	A list of those undertaking SI's and SEA's is submitted weekly to the senior operations meeting to ensure representation from across the CGTs and that the same people are not being asked again and again	Nursing & Quality Team admin	Senior Operations	Weekly
All SI's and SEA's are completed in a timely manner	Monitoring of SI and SEA tracker within CRMG	Nursing & Quality Team	CRMG	Weekly
All reports submitted to the CCG/NHSE are received as acceptable	Feedback from SI Panel	Director of Nursing	CCG SI Panel	Monthly
Actions plans from SI's are completed within the timescales agreed	Monitoring via CRMG & QPaS	Care Groups	CRMG	Monthly
Trends and themes are monitored quarterly	Reports to QPaS	Nursing & Quality Team	Board	Quarterly
Learning from serious incidents and significant events are shared across the organisation	Learning events held for range of staff from across Care Groups	Nursing & Quality Team	Board	6 monthly
	Practice notes disseminated to relevant Care Group Triumvirates.	Nursing & Quality Team	CRMG	As required
	Key themes shared with staff through Lessons Learned for Quality via Quarterly News Letter.	Nursing & Quality Team CRMG	QPaS	Quarterly

15. TRAINING

The appointed lead investigator will be trained in Root Cause analysis and will receive refresher training every 3 years.

16. REFERENCES/EVIDENCE/GLOSSARY/DEFINITIONS

NHS England (2015), Serious Incident Framework, London, NHS England
NHS Education for Scotland (2011) Significant Event Analysis, guidance for primary care teams.

Williams, C (2014) Enhanced Significant Event Analysis, a human factors system approach for primary care.

NMC (2015) Professional duty of candour, NMC

GMC (2015) Openness and Honesty when things go wrong the professional duty of candour, GMC.

HM Government (2015) Working together to safeguard children

17. RELEVANT POLICIES/PROCEDURES/PROTOCOLS/GUIDELINES

- P209 Duty of Candour policy
- Mortality Pathway & Mortality Guidance
- CQC Learning, Candour & Accountabilityw

18. APPENDICES

Appendix 1- Incident Flow Chart

Appendix 2 - Concise SI Process (involving Humber NHS Foundation Trust ONLY)

Appendix 3 - Comprehensive SI Process (A Multi-Agency incident)

Appendix 4 - External SI Process (An Independent neutral investigator)

Appendix 5 - Homicide SI Process (An Independent neutral investigator)

Appendix 6 - SEA Process

Appendix 7 - SI Action Plan Completion and Lessons Learned Flow Chart

Appendix 8 - Action plan template guidance

Appendix 9 - Levels of Harm, Definitions and their Investigation.

Appendix 10 - Buddy role for Serious Investigations

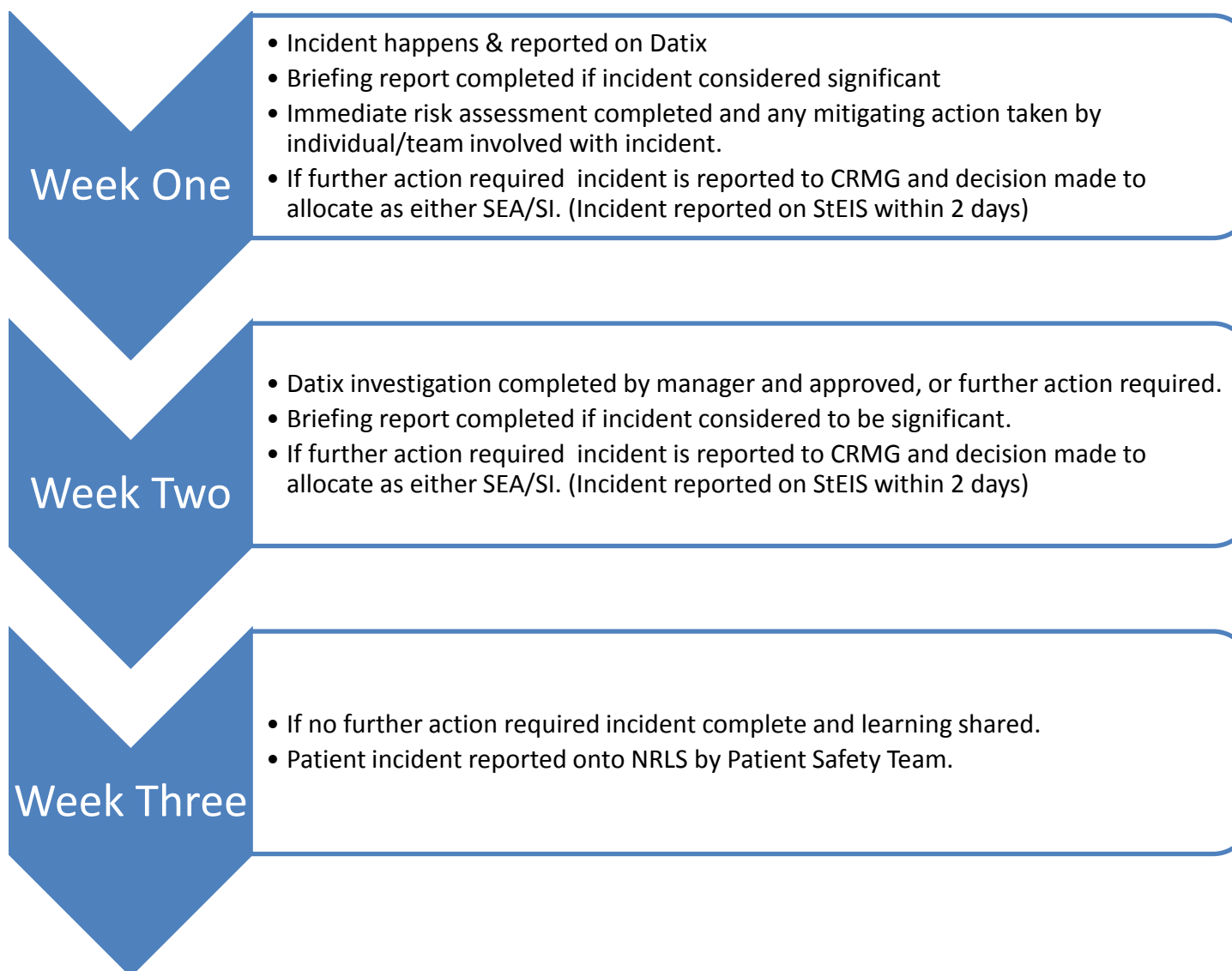
Appendix 11 - Safeguarding Children reviews

Appendix 12 - Human Factors Framework

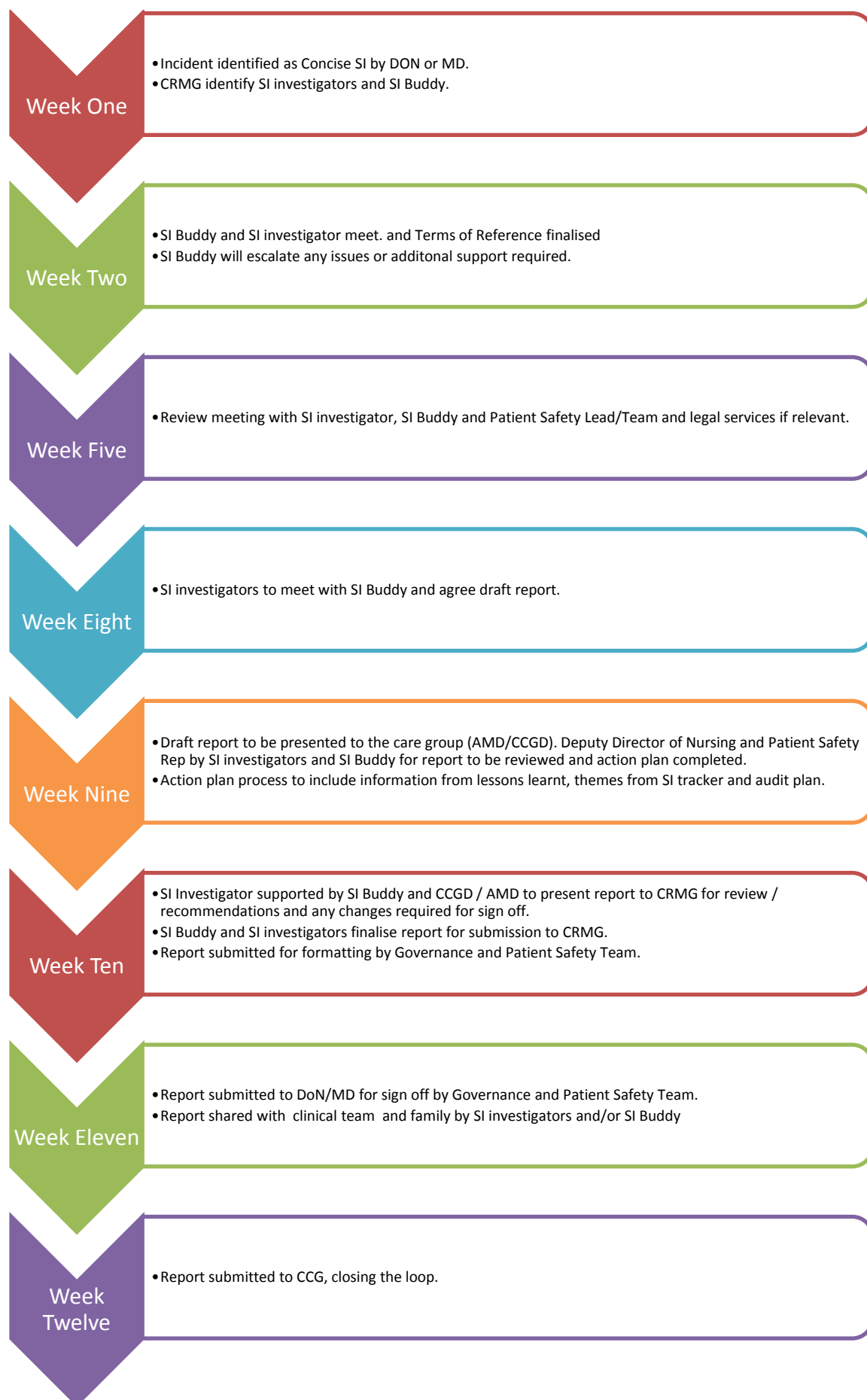
Appendix 13 - Confidential Briefing Report Template

Appendix 15 - 7 Stages of Significant Events Analysis (SEA)

Appendix 16 - Root Cause Analysis Tools



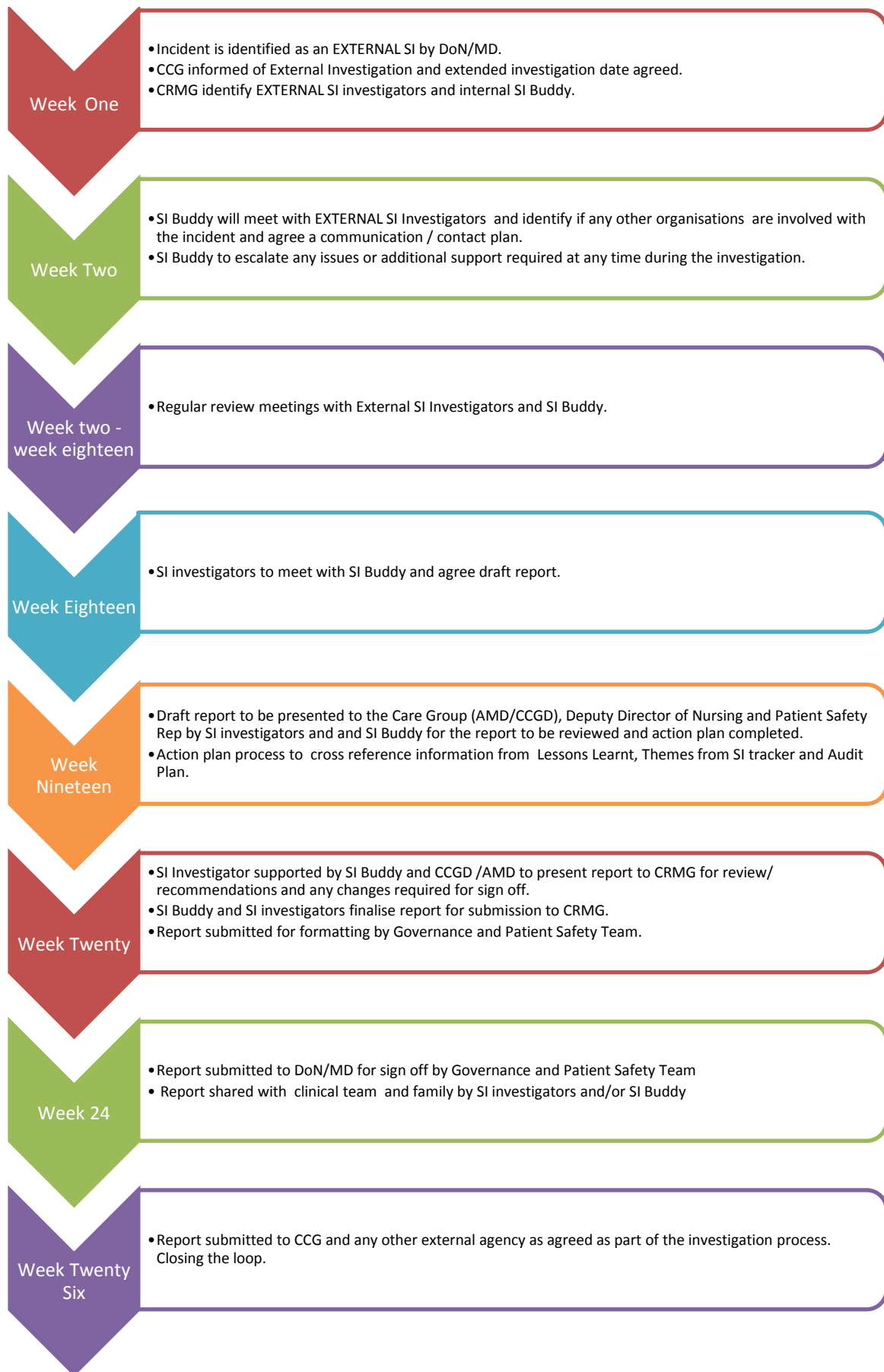
Appendix 2 – Concise SI Process (involving Humber NHS Foundation Trust ONLY)

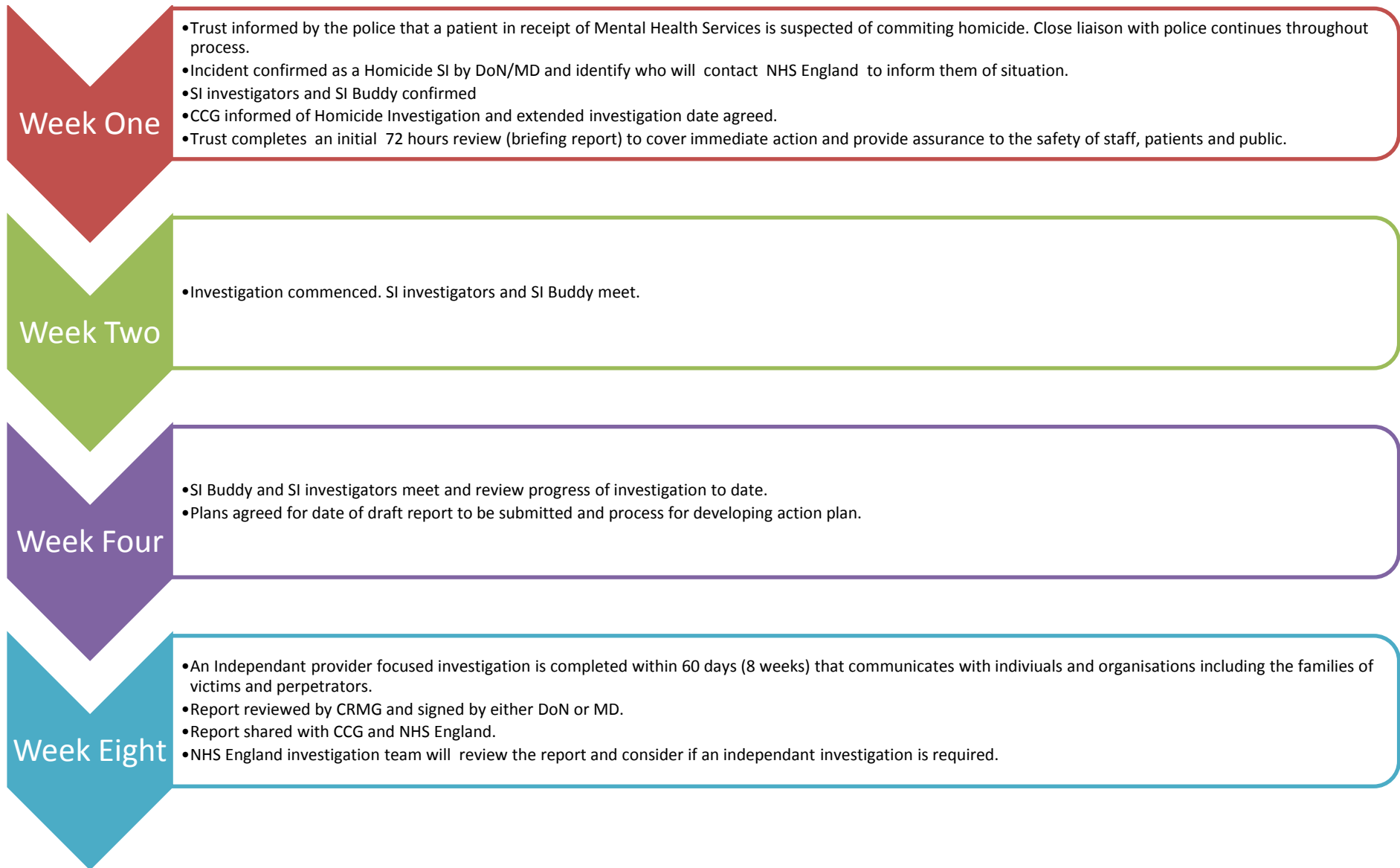


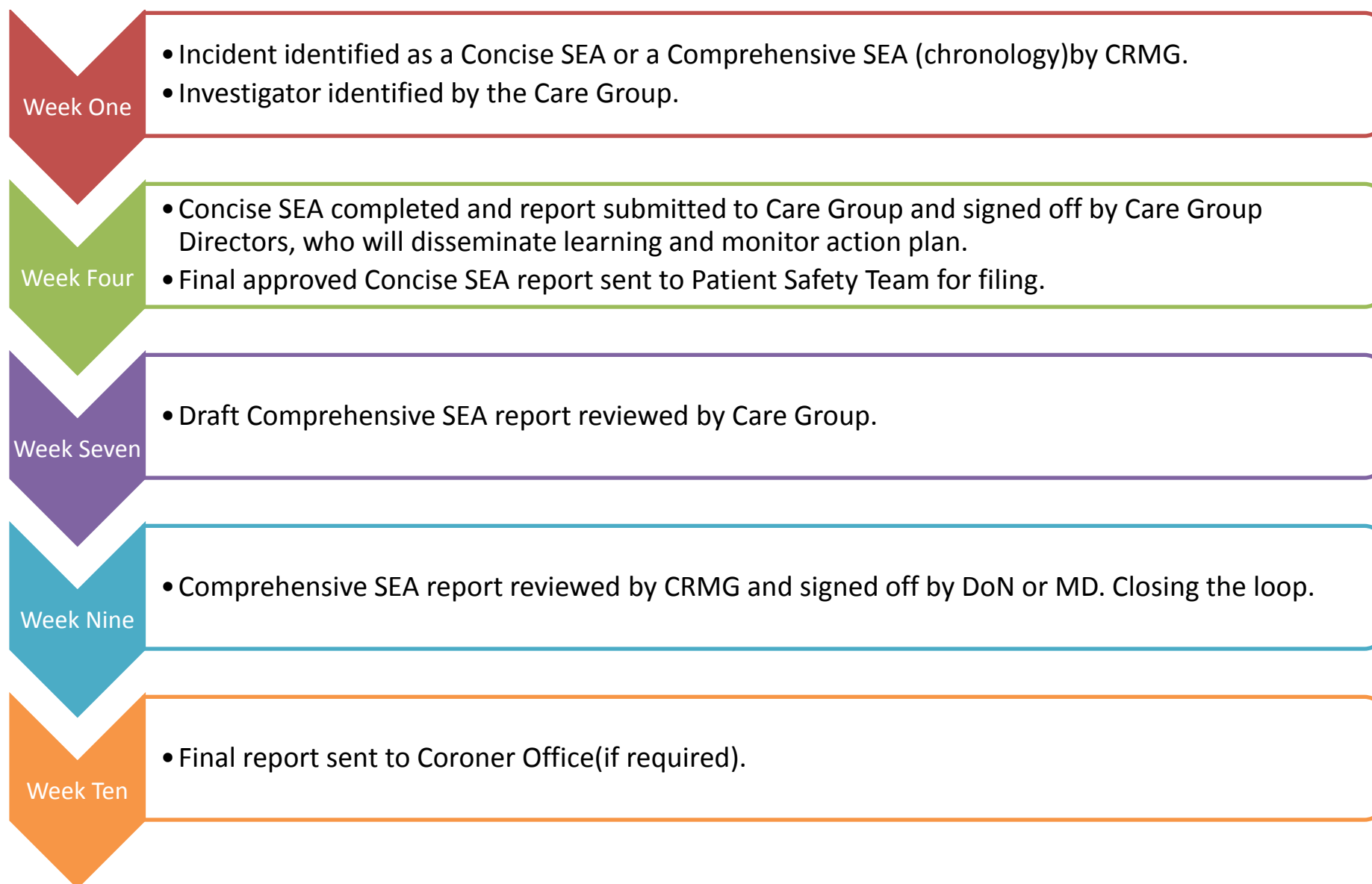
Appendix 3 – Comprehensive SI Process (A multi-Agency incident)



Appendix 4 – External SI Process (An Independent neutral investigator)







Appendix 7 – SI Action Plan Completion and Lessons Learned Flow Chart



Standard Action Plan Template Guidance

All Action Plans must be SMART (specific, measurable, attainable, relevant & timely)

Action plans should aim to triangulate work streams and avoid duplication. Action plans will be measured against the Quality improvement agenda and ensure direct links between concerns highlighted, quality initiatives and the ability of Trust Board to act proactively in avoiding reoccurrence of issues, understand themes and continuously improve services.

Areas of the action plans are explained below

Consultation - To ensure leads are aware of their involvement, increase linkage to other action plans and reduce the likelihood of duplication you must list all those consulted in the development and implementation of action plans.	<h3>Key Lines of Enquiry (KLOEs)</h3> <p>To ensure standardisation the themes identified in the action plans must be taken from the CQC's Key Lines of Enquiry below:</p> <p>Are Services <i>safe</i>? This KLOE looks at how people are protected from abuse and avoidable harm. Abuse can be physical, sexual, mental or psychological, financial, neglect, institutional or discriminatory abuse. The CQC will look at incidents, safety and risks amongst other things.</p> <p>Are Services <i>effective</i>? This means the CQC look at people's care, treatment and support to see if it achieves good outcomes and promotes a good quality of life They also look at whether care and treatment is based on the best available evidence and whether staff have all the necessary training and information to provide the best care for people.</p> <p>Are Services <i>caring</i>? This means that staff involve and treat people with compassion, kindness, dignity and respect. It also includes looking at how people and their relatives are involved in their care and explores patient feedback.</p> <p>Are Services <i>responsive</i>? This is where the CQC will look at how services are organised to ensure that they meet people's needs, especially those who are vulnerable and how accessible services are.</p> <p>Are Services <i>well led</i>? This section looks at the leadership, management and governance of the organisation to assure the delivery of high quality person-centred care. It also looks at the support for learning and innovation, and how the organisation promotes an open and fair culture.</p>	<h3>Approval Process</h3> <ul style="list-style-type: none"> • Originating document is completed e.g. SI and presented at week 9 to CCGD/AMD by SI Lead/Buddy • Lead manager agreed • CCGD/AMD to complete action plan for week 10 presentation at CRMG supported by Buddy (for SIs) <p>(please note should include consultation with other stakeholders e.g. safeguarding and care group meetings prior to this point)</p> <ul style="list-style-type: none"> • Submit to CRMG for approval (week 10) • Once approved ensure monitoring/measuring is actioned and dates are added to calendar • Actions and evidence to be added to action plan by lead and submitted to Deputy Director of Governance & Patient Experience for approval • Review to be completed at end of financial year if action still outstanding as part of the ongoing action plan monitoring.
Action – The SMART criteria must be applied here. Leads should consider what is realistically achievable and avoid setting targets that are not in line with the Trusts business plans/contracts, although these should also reflect the best practice models and seek to improve services through quality improvement and innovation		
Issue – This column should provide information about why the action is necessary. The delivery of action plans may be monitored by Committees without the accompanying report and this rationale will assist those receiving the action plans to improve their understanding and offer support to leads.		
Outcome & Benefits –All actions must result in improvement to our service. Details should be provided of which outcomes will be provided by completion of this action.		
Measurement – To ensure the action is monitored and reported this column must detail how and where the action will be monitored and reviewed. This should be linked directly to the expected outcome and benefits.		
Target Dates – to be SMART compliant target dates must be agreed by the lead manager and the receiving committee or group. These must allow sufficient time for the work to be completed but must also ensure actions that could result in immediate improvements are completed as a matter of urgency. By limiting the action plans to financial year this ensures we do not have an ever increasing number being monitored at any one time and all action plans remain relevant.		
Evidence – This should include minutes, memos, policies, training etc that has been completed to evidence the action has taken place. This may be required by external agencies and provides the lead with a storage location for the action plan if it is requested.		
Lead Managers Role – Lead Managers are responsible for ensuring the action plans are, implemented, on behalf of the Care Group. They retain overall responsibility for action plans even where several leads may be identified on the actions. They are also responsible for escalating issues in delivery of the action plans to the care group triumvirate or committee and requesting changes if necessary	Care Group / Committee Role - The Care Group / Committees will approve action plans following consideration of the impact, duplication, adherence Trust business plan and associated risks. They should also offer support and guidance to the lead managers and ensure regular reviews and monitoring is undertaken as set out in the action plan. They are also responsible for sign off of any changes, amendment to target times and links to Risk Registers	

Action Plan 2016/17

Number	Issue raised <i>(SIRI Recommendation)</i>	Theme <i>(align with KLOE)</i>	Action	Outcome and Benefits	Risk	Lead / Involved	Target Date	Evidence
	<i>This must be specific and reference the section or page number of the accompanying document. This must include any other sources where the issue has been identified such as complaints, datix reports</i>	<i>Specify a theme this action relates to (e.g. Safe, Effective, Caring, Responsive, Well led)</i> <i>Themes to be taken from CQC Key Lines of Enquiry to improve standardisation across service areas and compliance checks</i>	<i>This must be specific and realistic. Actions identified here will need to be monitored and evidenced. Actions requiring a change in operational approach or Trust policy must be checked with a specialist lead in that area. Learning should be demonstrated through the solution offered and should include the wider impact of the issue and related action.</i>	<i>All actions must result in improvement to our service. Details should be provided of which outcomes will be provided by completion of this action.</i>	<i>This should include specific details about how any risks will be mitigated between the present and the completion of the action.</i>	<i>The action must be assigned to a senior manager, care group, Trust Committee or Executive Director only. Others may be included as 'involved' to reflect them completing delegated work. But it is the lead who (>8) who will be accountable for the completion of the action plan.</i>	<i>Action plans will only remain valid until the end of the financial year. Actions expected beyond this should be reflected as information/ data being passed to project leads i.e. CIP's or project leads eg transformation or will need to be submitted inclusion in the following years Care Group or Committee action or quality improvement plan All actions should be completed in the shortest possible timescale but must be realistic in their aims.</i>	<i>This area should include links to documents that provide assurance that the action has been completed. This may be minutes, training presentations no evidence will be accepted that cannot be demonstrated.</i>

Levels of Harm, Definitions and their Investigation.

Level of Harm	Description	Type of Investigation	Investigator
Near Miss	Impact prevented. This is any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care.	Datix incident review.	Team member or team manager.
No Harm	Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.	Datix incident review.	Team member or team manager.
Low	Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care.	Datix incident review.	Team member or team manager.
Moderate	Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm,	Datix incident review or SEA investigation.	Team manager or service manager.

	to one or more persons receiving NHS-funded care.		
Severe	Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.	SI or SEA	Service Manager and another experienced member of staff.
Death	Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care.	SI	Service Manager and another experienced member of staff.

The Buddy Role for Serious Investigations

The Buddy role has been established to provide support and advice to the investigators that have been allocated to complete the investigation. The buddy is not the investigator themselves, but should be fully aware of what is happening with the investigation, providing leadership and oversight.

The buddy will be allocated to an investigation by the CRMG. Once allocated a buddy will be expected to:

1. Arrange to meet with the investigators to discuss the SI, how the investigators plan to investigate, time frames and any further support the investigators feel they require. The buddy will arrange this meeting during the first week that the investigators have been allocated, to take place before the end of week 2 and arrange at this meeting regular meetings with the investigators for the life of the investigation.
2. Confirm the investigation Terms of Reference, scope of the investigation and confirm that the investigators understand what is expected of them during the investigation.
3. Advise on completing the pre investigation and post investigation risk assessment that is included in the report template.
4. Identify any internal or external policies and guidance that needs to be considered within the investigation.
5. Advise on completing the Duty of Candour requirements and supporting/meeting families, understanding what they would want from the investigation and how to feedback information from the report to families.
6. Signpost investigators towards those with specialist knowledge who may provide knowledge and information for the investigation.
7. Keep in regular contact with the investigators to ensure that the investigation remains on track and provide regular updates about the progress of the investigation to CRMG. This includes raising any emerging concerns.
8. Agree a mid-investigation meeting with the investigators.
9. The role provides additional scrutiny to the investigation and the buddy should receive an electronic update of the investigation report at regular intervals so that the buddy can evaluate progress and advise where relevant.
10. Receive and proof read the first draft of the report before it is shared with the Care Group.
11. Help to identify learning during the investigation to ensure, where necessary, it can be quickly actioned.
12. Be responsible for presenting the investigation report to CRMG.
13. Taking forward any risk issues or concerns that arise from the investigation as it is being undertaken.
14. Facilitate meetings with other organisations and the team involved with investigating the SI.

Buddy Role for Serious Investigations where an External Investigation has been Commissioned

Where an external investigator has been commissioned the Buddy facilitates and supports the investigator in an administrative role, specifically they will:

1. Agree the Terms of Reference with the commissioner of the external investigation.
2. Arrange to meet with the investigator to discuss the SI, how the investigator plans to investigate, time frames, costs and any further support the investigator feels they require. The buddy will arrange this meeting during the first week that the investigators have been allocated, or as soon as possible, hopefully before the end of week 2. Arrange at this meeting regular contact with the investigators for the life of the investigation.
3. Discuss the investigation Terms of Reference and confirm that the investigators understand what is expected of them during the investigation.
4. Agree how information can be communicated between the investigator and the Trust. Refer to <http://systems.digital.nhs.uk/nhsmail/secure/senders.pdf> for sending secure emails to non-encrypted email addresses and ensure standard IG paragraph is included in the Terms of Reference as follows:

Information Governance Requirements

A central log of all documents provided to the investigator will be kept by the administrative support provider. The investigator will hold and transfer all confidential documentation in line with the requirements of the NHS Code of Practice on Confidentiality. No confidential information will be divulged to any third party outside of the Trust without prior authorisation from the Trust's Senior Information Risk Owner (SIRO).

5. Provide any documentation required by the investigator, for example policies and guidance that needs to be considered within the investigation.
6. Facilitate the arrangement of any interviews with staff.
7. Where a death is the subject of an inquest, Liaise with Legal Services to ensure investigator is aware of the date of the inquest and is given support and advice should the investigator be called to give evidence at an inquest.
8. Keep in regular contact with the investigators to ensure that the investigation remains on track and provide regular updates about the progress of the investigation to CRMG. This includes raising any emerging concerns.
9. Ensure that the investigation does not exceed the scope of the Terms of Reference without the agreement of the commissioner of the investigation.

10. Escalate appropriately and in a timely manner any areas of concern raised by the investigator which may pose an immediate risk to patient safety.
11. Ensure that the first draft of the report is circulated to CRMG for proof reading, challenge and comments.
12. Liaise with Risk Management Team to ensure final draft is signed off.

Safeguarding Children Reviews

NHS England has a statutory role in performance managing and supporting the development of NHS Trusts arrangements to safeguard and promote the welfare of children, this includes a responsibility for ensuring safeguarding children serious incidents are appropriately managed

A number of safeguarding children serious incidents may also meet the criteria outlined within Working together to safeguard children (2015) for a serious case review (SCR).

Regulation 5 of Local Safeguarding Children's Board (LSCB'S) regulations sets out the functions of LSCB'S. This includes the requirement for LSCB'S to undertake reviews of serious cases in specified circumstances;

A serious case review (SCR) is one where:

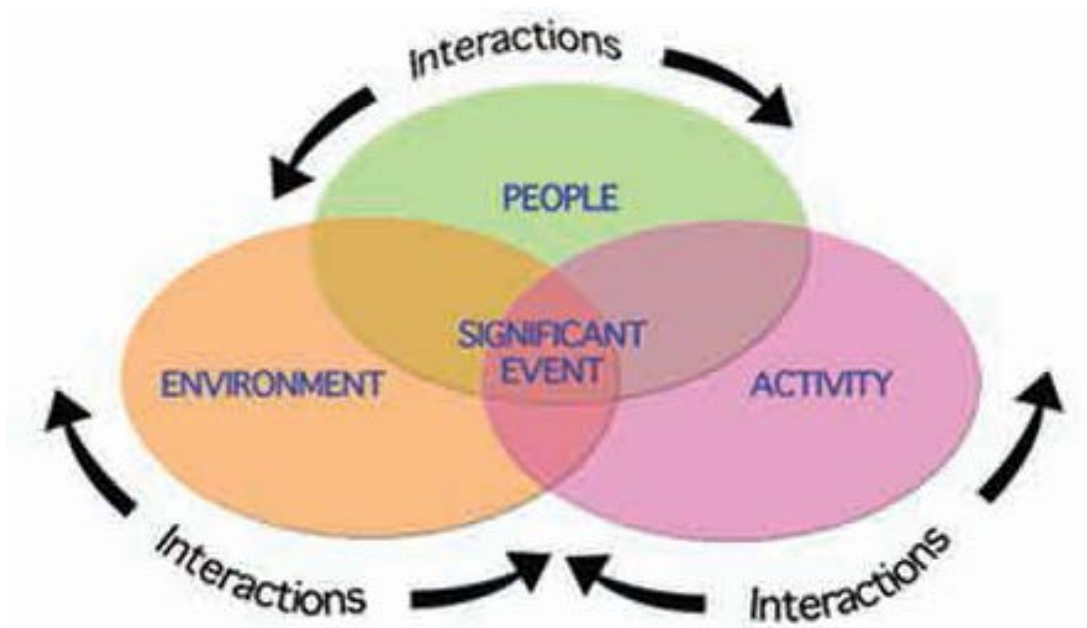
- a) Abuse or neglect of a child is known or suspected; and
- b) Either- the child has died; or the child has been seriously harmed and there is a cause for concern as to the way in which the authority, their board partners or other relevant persons have worked together to safeguard a child.

Reviews are not ends in themselves. The purpose of these reviews is to identify improvements that are needed and to consolidate good practice.

The different types of reviews include;

- Serious case reviews as above
- Child death review a review of all child deaths;
- Review of a child protection incident which falls below the threshold for an SCR
- Review or audit of practice in one or more agencies.

The Trust in its duty of protecting children needs to reflect on the quality of its services and learn from our own practices and that of others. Good practice should be shared so that there is a growing understanding of what works well. Conversely, when things go wrong there is a need to be rigorous, objective analysis of what happened and why, so that important lessons can be learnt and services improved



PEOPLE	ACTIVITY	ENVIRONMENT
Individual e.g. physical, psychological, personality or social issues; cognitive factors, competence, skills, attitudes, risk perception, training issues Team e.g. roles, support, communication, leadership Patient e.g. clinical condition, physical, social, psychological, relationship factors Others e.g. other health and social services	Complexity of work process or task, guidelines, policies and procedures e.g. not up-to-date, not available, unclear/unusable, not followed Design or organisation of work process of system e.g. level of complexity, workload, poor design Equipment e.g. positioning, not available, not working, not calibrated, usability issues	Work setting e.g. staffing, environmental conditions, workload or hours of work, design of physical environment, administrative and/or time factors Organisational e.g. safety culture, priorities, external risks, organisational structure Communication e.g. verbal, written, non verbal systems, poor communication, failure to communicate Education and training e.g. supervision, competence, availability/accessibility, appropriateness Societal, cultural and regulatory influences



CONFIDENTIAL BRIEFING REPORT

Always ensure that the either the on call manager or the Care Group Director is made aware of the incident - Complete ALL SECTIONS in full and once completed email to

HNF-TR.briefingreports@nhs.net

All identifiable information in the shaded areas will be removed prior to circulation to CRMG

Details of Person Completing Report

Name of Author:	
Job Title:	
Ward / Department / Team:	
Date staff became aware of incident	
Name of senior manager informed	

Details of Patient

Name:		
Date of Birth:		Age:
NHS Number:		
Legal Status:		
Name of the GP Practice:		
Next of Kin:		
Relationship of Next of Kin:		
Address of Next of Kin:		

Date of Incident:	
Key Professionals Involved: Please include full names, job titles, service and organisation (if not a Trust service)	

Severity of Harm:				
<i>None - No Harm</i>	<i>Low - Minimal Harm – requires extra observations or minor treatment</i>	<i>Moderate - Causes significant but not permanent harm. Moderate increase in treatment</i>	<i>Severe - Appears to have resulted in permanent harm</i>	<i>Death - Caused by the patient safety incident</i>
Actual (please tick appropriate box):				
None <input type="checkbox"/>	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	Severe <input type="checkbox"/>	Death <input type="checkbox"/>
Potential harm (please tick appropriate box):				

None <input type="checkbox"/>	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	Severe <input type="checkbox"/>	Death <input type="checkbox"/>
Is this a serious near miss?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Is this a never event?	Yes <input type="checkbox"/> No <input type="checkbox"/>

What is the Incident

Provide BRIEF detail as to what the incident is, e.g. Patient died, Patient went missing from unit, Self-harmed

Events Leading Up To The Incident

Please give details as to what led up to the incident. If the Incident relates to a patient then also provide a brief background to their circumstances e.g. was the patient already known to the Trust, were they on an existing caseload, were they waiting for a service, were they referred to the service but did not attend, were they discharged etc

Immediate Actions Taken - Are there any immediate concerns?

From the information available at the time of the incident, do you have any concerns in relation to this incident, for example, has there been a history of complaints or concerns expressed about the care provided to the patient, have there been problems prior to the incident (especially ones of a similar nature where a Briefing Report has been submitted), failures in communication etc.

Safeguarding - Is this an Adult / Children safeguarding issue?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If Yes, has an Alerter been generated? Yes <input type="checkbox"/> No <input type="checkbox"/> <i>Copy of Alerter must be attached.</i> If Yes, is the issue relating to an Adult <input type="checkbox"/> Child <input type="checkbox"/>		
Feedback provided by the Safeguarding Team (if applicable)		

Involvement of other agencies*Multi agency incident, police, safeguarding, HSE investigation, inquest, CQC involved***Duty of Candour – The patient and / or their family must be informed of the incident**

Has the incident been discussed with the Patient / Relative / Carer?

Yes ☐No ☐If **Yes**, please answer the following:

Date Incident Identified (If Different To Incident Date):

Date discussion took place:

Name of person incident discussed with:

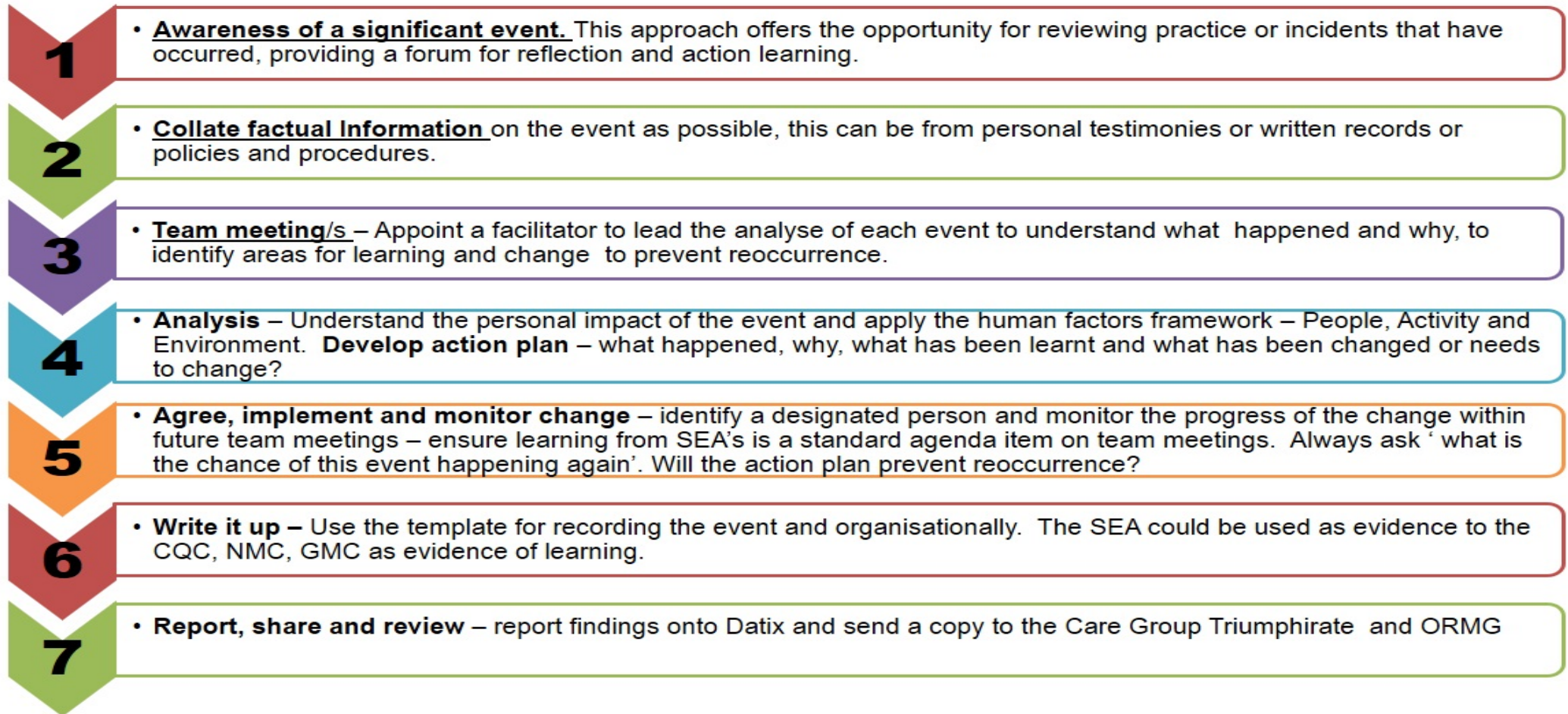
Relationship:

Name & Designation of staff member who discussed incident:

If **No**, please state the reason below for not informing the patient / relative / carer:**Support for staff involved**

7 Stages of Significant Event Analysis (SEA)

A significant event is any event which there is both good practice or an area of concern, in the care of a patient or within the systems and processes within services.





Root cause Analysis Investigation tools

Five Why's

Issue to be explored:

Why?

Why?

Why?

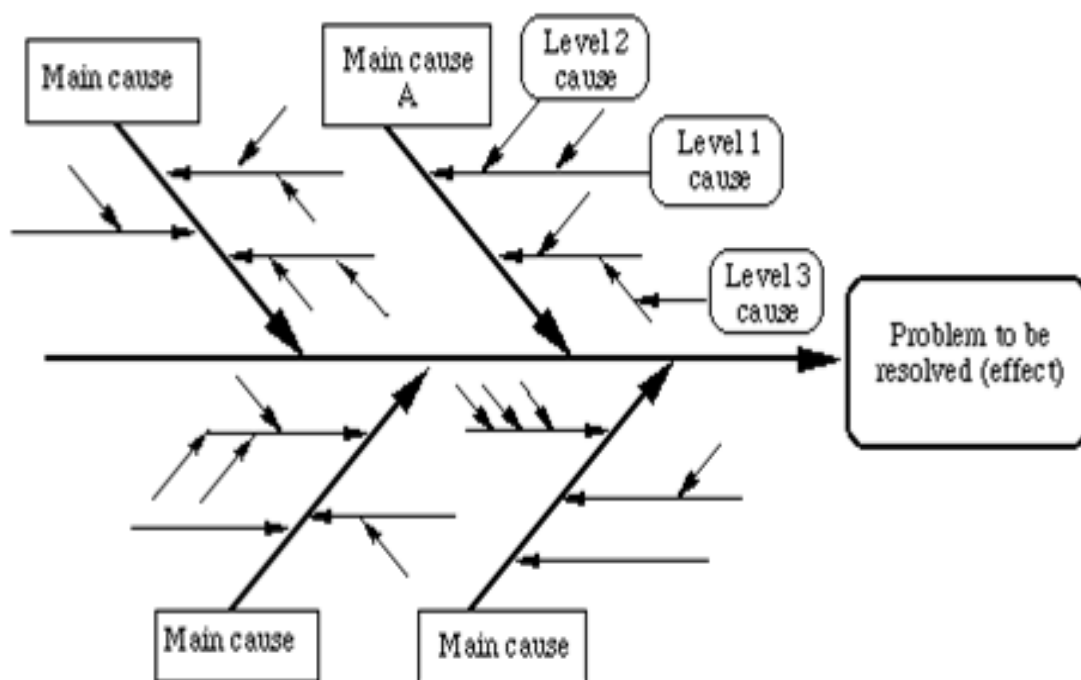
Why?

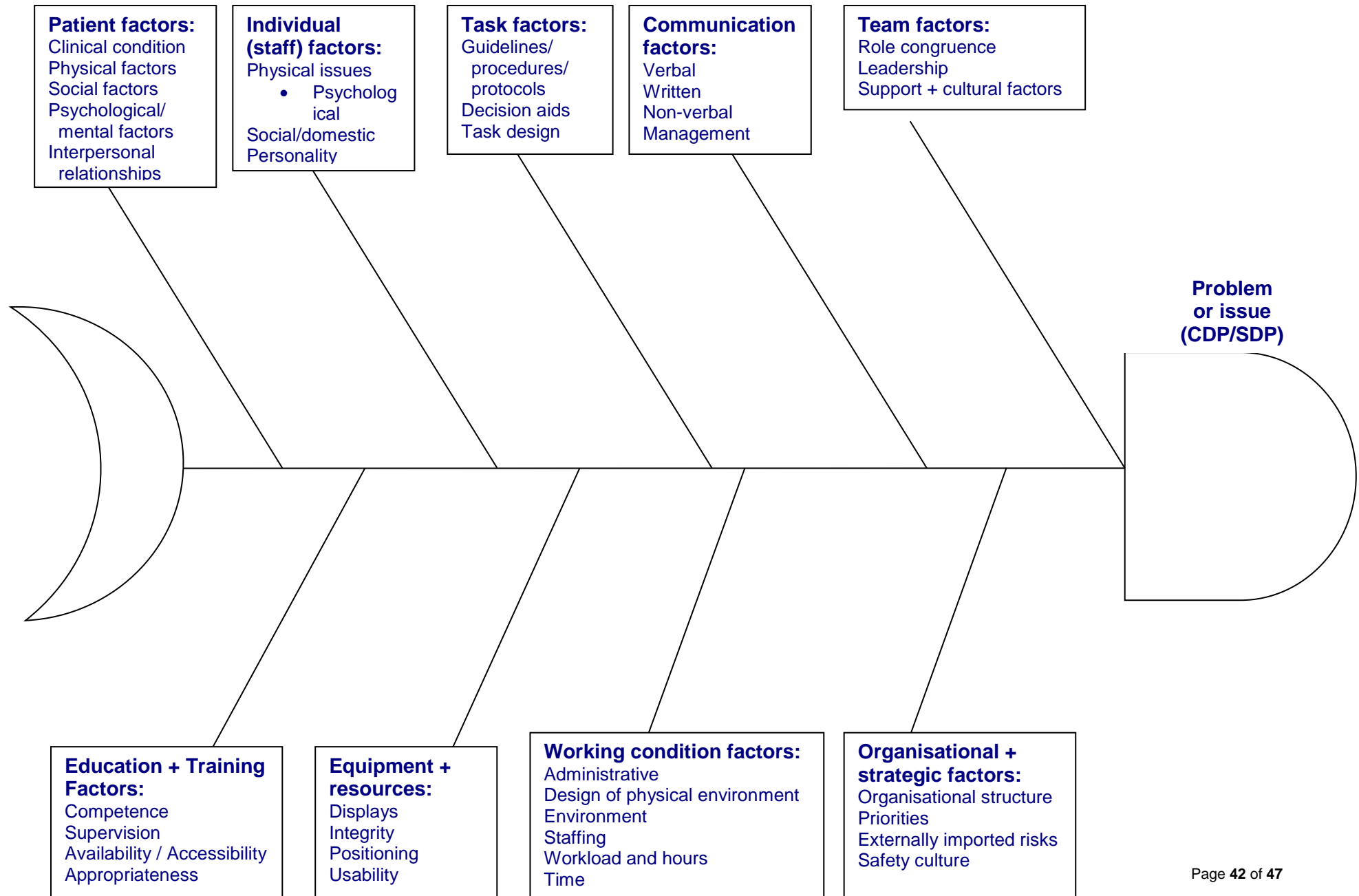
Why?

Fishbone

The main goal of the Fishbone diagram is to illustrate in a graphical way the relationship between an outcome and all the factors that influence this outcome. The main objectives of this tool are:

- Determining the root causes of a problem.
- Focusing on a specific issue and identifying areas where there is a lack of data.
- Focus attention on one specific issue or problem.
- Focus the team on the causes, not the symptoms.
- Organise and display graphically the various theories about what the root causes of a problem may be.
- Show the relationship of various factors influencing a problem.
- Reveal important relationships among various variables and possible causes.
- Provide additional insight into process behaviours.





Root Cause Analysis Investigation tools

Contributory Factors Classification Framework

Patient Factors	Components
Clinical condition	<input type="checkbox"/> Pre-existing co-morbidity <input type="checkbox"/> Complexity of condition <input type="checkbox"/> Seriousness of condition <input type="checkbox"/> Limited options available to treat condition <input type="checkbox"/> Disability
Physical Factors	<input type="checkbox"/> Poor general physical state <input type="checkbox"/> Malnourished <input type="checkbox"/> Dehydrated <input type="checkbox"/> Age related issues <input type="checkbox"/> Obese <input type="checkbox"/> Poor sleep pattern
Social Factors	<input type="checkbox"/> Cultural / religious beliefs <input type="checkbox"/> Language <input type="checkbox"/> Lifestyle (smoking/ drinking/ drugs/diet) <input type="checkbox"/> Sub-standard living accommodation (e.g. dilapidated) <input type="checkbox"/> Life events <input type="checkbox"/> Lack of support networks / (social protective factors -Mental Health Services) <input type="checkbox"/> Engaging in high risk activity
Mental/ Psychological Factors	<input type="checkbox"/> Motivation issue <input type="checkbox"/> Stress / Trauma <input type="checkbox"/> Existing mental health disorder <input type="checkbox"/> Lack of intent (Mental Health Services) <input type="checkbox"/> Lack of mental capacity <input type="checkbox"/> Learning Disability
Interpersonal relationships	<input type="checkbox"/> Staff to patient and patient to staff <input type="checkbox"/> Patient engagement with services <input type="checkbox"/> Staff to family and family to staff <input type="checkbox"/> Patient to patient <input type="checkbox"/> Family to patient or patient to family <input type="checkbox"/> Family to family (Siblings, parents, children)

Staff Factors	Components
Physical issues	<input type="checkbox"/> Poor general health (e.g. nutrition, hydration, diet, exercise, fitness) <input type="checkbox"/> Disability (e.g. eyesight problems, dyslexia) <input type="checkbox"/> Fatigue <input type="checkbox"/> Infected Healthcare worker
Psychological Issues	<input type="checkbox"/> Stress (e.g. distraction / preoccupation) <input type="checkbox"/> Specific mental illness (e.g. depression) <input type="checkbox"/> Mental impairment (e.g. illness, drugs, alcohol, pain) <input type="checkbox"/> Lack of motivation (e.g. boredom, complacency, low job satisfaction)
Social Domestic	<input type="checkbox"/> Domestic problems (e.g. family related issues) <input type="checkbox"/> Lifestyle problems (e.g. financial/housing issues) <input type="checkbox"/> Cultural beliefs <input type="checkbox"/> Language
Personality Issues	<input type="checkbox"/> Low self confidence / over confidence (e.g. Gregarious, reclusive, interactive) <input type="checkbox"/> Risk averse / risk taker <input type="checkbox"/> Bogus Healthcare worker
Cognitive factors	<input type="checkbox"/> Preoccupation / narrowed focus (Situational awareness problems) <input type="checkbox"/> Perception/viewpoint affected by info. or mindset (Expectation/Confirmation bias) <input type="checkbox"/> Inadequate decision/action caused by Group influence <input type="checkbox"/> Distraction / Attention deficit <input type="checkbox"/> Overload <input type="checkbox"/> Boredom

Task Factors	Components
Guidelines, Policies and Procedures	<ul style="list-style-type: none"> <input type="checkbox"/> Not up-to-date <input type="checkbox"/> Unavailable at appropriate location (e.g. Lost/missing/non-existent/not accessible when needed) <input type="checkbox"/> Unclear/not useable (Ambiguous; complex; irrelevant, incorrect) <input type="checkbox"/> Not adhered to / not followed <input type="checkbox"/> Not monitored / reviewed <input type="checkbox"/> Inappropriately targeted/focused (i.e. not aimed at right audience) <input type="checkbox"/> Inadequate task disaster plans and drills
Decision making aids	<ul style="list-style-type: none"> <input type="checkbox"/> Aids not available (e.g. CTG machine; checklist; risk assessment tool; fax machine to enable remote assessment of results) <input type="checkbox"/> Aids not working (e.g. CTG machine, risk assessment tool, fax machine) <input type="checkbox"/> Difficulties in accessing senior / specialist advice <input type="checkbox"/> Lack of easy access to technical information, flow charts and diagrams <input type="checkbox"/> Lack of prioritisation of guidelines <input type="checkbox"/> Incomplete information (test results, patient history)
Procedural or Task Design	<ul style="list-style-type: none"> <input type="checkbox"/> Poorly designed (i.e. Too complex; too much info.; difficult to conceive or remember) <input type="checkbox"/> Guidelines do not enable one to carry out the task in a timely manner <input type="checkbox"/> Too many tasks to perform at the same time <input type="checkbox"/> Contradicting tasks <input type="checkbox"/> Staff do not agree with the 'task/procedure design' <input type="checkbox"/> Stages of the task not designed so that each step can realistically be carried out <input type="checkbox"/> Lack of direct or understandable feedback from the task <input type="checkbox"/> Misrepresentation of information <input type="checkbox"/> Inappropriate transfer of processes from other situations <input type="checkbox"/> Inadequate Audit, Quality control, Quality Assurance built into the task design <input type="checkbox"/> Insufficient opportunity to influence task/outcome where necessary <input type="checkbox"/> Appropriate automation not available

Communication	Components
Verbal communication	<ul style="list-style-type: none"> <input type="checkbox"/> Inappropriate tone of voice and style of delivery for situation <input type="checkbox"/> Ambiguous verbal commands / directions <input type="checkbox"/> Incorrect use of language <input type="checkbox"/> Made to inappropriate person(s) <input type="checkbox"/> Incorrect communication channels used
Written communication	<ul style="list-style-type: none"> <input type="checkbox"/> Inadequate patient identification <input type="checkbox"/> Records difficult to read <input type="checkbox"/> All relevant records not stored together and accessible when required <input type="checkbox"/> Records incomplete or not contemporaneous (e.g. unavailability of patient management plans, patient risk assessments, etc) <input type="checkbox"/> Written information not circulated to all team members <input type="checkbox"/> Communication not received <input type="checkbox"/> Communications directed to the wrong people <input type="checkbox"/> Lack of information to patients <input type="checkbox"/> Lack of effective communication to staff of risks (Alerts systems etc)
Non verbal communication	<ul style="list-style-type: none"> <input type="checkbox"/> Body Language issues (closed, open, body movement, gestures, facial expression)
Communication Management	<ul style="list-style-type: none"> <input type="checkbox"/> Communication strategy and policy not defined / documented <input type="checkbox"/> Ineffective involvement of patient/carer in treatment and decisions <input type="checkbox"/> Lack of effective communication to patients/relatives/carers of risks <input type="checkbox"/> Lack of effective communication to patients about incidents (being open) <input type="checkbox"/> Information from patient/carer disregarded <input type="checkbox"/> Ineffective communication flow to staff up, down and across <input type="checkbox"/> Ineffective interface for communicating with other agencies (partnership working) <input type="checkbox"/> Lack of measures for monitoring communication

Equipment	Components
Displays	<input type="checkbox"/> Incorrect information / feedback available <input type="checkbox"/> Inconsistent or unclear information <input type="checkbox"/> Illegible information <input type="checkbox"/> Interference/unclear equipment display
Integrity	<input type="checkbox"/> Poor working order <input type="checkbox"/> Inappropriate size <input type="checkbox"/> Unreliable <input type="checkbox"/> Ineffective safety features / not designed to fail safe <input type="checkbox"/> Poor maintenance programme <input type="checkbox"/> Failure of general services (power supply, water, piped gases etc)
Positioning	<input type="checkbox"/> Correct equipment not available <input type="checkbox"/> Insufficient equipment / emergency backup equipment <input type="checkbox"/> Incorrectly placed for use <input type="checkbox"/> Incorrectly stored
Usability	<input type="checkbox"/> Unclear controls <input type="checkbox"/> Not intuitive in design <input type="checkbox"/> Confusing use of colour or symbols <input type="checkbox"/> Lack of or poor quality user manual <input type="checkbox"/> Not designed to make detection of problems obvious <input type="checkbox"/> Use of items which have similar names or packaging <input type="checkbox"/> Problems of compatibility

Work Environment	Components
Administrative factors	<input type="checkbox"/> Unreliable or ineffective general administrative systems (Please specify e.g.: Bookings, Patient identification, ordering, requests, referrals, appointments) <input type="checkbox"/> Unreliable or ineffective admin infrastructure (e.g. Phones, bleep systems etc) <input type="checkbox"/> Unreliable or ineffective administrative support
Design of physical environment	<input type="checkbox"/> Poor or inappropriate office design (computer chairs, height of tables, anti-glare screens, security screens, panic buttons, placing of filing cabinets, storage facilities, etc.) <input type="checkbox"/> Poor or inappropriate area design (length, shape, visibility, provision of space) <input type="checkbox"/> Inadequate security provision <input type="checkbox"/> Lack of secure outside space <input type="checkbox"/> Inadequate lines of sight <input type="checkbox"/> Inadequate/inappropriate use of colour contrast/patterns (walls/doors/flooring etc)
Environment	<input type="checkbox"/> Facility not available (failure or lack of capacity) <input type="checkbox"/> Fixture or fitting not available (failure or lack of capacity) <input type="checkbox"/> Single sex accommodation limitation/breach <input type="checkbox"/> Ligature/anchor points <input type="checkbox"/> Housekeeping issues – lack of cleanliness <input type="checkbox"/> Temperature too high/low <input type="checkbox"/> Lighting too dim or bright, or lack of <input type="checkbox"/> Noise levels too high or low <input type="checkbox"/> Distractions
Staffing	<input type="checkbox"/> Inappropriate skill mix (e.g. Lack of senior staff; Trained staff; Approp. trained staff) <input type="checkbox"/> Low staff to patient ratio <input type="checkbox"/> No / inaccurate workload / dependency assessment <input type="checkbox"/> Use of temporary staff <input type="checkbox"/> High staff turnover
Work load and hours of work	<input type="checkbox"/> Shift related fatigue <input type="checkbox"/> Excessive working hours <input type="checkbox"/> Lack of breaks during work hours <input type="checkbox"/> Excessive of extraneous tasks <input type="checkbox"/> Lack of social relaxation, rest and recuperation
Time	<input type="checkbox"/> Delays caused by system failure or design <input type="checkbox"/> Time pressure

Organisational	Components
Organisational structure	<ul style="list-style-type: none"> <input type="checkbox"/> Hierarchical structure/Governance structure not conducive to discussion, problem sharing, etc. <input type="checkbox"/> Tight boundaries for accountability and responsibility <input type="checkbox"/> Professional isolation <input type="checkbox"/> Clinical versus the managerial model <input type="checkbox"/> Inadequate maintenance <input type="checkbox"/> Lack of robust Service level agreements/contractual arrangements <input type="checkbox"/> Inadequate safety terms and conditions of contracts
Priorities	<ul style="list-style-type: none"> <input type="checkbox"/> Not safety driven <input type="checkbox"/> External assessment driven e.g. Annual Health checks <input type="checkbox"/> Financial balance focused
Externally imported risks	<ul style="list-style-type: none"> <input type="checkbox"/> Unexpected adverse impact of national policy/guidance (from Department of Health / Health authorities /Professional colleges) <input type="checkbox"/> Locum / Agency policy and usage <input type="checkbox"/> Contractors related problem <input type="checkbox"/> Equipment loan related problem <input type="checkbox"/> Lack of service provision <input type="checkbox"/> Bed Occupancy levels (Unplanned bed opening/closures) <input type="checkbox"/> PFI related problems (Private Finance Initiative)
Safety culture	<ul style="list-style-type: none"> <input type="checkbox"/> Inappropriate safety / efficiency balance <input type="checkbox"/> Poor rule compliance <input type="checkbox"/> Lack of risk management plans <input type="checkbox"/> Inadequate leadership example (e.g. visible evidence of commitment to safety) <input type="checkbox"/> Inadequately open culture to allow appropriate communication <input type="checkbox"/> Inadequate learning from past incidents <input type="checkbox"/> Incentives for 'at risk'/risk taking' behaviors <input type="checkbox"/> Acceptance/tolerance of inadequate adherence to current practice <input type="checkbox"/> Ignorance/poor awareness of inadequate adherence to current practice <input type="checkbox"/> Disempowerment of staff to escalate issues or take action

Education and Training	Components
Competence	<ul style="list-style-type: none"> <input type="checkbox"/> Lack of knowledge <input type="checkbox"/> Lack of skills <input type="checkbox"/> Inexperience <input type="checkbox"/> Inappropriate experience or lack of quality experience <input type="checkbox"/> Unfamiliar task <input type="checkbox"/> Lack of testing and assessment
Supervision	<ul style="list-style-type: none"> <input type="checkbox"/> Inadequate supervision <input type="checkbox"/> Lack of / inadequate mentorship <input type="checkbox"/> Training results not monitored/acted upon
Availability / accessibility	<ul style="list-style-type: none"> <input type="checkbox"/> Training needs analysis not conducted/acted upon <input type="checkbox"/> On the job training unavailable or inaccessible <input type="checkbox"/> Emergency Training unavailable or inaccessible <input type="checkbox"/> Team training unavailable or inaccessible <input type="checkbox"/> Core skills training unavailable or inaccessible <input type="checkbox"/> Refresher courses unavailable or inaccessible
Appropriateness	<ul style="list-style-type: none"> <input type="checkbox"/> Inappropriate content <input type="checkbox"/> Inappropriate target audience <input type="checkbox"/> Inappropriate style of delivery <input type="checkbox"/> Time of day provided inappropriate

Team Factors	Components
Role Congruence	<input type="checkbox"/> Lack of shared understanding <input type="checkbox"/> Role + responsibility definitions misunderstood/not clearly defined
Leadership	<input type="checkbox"/> Ineffective leadership – clinically <input type="checkbox"/> Ineffective leadership – managerially <input type="checkbox"/> Lack of decision making <input type="checkbox"/> Inappropriate decision making <input type="checkbox"/> Untimely decision making (delayed) <input type="checkbox"/> Leader poorly respected
Support and cultural factors	<input type="checkbox"/> Lack of support networks for staff <input type="checkbox"/> Inappropriate level of assertiveness <input type="checkbox"/> Negative team reaction(s) to adverse events <input type="checkbox"/> Negative team reaction to conflict <input type="checkbox"/> Negative team reaction to newcomers <input type="checkbox"/> Routine violation of rules/regulations <input type="checkbox"/> Lack of team openness/communication with colleagues <input type="checkbox"/> Inadequate inter-professional challenge <input type="checkbox"/> Failure to seek support <input type="checkbox"/> Failure to address/manage issues of competence (whistle blowing)