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**CONTROL RECORD**

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|                                 | • Yorkshire and Humber Strategic Health Authority - Procedure for the Management of Serious Incidents (SI’s).
|                                 | • Yorkshire and Humber Strategic Health Authority - Good Practice Principles for Incident Management
|                                 | • An Organisation with a Memory, Department of Health, 2000 [Hyperlink](#)
|                                 | • Being open – Communicating patient safety incident with patients and their carers, NPSA, 2005 [Hyperlink](#)
|                                 | • Seven Steps to Patient Safety, NPSA, 2004 [Hyperlink](#)
|                                 | • The NHS Confidentiality Code of Practice, Department of Health, 2003 [Hyperlink](#)
|                                 | • The Operating Framework for the NHS in England 2010/11
|                                 | • Never Events Policy (DH)
|                                 | • National Framework for Reporting and Learning from Serious Incidents Requiring Investigation
|                                 | • Procedure for the management of Serious Incidents (SIs) Version 6 – October 2010 [Hyperlink](#)
|                                 | • Integrated Risk Management Framework
|                                 | • Whistleblowing,
|                                 | • Being Open Policy
|                                 | • Health and Safety Policy

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Incident and Near Miss Reporting Policy and Procedure incorporating Serious Incident Procedure

Introduction

1.1 NHS Barnsley Clinical Commissioning Group places high value on the importance of establishing a safety and reporting culture within the organisation, which appreciates the significance of effective incident management. Incident reporting is one of the fundamental tools of risk management, the aim of which is to collect information about incidents, including near misses, ill health and hazards, which will help to facilitate wider organisational learning and to minimise recurrence.

1.2 Reporting of incidents is more likely to take place in an organisation where there is a well-developed safety culture and where there is strong leadership. To support this, NHS Barnsley Clinical Commissioning Group has developed a culture to ensure that risk management is an integral part of everything we do as defined within the NHS Barnsley Clinical Commissioning Group Integrated Risk Management Framework. The Integrated Risk Management Framework defines the systematic assessment of all risks the organisation faces including those associated with the reporting and management of all incidents.

1.3 NHS Barnsley Clinical Commissioning Group promotes an open and fair approach to incident reporting, management and investigation for both staff and patients. NHS Barnsley Clinical Commissioning Group wishes to foster an environment where staff, patients and the public are encouraged to report incidents and near misses that raise concern about the quality and safety of patient care and the safety of staff, visitors, contractors and the public.

1.4 NHS Barnsley Clinical Commissioning Group has a legal responsibility to report all incidents and accidents as well as near misses. There is also a requirement to monitor and investigate immediate and underlying causes of incidents and accidents to staff, patients and visitors, to report their findings and learn from them to minimise recurrence. NHS Barnsley Clinical Commissioning Group will take all reasonably practicable corrective action to ensure the health, safety and wellbeing of its employees, patients, contractors and any other persons affected by its services. Additionally, the requirements associated with Care Quality Commission, Health and Safety Executive, NHS Counter Fraud & Security Management Service, Clinical Governance, the NHS Litigation Authority Scheme for Trusts, High Level enquires, National Safety Patients Agency (NSPA), ‘Control of Substances Hazardous to Health’ (COSHH) and ‘Reporting of Incidents, Diseases and Dangerous Occurrences Regulations’ (RIDDOR) standards require reporting, recording and monitoring systems to be in place.

1.5 NHS Barnsley Clinical Commissioning Group has a common reporting system, and a centrally maintained database for all types of incidents. Reporting of all incidents and near misses, regardless of severity, is mandatory.

The Department of Health publications “An Organisation with a Memory” and “Building a Safer NHS for Patients”, and the National Patient Safety Agency publication “Seven Steps to Patient Safety - A Guide for NHS Staff”, have all identified the significant opportunities that exist to reduce unintended harm to patients arising during NHS care, and helping to establish a safety culture within NHS Barnsley Clinical Commissioning Group and the services it commissions.
1.6 NHS Barnsley Clinical Commissioning Group has devolved responsibility, from NHS Yorkshire and the Humber for the performance management of Serious Incidents (SIs) reported by Barnsley NHS Foundation Trust and South West Yorkshire Partnership Foundation Trust. NHS Bradford and Airedale Clinical Commissioning Group has devolved responsibility for the performance management of Serious Incidents reported by Yorkshire and South Humber (Ambulance Service) (YAS). NHS Bradford and Airedale Clinical Commissioning Group produce an annual report of their performance management activity and this is discussed at bi-monthly clinical quality review meetings with all commissioners.

1.7 NHS Barnsley Clinical Commissioning Group has a responsibility to ensure that the investigation and management of Serious Incidents in services which they have commissioned in the Independent Sector are robust and reported to the NHS Yorkshire and Humber in the usual way, indicating what actions will have been taken. NHS Yorkshire and the Humber will be superseded by the National Commission Board.

1.8 NHS Barnsley Clinical Commissioning Group leads on the reporting of low level concerns within local care homes and domiciliary agencies. This provides a picture of quality and standards of care provided by these agencies and also early alerts to providers not meeting expected standards and issues in relation to patient safety and quality.

Purpose

2.1 NHS Barnsley Clinical Commissioning Group recognises the importance of learning from accidents, incidents, adverse events and near miss situations in order to reduce the number of incidents and severity of outcomes experienced. It should be noted that an organisation which has a number of incidents reported demonstrates a culture of openness.

2.2 The need to ensure that healthcare organisations report and learn from adverse events was emphasised in two key publications ‘Organisation with a Memory’ (DoH 2000) and ‘Building A Safer NHS For Patients: Implementing An Organisation With A Memory’ (DoH 2001). Learning from incidents enables appropriate actions and strategies to be developed and implemented by the organisation, to work towards reducing incidents and improving the safety of patients, staff, visitors, contractors and the public.

2.3 NHS Barnsley Clinical Commissioning Group needs to be satisfied that all incidents are managed, recorded and investigated as appropriate and that learning from incidents takes place. Qualitative and quantitative data analysis will be used to highlight trends which may be occurring and uncover any further need for intervention. In addition specific types of incidents will be investigated to ensure specific learning from these types of incidents.

2.4 Incidents are uncommon in relation to the high volume of care provided, but when they do occur they can have devastating consequences and must be handled and reported on sensitively and in a timely way.

2.5 Incident reporting is the foundation of an effective risk management system and it is NHS Barnsley Clinical Commissioning Group’s aim that incident reporting operates in an open and just environment.

2.6 Incident investigation at the appropriate level is necessary to ensure that the underlying causes of incidents may be identified, especially those incidents of a serious nature in
order to take appropriate action, to learn from mistakes, and to reduce the likelihood of recurrence.

2.7 Reporting internally is necessary to support the learning process within the organisation and to support a change culture. Key external stakeholders are required to be informed to share lessons across healthcare and other organisations.

2.8 The National Patient Safety Agency encourages clinical staff and managers to be honest and transparent with patients and their families when an incident has occurred.

2.9 It is important throughout the investigation process to recognise the effect an incident can have on staff and others, including patients. This is particularly important regarding Serious Incidents. These individuals should be treated with sensitivity and kept informed of progress in regard to the investigation and remedial action that is being taken. Appropriate levels of support should be given which includes timely feedback, counselling, referral to Occupational Health, including staff support if appropriate or requested, and Team de-briefs. Support can be formal or informal and an assessment of individual need should be made to ensure the appropriate support is provided. Incidents of any nature can have a traumatic effect on staff directly and indirectly involved. It is important that individuals do not feel isolated when involved in an adverse event. Support for staff involved in traumatic/stressful incidents, complaints or claims is essential to ensure that those involved are not adversely affected by the situation and helps to gain the confidence of staff to report incidents and to enable learning to take place. Patients and their families should also be supported as identified in the Procedure (Appendix 7). This Policy is supported by a series of procedures and establishes the principles to be adopted by the NHS Barnsley Clinical Commissioning Group as it works to achieve improvements in service delivery.

This Policy should not be read in isolation but in conjunction with related Policies and Procedures identified above.

Scope

3.1 This policy covers all incidents, near misses and serious incidents no matter who or what may be involved or how serious or minor the incident.

3.2 This policy applies to everyone employed by NHS Barnsley Clinical Commissioning Group (wherever they are based) and anyone working on or visiting NHS Barnsley Clinical Commissioning Group premises.

3.3 It includes events involving service users, visitors, contractors, and those providing services under service level agreement, volunteers, students, people on work experience or secondment, agency and bank staff etc.

3.4 NHS Barnsley Clinical Commissioning Group encourages patients, service users, carers, and visitors to report adverse events that occur in commissioned services. Only by having a clear understanding of all events will NHS Barnsley Clinical Commissioning Group be able to develop an appropriate response to the risks that face the organisation, its staff and the public of Barnsley.

3.5 This policy covers the delegated responsibilities for the performance management of Serious Incidents reported by providers of Commissioned Services.
The Risks of not having this policy in place

4. If this policy is not in place and implemented, NHS Barnsley Clinical Commissioning Group:

- Will not be able to meet its statutory obligations.
- Will not have in place an early warning system in relation to patient safety and quality and these may not be identified in a timely manner.
- May lead to poor monitoring of types and numbers of Accidents and Incidents resulting in failure to learn across the service.
- Will be inhibited in fostering a culture of openness.
- Will not be able to effectively communicate to partnership organisation their roles and responsibility in reporting and investigating incidents.
- May fail to recognise the equality, diversity, values and human rights of people who we commission services for.
- Has the potential to harm the reputation of the NHS Barnsley Clinical Commissioning Group.

Definitions

5.1 Incidents are:

Any unplanned or unexpected event or omission that has, or could have, led to death, physical or psychological injury, ill health, damage or other loss, and this includes the common understanding of accidents.

Included in the definition of incidents are any events which have failed to result in harm/loss on this occasion, whether or not through preventative or compensating action, but which have the potential for harm/loss should a similar event occur in the future.

(Older terms included in the definition of an incident are; adverse incidents, adverse healthcare events, critical incidents, significant events and medical/clinical error).

5.2 Near Misses

Near misses may also constitute SIs and can be defined where the contributory causes are serious and under different circumstances they may have led to serious injury, major permanent harm, or unexpected death, but no actual harm resulted on that occasion. A possible example is that of a system failure, the result of which is incorrect/delayed diagnosis. This may not have any serious consequences for some patients, but for others could lead to the wrong treatment/serious delay in treatment and ultimately to death.

5.3 A Patient Safety Incident
A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS/funded care.

5.4 What is a SI?

A serious incident requiring investigation is defined by the NPSA in the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation as an incident that occurred in relation to NHS-funded services and care resulting in one of the following:-

- **Unexpected or avoidable** death of one or more patients, staff, visitors or members of the public;

- **Serious harm** to one or more patients, staff, visitors or members of the public or where the outcome requires life-threatening intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy or result in prolonged pain or psychological harm (the includes incidents graded under the NPSA definition of severe harm);

- A scenario that prevents or threatens to prevent a provider organisation’s ability to continue to deliver health care services, for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment, or IT failure;

- Allegations of abuse

- Adverse media coverage or public concern about the organisation or the wider NHS;

- One of the core set of Never Events. Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by providers. All Never Events should be reported as SIs. The Operating Framework for the NHS in England 2010/11 reaffirms that ORGANISATIONS’s should:
  
  o use the national set of Never Events as part of their contract arrangements with providers;

  o ensure that patient safety incidents which are Never Events are reported to the NPSA; and

  o publish the numbers and types of events on an annual basis.

Examples of other incidents which are reportable as SIs are shown in the Yorkshire & Humber Procedure for the management of Serious Incidents – Version 6 – October 2010.

5.5 Never Events

These are serious, largely preventable patient safety incidents that should not occur if avoidable preventative measures have been implemented by providers. All Never Events should be reported as SIs and to the National Patient Safety Agency (NPSA) by the provider.

5.6 Hazard and Risk
**Hazard** is defined as something with the inherent potential to cause harm or injury.

**Risk** is the chance that something will happen that will have an impact on achievement of an objective.

It is also the responsibility NHS Barnsley Clinical Commission Group to inform the Yorkshire & the Humber Deanery of those incidents directly involving trainee doctors (Procedure for the management of Serious Untoward Incidents (SUIs) NHS Yorkshire & the Humber December 2010).

5.7 **Patient safety** – ‘The process by which an organisation makes patient care safer. This should involve risk assessment; the identification and management of patient risks; the reporting and analysis of incidents; and the capacity to learn from and follow on incidents and implement solutions to minimise risk of them recurring’ (NPSA 2004).

5.8 **Root cause analysis** – (RCA)

‘A methodology that enables you to ask the questions ‘How’ and ‘Why’ in a structured and objective way to reveal all the influencing and causal factors that have led to a patient safety incident. The aim is to learn how to prevent similar incidents happening again, not to apply blame.’ (NPSA 2004).

5.9 **Significant Event Audit/Analysis (SEA)**

A mutually supportive, multidisciplinary, rigorous, retrospective analysis of key events occurring in a clinical setting, by those involved, with a view to learning lessons and making necessary changes in order to improve future quality of care.

5.10 **STEIS (also know as UNIFY)**

The Strategic Executive Information System (STEIS) developed by the Department of Health and launched in 2002, is a web-based system currently being used by Yorkshire and Humber SHA to gather situation report (SITREP) information and data directly from the Trusts. STEIS contains a Serious Untoward Incident module which allows Trusts to add Serious Untoward Incident data directly onto STEIS and is then accessible by the Strategic Health Authority.

5.11 **Serious Case Review (SCR)**

Local Authority led multi-agency review of a child protection serious incident) underpinned by national legislation and guidance and is undertaken when a child dies or is seriously injured from abuse or neglect. It involves all agencies involved with the child and its family and may extend back over several years. In addition although not in Statute the term may also apply to an incident involving an Adult

5.12 **Medicines and Healthcare Products Regulatory Agency (MHRA)**

The MHRA is the Executive Agency of the Department of Health protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.

5.13 **The National Patient Safety Agency (NPSA)**
The National Reporting and Learning System (NRLS) is a national system of reporting anonymous incidents to the National Patient Safety Agency (NPSA). The System is designed to collect information on patient safety errors and systems failures with a view to identifying national patient safety trends and priorities in order to develop practical solutions to these. The overall aim of the NRLS is to support the NHS to learn from things that go wrong.

NHS Barnsley Clinical Commissioning Group reports patient safety incidents anonymously to the National Patient Safety Agency (NPSA) through the electronic extraction of data from the Trust’s incident reporting system. Anonymised data will be uploaded to the National Reporting and Learning System (NRLS) on a two-weekly basis on behalf of the Head of Patient/Deputy Chief Nurse.

Staff are able to report independently to the NRLS should they wish through completing an online electronic reporting form, details of which may be found on the NPSA website: [www.npsa.nhs.uk](http://www.npsa.nhs.uk)

5.14 (RIDDOR) Reporting of Injuries, Disease and Dangerous Occurrences

RIDDOR requires that specified injuries, disease and dangerous occurrences are notified to the Health and Safety Executive through the Incident Reporting Centre in Caerphilly. Failure to comply is a criminal offence and liability lies with the “responsible person” i.e. the person in charge of the work activity in that area in line with managers’ responsibilities.

5.15 Data Protection Act

To comply with the Data Protection Act 1998 (DPA), personal details entered in accident books and/or incident reports must be kept confidential. Managers responsible for completing and retaining accident and incident records must ensure that they are stored securely and only made available to authorised personnel associated with the incident reporting procedure.

5.16 Low level concerns

Relates to either wider concern about poor standards of care, such as unhygienic living environment or lack of social activities, or alerts that fall outside the threshold for Safeguarding Adult procedures and can be addressed by other means.

Accountability and Responsibilities

6.1 Governing Body

The NHS Barnsley Clinical Commissioning Group Governing Body has the responsibility:

- To ensure effective incident and investigating reporting procedures are followed in the Trust and that external organisations are informed of any serious incidents under existing reporting arrangements.
- To promote a culture which encourages individuals to report incidents and near misses to encourage the learning from incidents.
- To ensure themselves that risks are managed effectively and that the organisation has in place robust systems of risk assessment and monitoring processes for incidents, complaints and claims including analysis.
To assure themselves that risks are managed effectively and that the organisation has in place robust systems of risk assessment and monitoring processes for incidents, complaints and claims including analysis.

6.2 Quality & Patient Safety Committee

The Quality & Patient Safety Committee will receive, as a standing agenda item, statistics including trend analysis regarding incidents. The Committee will review these statistics and also monitor the progress of action plans agreed following all serious incidents. The Complaints, SI and Claims Group will receive completed investigation reports and undertake the performance management of these. This Group will recommend that submitted reports show that a robust investigation process has been completed, including progress against identified actions, and outstanding issues, including making appropriate challenges to ensure assurance. This Group will provide assurance to the Governing Body via the Quality and Patient Safety Committee.

6.3 The Chief Officer

The Chief Officer is ultimately responsible for ensuring compliance with the Health and Safety at Work Act and associated legislation and that this policy is effective and communicated to all staff.

The Chief Officer is also responsible for the reporting of physical assaults to staff, under the Secretary of States directions for tackling violence supported by the Head of Corporate Affairs.

6.4 Chief Nurse

The Chief Nurse has overall responsibility for the development and monitoring of the incident reporting system including responsibility for Serious Incident Performance Management across NHS Barnsley Clinical Commissioning Group and its commissioned services, supported by the Head of Patient Safety/ Deputy Chief Nurse.

If an incident is identified as a serious incident, the Chief Nurse will ensure that the check list for action on discovering a serious incident is followed and section Three of this document and that full written contemporaneous records are maintained of all actions taken.

6.5 All Managers

All Managers are responsible to the Organisation for implementing this policy and procedure. The Managers will through their staff ensure within their sphere of responsibility are aware of the need to report incidents, never events, near misses and patient safety incidents and complete the web based Safeguard Incident Report or telephone reporting system. RIDDOR (F2508) Reporting of Injuries, Disease and Dangerous Occurrence Regulations form.

All Managers are responsible for the safety of their workforce and will ensure that systems of incident reporting are implemented within their area of responsibility. They will maintain records and monitor the occurrence of all incidents, accidents and near misses, affecting and involving their workforce, patients, service users, volunteers and members of the public and be responsible for reporting their findings as appropriate.
Managers should also record the immediate actions taken, which might include, making the area safe, wearing protective clothing, removal of similar equipment and undertake risk assessments.

6.6 Staff

All staff have a legal responsibility to report all incidents, near misses or hazards to their Line Manager as soon as is reasonably practicable but within the timescales detailed (see action appendix 4). Should any situation pose imminent danger to others, all staff should attempt to reduce the risk of occurrence by their direct action, i.e. removing obstacles on pathways/roads, having temporary barriers placed around holes, spillages etc. They will ensure that the incident is reported as soon as practicable to their line manager and the web based Safeguard Incident Report or telephone reporting system is completed.

6.7 Independent Contractors

Independent Contractors are strongly recommended to report all incidents to NHS Barnsley Clinical Commissioning Group. Incidents should be reported web based Safeguard Incident Report or telephone reporting system NHS Barnsley Clinical Commissioning Group’ would expect Independent Contractors, as part of their professional duty, to report all serious and dangerous events and those which are initially coded as moderate or high risk, we would expect them to investigate and to share their findings with Clinical Commissioning Group.

However, employees must also be aware that where the investigation reveals:

- an intention to harm/malicious act
- a criminal act/breach of law
- wilful negligence or professional misconduct/malpractice
- acts of gross misconduct
- acts that foresee ably put safety at risk
- several repeated mistakes
- deliberate contraventions of acceptable practice

Action will be taken in accordance with the organisations disciplinary policies and procedures

6.8 Delegated responsibility

The Head of Patient Safety/Deputy Chief Nurse will, ensure on behalf of the Chief Nurse that the following action is taken:

- Ensure in conjunction with the Quality Manager/Risk Co-ordinator, that training/familiarisation of the incident reporting module is provided for all staff, including documentation and procedures.

- Ensure in conjunction with Quality Manager/Risk Co-ordinator, that a reporting system for the reporting of incidents is maintained and that all incidents are entered onto the Incident Reporting Module. The system will keep a record of the incident and will produce records, identify trends in frequency and causation of accidents and incidents, and reports will be provided.

- Ensure that regular monitoring and, as necessary, audit of the operation of this policy and procedure will be carried out to ensure its effective implementation.
- Ensure that completion of appropriate documentation for all physical assaults to staff is undertaken and reported to the Security Management Service by the Head of Corporate Affairs.

- Ensure, in conjunction with the Head of Corporate Affairs, that training/familiarisation on the requirements of the RIDDOR regulations is provided in order that managers can fulfil their responsibilities.

- Ensure that regular monitoring and, as necessary, audit of actions taken by managers in response to accidents and incidents reportable under RIDDOR is undertaken.

- Inform all internal and external stakeholders of incidents, as appropriate.

- Act as a resource providing assistance to managers in carrying out their responsibilities for the reporting and investigation of accidents/incidents and ensuring suitable follow up actions are taken.

- Ensure the adaptation and implementation of the incident reporting module contained in Safeguard (a computer based risk system developed for the NHS).

- Prepare integrated reports as necessary.

- Report as appropriate patient safety incidents through the NPSA via the National Reporting and Learning System and for all Serious Incidents, report these to the Strategic Health Authority, via the electronic reporting system - UNIFY (previously STEIS - Strategic Executive Information System).

- Ensuring that performance management processes are undertaken in a timely and appropriate manner.
- Act as a resource for providers regarding the reporting and investigation of SIs.
- Inform the Chief Officer Chief Nurse, and Medical Director of any reported SI
- Maintaining accurate records of SIs reported.
- Liaising with the identified performance management Clinical Commissioning Groups regarding SIs concerning Barnsley residents receiving care either out of area or from other NHS organisations within Barnsley e.g. RDaSH, YAS, and Sheffield Teaching Hospitals.
- Ensuring that the performance management of SIs reported by Barnsley Hospitals NHS Foundation Trust (BHNFT), and South West Yorkshire Partnership Foundation Trust (SWYPFT) is undertaken in a timely and appropriate manner, including the management of appropriate challenges and ensuring the appropriate attendance at the SI committee.
- Monthly reports are submitted by the Governing Body, regarding SI statistics.
- Reports including SI statistics, performance management and action plan monitoring are submitted to the Quality and Safety Committee.

Ensuring regular communication with GP practices where incidents/Serious Incidents have taken place within a GP practice, or involve NHS Barnsley Clinical Commissioning Group employed staff whilst working on GP premises.

Communications should be informed where there could be media interest involving staff, patients, relatives and adverse publicity relating to NHS Barnsley Clinical Commissioning Group. This person will be responsible for dealing with the media in all circumstances.

Sharing the Learning
7. The investigation into any incident should include an analysis regarding the lessons learnt, to prevent recurrence. All learning identified will be shared throughout the Health Community and with independent contractors. Mechanisms for achieving this dissemination will include Team Briefings, Staff newsletter, external newsletters, mandatory training for staff and through reports to Quality and Patient Safety Committee.

Procedure

8. NHS Barnsley Clinical Commissioning Group is committed to educating and training staff in order to minimise risk. Each manager shall ensure that all members of their staff receive appropriate training so that they fulfil their individual responsibility under the regulations. A number of staff will be registered to be trained in the NPSA Root Cause Analysis techniques, and this will be dependent on their role in incident investigation.

NHS Barnsley Clinical Commissioning Group Risk Register

9. To ensure there is a clear and developed link between incidents and NHS Barnsley Clinical Commissioning Group Risk Register. Incidents categorised as red will be placed in the Risk Register and reviewed quarterly.

Monitoring the compliance and effectiveness of this policy

10. NHS Barnsley Clinical Commissioning Group Performance in the Management of Incidents will be monitored by qualitative and quantitative indicators as detailed below and through regular integrated reports to the Quality and Patient Safety Committee

Quantitative
The number of incident reports completed.
The number of serious incident reports completed.
Attendees for awareness sessions and managing people

Qualitative
Actions taken.
Recommendations made.
Sharing all learning.
Improvement in final report completion.

The Serious Incident Group will review/monitor the indicators at their regular meetings through the integrated reports produced for meetings and Annual report

Paying Due regard to equality

11. As part of its development, this policy and its impact on equality, have been reviewed in consultation with the Trust Equality Scheme and Equal Opportunities Policy, and no detriment was identified. The purpose of the assessment is to minimise, and if possible, remove any disproportionate impact on the grounds of race, sex, disability, age, sexual orientation or religious beliefs

Policy Review

12. This policy will be reviewed every three years. However, the policy may need earlier revision should there be a new requirement to meet statutory mandatory or good practice standards. It will require further review following the publication of the Francis report
Incident Reporting Procedure

1. Benefits of reporting incidents

Staff will normally recognise where there are problems which may cause risk in their work environment. All members of staff do therefore have an important role to play by identifying and minimising inherent risks using the incident reporting procedure. The main purpose of any investigation will be to identify causes of incidents/accidents, using root cause analysis where appropriate (see Appendix 6, Guidance on Incident Investigation and Root Cause Analysis) to learn lessons and prevent recurrence. NHS Barnsley Clinical Commissioning Group’s supports an open, fair and a positive learning culture. Staff are positively encouraged to report all incidents and near misses. However, in rare circumstances, where there has been maliciousness, criminal or gross misconduct this could lead to disciplinary action being taken e.g.

Repeat occurrences of incidents involving the same individual
Deliberate failure to report incidents
Failure to co-operate fully in subsequent investigations.

This approach will enable NHS Barnsley Clinical Commissioning Group to:

- Learn from incidents and Patient experience
- Prevent recurrences
- Review existing practices and make adjustments to policies, procedures and processes
- Improve the working environment
- Identify training / retraining needs
- Respond appropriately to any complaints arising subsequently

2. Procedure for Reporting Incidents

2.1 A Web Based Incident Form is available on the intranet for staff and Independent Contractors to report incidents

NHS Barnsley Clinical Commissioning Group staff will, when an incident occurs, assess immediately the severity of the incident, and if considered a Serious Incident they will follow the procedure for reporting SI’s – see section 3 of this procedure, and Appendix 5 - ‘Checklist for Action on Identifying a Serious Incident’. In all incidents, staff will first ensure that any injured person(s) including, staff, patients and any other receives the most appropriate treatment or medical advice.

2.2 Managers will upon receipt of the alert (from the web based tool) score the severity of the incident by completing the ‘Incident Categorisation Matrix’ chart at the bottom of the form. Guidance for completing the risk evaluation chart is shown in Appendix 3.

If an incident is identified as a Serious Incident (see Appendix 4 criteria) they will immediately ensure that the step by step process included in ‘Check List of Action on Identifying a Serious Incident’, as detailed in (Appendix 5) of this policy has been followed and implemented.

Dependent on the incident grade, the following timescales for the reporting of incidents must be strictly adhered to by staff and managers as per the flow chart, detailed in Appendix 8.
Red - within 24 hours – All red incidents involving physical assault or patient death and those deemed as SIs

Amber - within 72 hours

Yellow - within 7 days.

Green - within 7 days.

Where an incident involves suspected fraud, the Chief Finance Officer or Local Counter Fraud Specialist should be informed, in line with the Fraud Policy and Response Plan.

**Line Managers** will ensure that all incidents, within their area of responsibility, which are categorised as red and amber incidents (using the incident categorisation matrix - Appendix 2) are **reported** within the above timescales and undertake an **investigation** to identify the root cause. Details of the investigation and actions taken to be completed on the web based tool. If an incident is categorised as a Serious Incident then the Chief Nurse will ensure that the ‘Checklist for Action on Discovering a Serious Incident’ has been followed and implemented. Investigating Managers can assign a small team of staff to assist them in carrying out a more complex investigation (see Appendix 6 - Guidance re: Incident Investigation and Root Cause Analysis). It is important that communication with staff involved in the incident itself is carried out both pre and post investigation. The Investigating Officer will be responsible for maintaining communication links and records relating to the investigation. A record of the investigation should be maintained and actions should include:

1. Reviewing risk assessments
2. Removing equipment from service - notify MHRA
3. Amend policies, procedures and processes
4. Re-assess training requirements
5. Making the area safe
6. Wearing protective clothing
7. On completion of investigation, rescore the severity of incident to determine the reduction in risk
8. An action plan should be developed with realistic timescales, managers should then monitor the action plan to ensure that all actions have been implemented
9. On implementing the full action plan the incident should be re-graded to evidence a reduction in the risk of similar type and incidents occurring again.

Consideration should be given whether to report amber/red incidents to the NPSA using the National Reporting and Learning System (NRLS). If appropriate it should be reported within 3 working days of the occurrence by the Quality Manager/Risk Coordinator.

The Line Manager has the responsibility to determine whether an investigation should commence for incidents categorised either green or yellow. Where the decision is made to conduct an investigation, they will decide on the most appropriate person in their team to carry out the investigation, and this should commence immediately.
Appendix 2

External Reporting Arrangements


In addition to the web based form there are some incidents which by nature of their seriousness have to be reported under RIDDOR to the Health and Safety Executive.

- Managers must notify the HSE without delay, if there is an incident connected with work and:
  - An employee or a self employed person working on the organisation's premises is killed or suffers a major injury (including as a result of physical violence) or;
  - A member of the public is killed or taken to hospital or;
  - There is a dangerous occurrence listed in the regulations (see Appendix 5)

- Managers must also report to the HSE any notifiable incident (See Appendix 5) or;
  - Any other injury to an employee (including an act of physical violence) which results in their absence from work or being unable to do their normal work for more than three days (including days which would not normally be working days);
  - Any other cases of ill health listed in the regulations (see Appendix 5)

2. Reports to the HSE may take the following format:

- Form F2508 to be used for reporting injuries and dangerous occurrences
- Form F2508A to be used for cases of diseases

Forms F2508 and F2508A are available on the internet at www.riddor.gov.uk

The F2508 and F2508A, not submitted online, must be forward to:

The Incident Contact Centre
Caerphilly Business Park
Caerphilly
CF83 3GG

- Details can also be phoned in on 084 300 9923
- Or faxed on 0845 300 9924
- Or sent by e-mail on riddor@nalbrit.com

3. Managers must record any injury, dangerous occurrence or case of infectious disease on the web based form. A copy of the RIDDOR form should be attached to the electronic copy of the Incident Report including any RIDDOR Report Numbers provided by the Incident Contact Centre to designated input clerk.

4. NHS Estates

Heads of Estates are required to report incidents relating to fire, buildings, plant and non-medical equipment to NHS Estates at the following address:
Managers having such an incident should contact the Head of Corporate Affairs to complete an appropriate report form.

5. **Medicines and Healthcare Products Regulatory Agency (MHRA)**

Any incident relating to medical equipment should be notified formally to NHS Barnsley Clinical Commissioning Group’s’s MDA Liaison Officer who is currently the Head of Patient Safety/Deputy Chief Nurse who will then notify the MHRA through the Central Alert System (CAS).

6. **National Health Service Litigation Authority**

Incidents where there are likely to be civil claims require, where practicable, to be notified to the National Health Service Litigation Authority as early as possible.

The Head of Corporate Affairs will contact the Litigation Authority as appropriate:

The NHS Litigation Authority  
1st Floor  
151 Buckingham Palace Road  
London, SW1W 9SZ  
Telephone: 020 7811 2700  
Fax: 020 7821 0029

7. **Medicine Controls Agency (MCA)**

Incidents relating to adverse drug reactions are reportable to the MCA via the Head of Medicines Optimisation

8. **Police**

Particular incidents will, by their nature, be reported to the police. These will normally be assaults actual or threat, vandalism, suspicious activity of deaths, thefts etc, and in accordance with the Department of Health Memorandum of Understanding - Investigating patient safety incidents involving unexpected death or serious harm!

9. **Reporting to Strategic Health Authority**

See Appendix 13 and Appendix 14.

10. **Care Quality Commission (CQC)**

Care Quality Commission  
National Correspondence  
Citygate, Gallowgate  
Newcastle upon Tyne, NE1 4PA

- Telephone: on 03000 616161
• Contact by email on enquiries@cqc.org.uk
Appendix 3

Analysis and Investigation

The quantity of incidents reported in NHS Barnsley Clinical Commissioning Group means that it is unrealistic to suggest that all incidents should be analysed/investigated to the same degree or at the same level. The depth of investigation and analysis required for individual incidents is dependent upon the Risk Assessment which is completed on the web based form. This will help to ensure that NHS Barnsley Clinical Commissioning Group implements a structured and consistent approach to incident management.

The responsibility for Incident Grading rests with the person completing the investigation. The ‘Responsible Person’ should complete the investigation and overall Risk Assessment Process. It is the responsibility of managers to ensure that they have in place a system of appropriately trained ‘Responsible Persons’ and for those arrangements to be communicated to and understood by all of their staff.

The details of the Risk Assessment will be recorded on the web based form, with the exception of Serious Incidents (Amber/Red category incidents) where the records of Risk Assessment will be recorded in the detailed Investigation Report.

There will be incidents that may be outside the control and investigation of the ‘Responsible Person’ as defined above, for example information governance issues may need investigation at a corporate level. Therefore the investigation should be completed as far as practicable by the ‘Responsible Person’ and this investigation should then be forwarded to the most appropriate senior manager within that areas of expertise, with this action being documented on the form.

<table>
<thead>
<tr>
<th>Risk Rating</th>
<th>Priority Description/Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 Unacceptable Red</td>
<td>Prohibit. Investigate in line with Serious Incident Procedure. Investigation Team to be established. Root Cause Analysis to be carried out. Full Investigation Report required within 3 months of incident</td>
</tr>
<tr>
<td>16-20 High – Very High Amber</td>
<td>Very High Priority: Investigate in line with Serious Incident Procedure. Investigation Team to be established. Root Cause Analysis to be carried out. Full Investigation Report required within 3 months of incident</td>
</tr>
<tr>
<td>12-15 Medium – High Yellow</td>
<td>High Priority: Analyse at service level Undertake Root Cause Analysis. ‘Responsible Person’ to lead. Record results on web based form within 1 month of incident</td>
</tr>
<tr>
<td>6-10 Low – Medium Light Green</td>
<td>Medium Priority: Analyse at local level. ‘Responsible Person’ to lead Analyse and review within 5 working days. Record results on web based form</td>
</tr>
<tr>
<td>1-5 Low Dark Green</td>
<td>Low Priority: Review at local level. ‘Responsible Person’ to lead. Review within 5 working days. Record results on web based form. Analyse in more detail if deemed useful</td>
</tr>
</tbody>
</table>
Step 1 – Incident Grade

The ‘Responsible Person’ determines what the actual grade of the event was. This follows on from the grade allocated on the IR1 (section g) although the ‘Responsible Person’ is assessing the incident retrospectively and could increase or decrease the grade according to the outcome of the incident which may not be known at the time of completing the web based form.

- Using the Consequence table below
- The appropriate box should be ticked to indicate the choice made

Step 2 – Risk Assessment

The Risk Assessment is important as it determines the future risk of the incident should it occur again.

- Using the Consequence table assess what the worst case scenario could be should the incident occur again tomorrow.
- Using the Likelihood Table determine how likely it is that the incident will occur again.
- Each option in the grid has a number associated with it.
  E.g.  2 Minor x 3 Possible
- Multiply the consequence by the likelihood to determine the risk rating
  E.g.  2 Minor x 3 Possible = 6
- Note the Risk Rating in the form

Risk Scoring Matrix

Table 1 Consequence score (C)
Choose the most appropriate domain for the identified risk from the left hand side of the table. Then work along the columns in same row to assess the severity of the risk on the scale of 1 to 5 to determine the consequence score, which is the number given at the top of the column.

<table>
<thead>
<tr>
<th>Domains</th>
<th>Consequence score (severity levels) and examples of descriptors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient and Staff Safety</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Negligible</td>
</tr>
<tr>
<td>Minimal injury requiring no / minimal intervention or treatment.</td>
<td>1</td>
</tr>
<tr>
<td>Minor injury or illness, requiring minor intervention</td>
<td>2</td>
</tr>
<tr>
<td>Requiring time off work</td>
<td>3</td>
</tr>
<tr>
<td>No time off work</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Consequence score (severity levels) and examples of descriptors</td>
<td></td>
</tr>
<tr>
<td>--------------------</td>
<td>---------------</td>
</tr>
<tr>
<td><strong>Domains</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Negligible</strong></td>
<td>Minor</td>
</tr>
<tr>
<td>An event which impacts on a small number of patients</td>
<td></td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td>Overall treatment or service suboptimal</td>
</tr>
<tr>
<td>Peripheral element of treatment or service suboptimal</td>
<td>Formal complaint</td>
</tr>
<tr>
<td>Informal complaint/ inquiry</td>
<td>Local resolution</td>
</tr>
<tr>
<td>Single failure to meet internal standards</td>
<td>Minor implications for patient safety if unresolved</td>
</tr>
<tr>
<td>Reduced performance rating if unresolved</td>
<td></td>
</tr>
<tr>
<td><strong>Human Resources / Organisational Development</strong></td>
<td>Late delivery of key objective / service due to lack of staff</td>
</tr>
<tr>
<td>Short-term low staffing level that temporarily reduces service quality (&lt; 1 day)</td>
<td>Unsafe staffing level or competence (&gt;5 days)</td>
</tr>
<tr>
<td>Low staffing level that reduces the service quality</td>
<td>Loss of key staff</td>
</tr>
<tr>
<td>Consequence score (severity levels) and examples of descriptors</td>
<td>1</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>Domains</td>
<td>Negligible</td>
</tr>
<tr>
<td><strong>Statutory Duty / Inspections</strong></td>
<td></td>
</tr>
<tr>
<td>No or minimal impact or breech of guidance/ statutory duty</td>
<td></td>
</tr>
<tr>
<td>Breach of statutory legislation</td>
<td></td>
</tr>
<tr>
<td>Reduced performance rating if unresolved</td>
<td></td>
</tr>
<tr>
<td>Single breech in statutory duty</td>
<td></td>
</tr>
<tr>
<td>Challenging external recommendations / improvement notice</td>
<td></td>
</tr>
<tr>
<td>Enforcement action</td>
<td></td>
</tr>
<tr>
<td>Multiple breeches in statutory duty</td>
<td></td>
</tr>
<tr>
<td>Prosecution</td>
<td></td>
</tr>
<tr>
<td>Complete systems change required</td>
<td></td>
</tr>
<tr>
<td>Zero performance rating</td>
<td></td>
</tr>
<tr>
<td>Severely critical report</td>
<td></td>
</tr>
<tr>
<td><strong>Adverse Publicity / Reputation</strong></td>
<td></td>
</tr>
<tr>
<td>Rumours</td>
<td></td>
</tr>
<tr>
<td>Potential for public concern</td>
<td></td>
</tr>
<tr>
<td>Local media coverage – short-term reduction in public confidence</td>
<td></td>
</tr>
<tr>
<td>Elements of public expectation not being met</td>
<td></td>
</tr>
<tr>
<td>Local media coverage – long-term reduction in public confidence</td>
<td></td>
</tr>
<tr>
<td>National media coverage with &gt;3 days service well below reasonable public expectation</td>
<td></td>
</tr>
<tr>
<td>National media coverage with &lt;3 days service well below reasonable public expectation</td>
<td></td>
</tr>
<tr>
<td>Total loss of public confidence</td>
<td></td>
</tr>
<tr>
<td><strong>Business Objectives</strong></td>
<td></td>
</tr>
<tr>
<td>Insignificant cost increase / schedule slippage</td>
<td>&lt;5 per cent over project budget</td>
</tr>
<tr>
<td>Schedule slippage</td>
<td>Schedule slippage</td>
</tr>
<tr>
<td>Non-compliance with national</td>
<td></td>
</tr>
<tr>
<td>Incident leading &gt;25 per cent over project budget</td>
<td></td>
</tr>
<tr>
<td>Schedule slippage</td>
<td></td>
</tr>
</tbody>
</table>

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### Table 2 Likelihood score (L)

What is the likelihood of the consequence occurring?

The frequency-based score is appropriate in most circumstances and is easier to identify. It should be used whenever it is possible to identify a frequency.
Table 3 Risk scoring = consequence x likelihood ( C x L )
Calculate the risk score by multiplying the consequence score by the likelihood score.

<table>
<thead>
<tr>
<th>Risk Matrix</th>
<th>Likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(1) Rare</td>
</tr>
<tr>
<td>(1) Negligible</td>
<td>1</td>
</tr>
<tr>
<td>(2) Minor</td>
<td>2</td>
</tr>
<tr>
<td>(3) Moderate</td>
<td>3</td>
</tr>
<tr>
<td>(4) Major</td>
<td>4</td>
</tr>
<tr>
<td>(5) Extreme</td>
<td>5</td>
</tr>
</tbody>
</table>

Step 3 - Level of Analysis/Investigation Required
The level of analysis/investigation is dependent on the Risk Rating obtained from Risk Assessment of the Incident.
Using the Risk Rating choose the appropriate level of investigation on the web based form. Guidance on how to proceed is on the identified above. Further information is available below:

- Dark Green Incidents - Low Risk (Risk Score 1-5)

Low Risk Incidents should be reviewed at a local level by the department in which the incident occurred. The lead will normally be the ‘Responsible Person’ for Incident Reporting/Management in a given area. It is important to identify, record and action any learning points and safety improvement measures identified as a result of the incident review.
Where the necessary improvements are not within the control of the department, the local manager is responsible for ensuring that the identified findings are appropriately communicated to the relevant management team for consideration.

The analysis and review of this category of incident should be completed within 5 working days of the incident occurring.

The results of the incident review should be recorded on the web based form

- **Pale Green Incidents** - Low -Medium Risk (Risk Score 6 - 10)

Low – Medium Risk Incidents will be reviewed and analysed at a local level by the department in which the incident occurred. The lead will normally be the ‘Responsible Person’ for Incident Reporting/ Management in a given area, but the ward/team or departmental manager, may also review the findings.

It is the responsibility of the local team to identify and implement the learning points and safety improvement measures. Where these are not within the control of the department the local manager is responsible for ensuring that the identified findings are appropriately communicated to the relevant management team for consideration.

The analysis and review of this category of incident should be completed within 5 days of the incident occurring.

The results of the incident review/analysis should be recorded on the web based form. The risk assessment process should be repeated and documented on the web based form to demonstrate how implementing the identified action will reduce the risk. The responsibility to follow up the action plan lies with the local team.

- **Yellow Incidents** – Medium – High Risk (Risk Score 12 - 15)

Medium – High Risk Incidents will be subject to modified Root Cause Analysis. The lead will normally be the ‘Responsible Person’ supported by a service manager. The Responsible Person should have been trained in root cause analysis techniques.

It is the responsibility of the relevant management team to ensure that all the learning points and safety improvements are appropriately identified and implemented where possible.

Where these are not within the control of the department, the local manager is responsible for ensuring that the identified findings are appropriately communicated to the relevant management team for consideration and action plans are followed up.

The analysis and review of this category of incident should be completed within 1 month of the incident occurring.

The results of the incident review should be recorded on the web based form with relevant information attached, where appropriate. The risk assessment process should be repeated and documented on the web based form to demonstrate how implementing the identified action will reduce the risk.

- **Amber and Red Incidents** - Serious Untoward Incidents

All incidents not initially graded as major or catastrophic on incident grading, but subsequently determined as of high – very high or unacceptable levels of risk on fuller risk assessment,
should be considered for investigation under NHS Barnsley’s’ Clinical Commissioning Groups Serious Incident procedure.

During the process of reporting incidents, NHS Barnsley Clinical Commissioning Group should ensure that all risks identified are considered for inclusion on the Risk Register.

**Step 4 – Incident Analysis**

The guidance for completing the Incident Analysis is determined within Section 3 of the web based form (see step 3 above). Once the level of the incident has been determined, the guidance on which aspects of the Incident Analysis require completion is stated within the box below on the table in Section 3 on the web based form.

The incident will also require a new risk rating indicating the level of risk once all actions have been taken. Generally the risk will reduce although it is possible that it may stay the same. The risks that have been identified should be monitored on the departmental baseline risk assessment.
Appendix 4

Serious Incidents (SI)

The following outlines NHS Barnsley Clinical Commissioning Group procedure for the management and investigation of Serious Incidents i.e. those on incident grading determined as major or catastrophic to ensure that work in relation to Serious Incidents is properly co-ordinated.

The investigation part of this procedure will also apply to those incidents which although not classified as serious on incident grading are subsequently shown at high-very high or unacceptable levels of risk on fuller risk assessment i.e. their future potential for serious consequences.

Staff should refer to the appropriate section of the procedures where their roles and responsibilities are explained.

What is a Serious Incident?

In guidance issued in December 2010, the NHS Yorkshire and the Humber Strategic Health Authority, defined a Serious Incident (SUI) as an:

‘incident where a patient, member of staff, or member of the public has suffered serious injury, major permanent harm, or unexpected death or where there is cluster/pattern of incidents or actions by NHS staff which have caused or are likely to cause significant public concern. Where a patient/member of staff makes a complaint about an NHS organisation direct to the media, it will be for the Trust/ NHS Barnsley Clinical Commissioning Group to determine in conjunction with the Integrated Governance team at the SHA whether this has substance and should therefore be reported as a SI. Media coverage alone (particularly that at local level) may not warrant a SI report.

‘Near misses’ may also constitute SIs, where the contributory causes are serious and under different circumstances they may have led to serious injury, major permanent harm, or unexpected death, but no actual harm resulted on that occasion. A possible example is that of a system failure, the result of which is incorrect/delayed diagnosis. This may not have any serious consequences for some patients, but for others could lead to the wrong treatment/serious delay in treatment and ultimately to death.’

It is the responsibility of NHS Barnsley Clinical Commissioning Group and Trusts to inform the Yorkshire & the Humber Deanery of those incidents directly involving trainee doctors.

Examples of Serious Incidents

Only the most serious of incidents require reporting to the NHS Barnsley Clinical Commissioning Group’s and SHA. It is difficult to be prescriptive, but the following are examples of events that would warrant reporting.

- Death or serious injury to a patient or member of the public which is alleged to be at the hands of another patient or member of the public while on NHS premises
- Suspected homicide by a person currently in receipt of mental health services (or within the last six months)
• Suicide/suspected suicide of a person currently in receipt of NHS mental health services (both out-patients and in-patients) or who have received NHS mental health services in the last six months

• Serious injury of a person currently in receipt of NHS care (or within the last six months) as a result of deliberate self-harm (e.g. attempted suicide) or accidental injury

• Patients detained under the Mental Health Act who abscond from NHS care and who present a serious risk to themselves and/or others. Of particular concern would be those patients who abscond from medium secure or specialist forensic services, those who are likely to pose a risk to the public, attract media attention and/or who commit an offence in the community

• Any death on GP premises (in line with Shipman recommendations)

• Safeguarding incidents meeting the criteria specified in section 9

• Death or serious injury to a member of staff (including independent contractors e.g. GPs, dentists, opticians, pharmacists) in the course of their NHS duties

• Medication incidents resulting in death/serious injury e.g. incorrect medication dispensed to patient; drugs given to patients with known allergy

• Failure of medical equipment resulting in death/major injury

• Clinical incidents resulting in death/serious injury e.g. surgery performed on wrong patient, wrong site, etc

• Serious fires or other serious damage, which occurs on NHS/Independent contractor premises. Of particular concern would be any fire which resulted in casualties or major disruption to services

• Serious or unexplained outbreaks of infection or disease in hospital or the wider community (e.g. food poisoning or Legionnaire’s Disease) or the confirmed transmission of serious infectious disease between an NHS staff member and a patient (e.g. HIV/Hepatitis B)

• Major system failure e.g. failure of laboratory services to provide accurate screening results; patient referral system failure for further consultation/treatment

• Major environmental incident (e.g. release of gas/chemicals, inappropriate disposal of clinical waste) which has or could have harmed the public

• Major service disruption e.g. due to power failure or flooding

• Incidents where a Healthcare Acquired Infection (HCAI) is the primary cause of death, should be reported as a SUI. Other cases which should be reported as SUIs include: clusters of HCAIs, outbreaks which result in ward closures, recurrent incidences within the same unit, and those which result in adverse media interest.

• Any case where there is prima facie evidence (i.e. initial indications) that a child has sustained a potentially life-threatening injury which may be through abuse or neglect or serious sexual abuse, or sustained serious and permanent impairment of health or development through abuse or neglect.
• A prima facie case where a child dies (including death by suicide) and abuse or neglect is known or suspected to be a factor in the child’s death and there will be a Serious Case Review (SCR). (‘Working Together’ 2006).

• Major breach of patient confidentiality e.g. theft of patient notes or computers/laptops containing patient information; discovery of patient records in public area.

• Any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious and be reported as a SUI in the usual way. It should be noted that the SHA has a role in notifying the DH of certain data loss incidents, depending on the severity.

• Incidents/concerns regarding the actions of NHS staff (including independent contractors). Examples include fraudulent behaviour, gross misconduct and actions resulting in harm to patients. This could lead to suspension/summary dismissal, media interest and the involvement of the criminal justice system.

• A pattern emerging that is causing concern such as a high number of complaints regarding a member of staff (including independent contractors), a particular service and/or hospital that may warrant further investigation and action.

• The misdiagnosis of swine flu that has a serious consequence on health should be reported as a SUI.

• It is the responsibility of NHS Barnsley Clinical Commissioning Group’s and Trusts to inform the Yorkshire & the Humber Deanery of those incidents directly involving trainee doctors.

• Abuse or neglect or serious sexual abuse, or sustained serious and permanent impairment of health or development through abuse or neglect.

• A prima facie case where a child dies (including death by suicide) and abuse or neglect is known or suspected to be a factor in the child’s death and there will be a Serious Case Review (SCR). (‘Working Together’, 2006).

• Major breach of patient confidentiality e.g. theft of patient notes or computers/laptops containing patient information; discovery of patient records in public area.

• Any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious and be reported as a SUI in the usual way. It should be noted that the SHA has a role in notifying the DH of certain data loss incidents, depending on the severity.

• Incidents/concerns regarding the actions of NHS staff (including independent contractors). Examples include fraudulent behaviour, gross misconduct and actions resulting in harm to patients. This could lead to suspension/summary dismissal, media interest and the involvement of the criminal justice system.

• A pattern emerging that is causing concern such as a high number of complaints regarding a member of staff (including independent contractors), a particular service and/or hospital that may warrant further investigation and action.

• The misdiagnosis of swine flu that has a serious consequence on health should be reported as a SUI.
• It is the responsibility of NHS Barnsley Clinical Commissioning Group’s and Trusts to inform the Yorkshire & the Humber Deanery of those incidents directly involving trainee doctors.

**Investigating a Serious Incident**

For all internal investigations an Investigating Officer will be appointed. The Investigating Officer will be trained in investigation and Root Cause Analysis techniques.

As part of the investigation, all serious incidents will have a comprehensive Root Cause Analysis undertaken:

The Investigating Officer will lead the investigation process and act as the contact and co-ordination point for all matters relating to the investigation.

As part of the investigation all serious untoward incidents will have a comprehensive Root Cause Analysis undertaken.

• Where a decision is made not to conduct a Root Cause analysis the decision should be clearly recorded.

• All investigations must be carried out in accordance with NHS Barnsley Clinical Commissioning Group’s guidance on undertaking of Investigations including Root Cause Analysis as set out in Appendix 6.

• Investigation reports with action plans must be completed within 12 weeks of the incident occurring.

• A copy of the report and action plan will be forwarded to NHS Yorkshire and the Humber Strategic Health Authority

**Information Governance SI**

The Department of Health have recently issued further guidance in relation to Information Governance SI and Near Misses. The following flow chart demonstrates the process to be followed and should be undertaken in conjunction with the above process. The Chief Officer may seek advice from the Senior Information Risk Owner and or the Caldicott Guardian in regard to these types of incidents. Internally any SI information governance incidents will follow the same process for all SIs.
Potential loss of Person Identifiable Data identified

Make initial assessment and provide ‘early warnings’ if appropriate

Initiate Incident Response Plan

Was the loss Person Identifiable Data?

Yes

Initial investigation and assessment of SUI level

Level 1 or above?

No

Manage locally

Yes

Report on STEIS; update STEIS

Level 3 or above?

Yes

SHA to escalate to DH Business Unit
Organisation to notify Information Commissioner

No

Review SUI Level in light of findings

Investigation

Final Report and lessons learnt

Close Incident
Publish on website in accordance with local procedures

Media Contact

It is inevitable that some Serious Incidents will attract media attention. All media enquiries should be directed to the External Communications. All contact with the media must be in line with NHS Barnsley Clinical Commissioning Groups Media Response Protocol.

For all serious incidents NHS Barnsley Clinical Commissioning Groups must consider the need for short and long term communications/media handling strategies, liaising with the Strategic Health Authority, (NCB) as appropriate.
Investigation Overview

It is essential that all incidents are investigated promptly and that the objectives of the investigation are clearly understood by everyone.

The prime objectives of an investigation are to:

- Determine the sequence of events leading to the incident
- Determine what was managed well
- Establish the unsafe systems of working, procedures, policies, acts and/or unsafe conditions within the sequence of events that contributed to the incident
- Determine the human, organisational and or job factors that gave rise to the unsafe acts and/or conditions
- Initiate short-term action to eliminate the immediate causes of the incident
- Establish a longer-term programme to correct and manage the underlying human, organisational and job factors, and hence prevent a recurrence of the same or similar incident or near miss

Investigations must be undertaken as soon as practicable after the event so as to ensure as much information is preserved and recorded as possible before memories fade and the scene becomes too disturbed (it may be necessary to cordon off the scene until a preliminary investigation has been completed).
CHECK LIST FOR
ACTION ON IDENTIFYING A SERIOUS INCIDENT

FOR USE BY NHS BARNsLEY CLINICAL COMMISSIONING GROUP’S EMPLOYED STAFF

In addition to this checklist a full, written, contemporaneous record should be kept of all actions taken and information given. The Investigating Officer to ensure the security of all records and that all records are clear and legible.

IR1 Reference Number ……………… Contact Name & ‘Phone No……………………………………

<table>
<thead>
<tr>
<th>IR</th>
<th>IMMEDIATE ACTION TO BE TAKEN BY MEMBER OF STAFF DISCOVERING A SERIOUS INCIDENT</th>
<th>Time &amp; Date when Action Taken</th>
<th>By Whom instigated</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IMMEDIATE ACTION TO BE TAKEN BY MEMBER OF STAFF DISCOVERING A SERIOUS INCIDENT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>The member of staff discovering an incident should take immediate action, summoning assistance and activate emergency calls as required, e.g. police, medical help, fire brigade, etc.</td>
<td></td>
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<tr>
<td>1.2</td>
<td>Inform Line Manager. In an emergency, the On-Call Manager can be contacted via the Rotherham NHS Foundation Trust Switchboard on 01709.820000.</td>
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</tbody>
</table>

2 IMMEDIATE ACTION TO BE TAKEN BY LINE MANAGER

2.1 Ensure appropriate emergency action has been initiated.

2.2 Inform the Chief Officer

Inform Chief Nurse

Inform Communications.

*The Rotherham NHS Foundation Trust Hospital Switchboard (01709 820000) has details of the on-call Gold rota (this is South Yorkshire wide)

2.3 Complete web based form.

2.4 Inform the staff that no contact with the media should be made and any enquiries received should be referred to Communications who will have responsibility for initiating and maintaining contact with the media and will liaise with the SHA’s Communication Team immediately if there is the possibility of adverse media coverage.

See also: NHS Barnsley Clinical Commissioning Groups Media Response Protocol. On how media enquiries should be handled.

2.5 Where a Serious Incident involves suspected fraud, it must be reported to the Chief Finance Officer in accordance with NHS Barnsley Clinical Commissioning Group Fraud Policy and Response Plan.

3 All Serious Incidents must be reported to the Chief Nurse who will act as coordinator to ensure that all appropriate steps have been taken.

The co-ordinator will then:-

3.1 Statements have been taken from everyone involved/witnessing the incident prior to staff going off duty. All statements must give time and date, be clear, legible and signed.
3.2 Evidence including Incident Report Forms, copied clinical records, statements and faulty equipment should be identified, labelled and stored safely and securely.

3.3 The Police have been informed where relevant – and in accordance with the Memorandum of understanding: Investigating patient safety incidents involving unexpected death or serious harm (Gateway ref: 5499)

3.4 The patient and/or relatives have been informed, where appropriate, following guidance given in Being Open Policy.

If there is a need to actively inform any relevant or specific members of the public about the incident, this should be done in co-operation with the Communications.

Any contact with patients and/or relatives or specific members of the public must always be made prior to information being given to the media and the co-ordinator should nominate the person(s) responsible for this.

All information given to be documented.

3.5 The Coroner has been informed in the event of death.

4 INITIATE WITHIN ONE WORKING DAY:

4.1 Report the event to the Chief Officer and Communications.

4.2 Establish with the Chief Officer that the incident is a Serious Incident and which external agencies should be notified. This may include: other CCG’s and Trusts, NHS Directorate of Health & Social Care, Social Services, Health Protection Agency, Local Safeguarding Boards etc.

Agree the contents of a media statement with Communications, if appropriate.

4.4 Consider the need for other external agencies to be involved in the investigation, e.g. enforcing agencies, external stakeholders, external advisors and act as appropriate.

4.5 Report the event to Yorkshire & Humber Strategic Health Authority (SHA) via the Department of Health STEIS system as soon as practically possible (at the latest within 24 hours of the incident during the working week). An update must be provided to the SHA on the STEIS system after 10 days of the original report. **12 weeks after a** report and action plan must be completed and forwarded to the SHA for consideration.

4.6 Report to the NPSA if it is a patient safety incident (using the NRLS).

4.7 Inform other senior managers if appropriate

4.8 Inform NHS Barnsley Clinical Commissioning Group Staff and Governing Body as appropriate.

**Staff should always be informed prior to information being given to the media.** They should be advised to have no contact with the media and to refer any enquiries to Communications

4.9 Report the event to RIDDOR as appropriate.

4.10 Report the event to the Health and Safety Executive as appropriate
<table>
<thead>
<tr>
<th></th>
<th>Time &amp; Date when Action Taken</th>
<th>By Whom instigated</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.11 Inform the NHS Litigation Authority.</td>
<td></td>
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<tr>
<td>4.12 Inform appropriate GP of a patient death within 24-hour period.</td>
<td></td>
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<tr>
<td>4.13 Report to the Medicines &amp; Healthcare Products Regulatory Agency in cases of potentially faulty/dangerous products</td>
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<tr>
<td>4.14 Seek legal assistance where appropriate and necessary.</td>
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<tr>
<td>4.15 Review the initial assessment of what led up to the event.</td>
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</table>

5 RISK MANAGEMENT

5.1 The cause of all incidents should be thoroughly investigated. Root Cause Analysis techniques should be followed following incidents as detailed above. Guidance on the use of Root Cause Analysis is included at Appendix of the Incident and Serious Incident Reporting Procedure.

A report and action plan should be prepared following all incidents and any measures which could prevent a recurrence should be defined. If a decision is reached that no further action is to be taken, this should be explicitly documented, giving the reason for that decision.

A repeat of the Risk Evaluation Process should be carried out on completion of the report and action plan.

5.2 A Register of Serious Incidents will be maintained.

5.3 An INTERNAL INVESTIGATION will be initiated by the appointment of an Investigating Officer by the Chief Officer/Chief Nurse. The investigating team should include a member of staff trained in Root Cause Analysis Techniques.

The Investigating Officer will obtain statements from all involved staff, patients and witnesses as appropriate, establishing a factual chronology of the action taken.

If the matter is deemed to be a staff disciplinary matter, then this will be dealt with through the organisation’s Disciplinary Procedure.

An initial verbal report should be made by the Investigating Officer to the Chief Officer within 2 hours of the event. An interim report for the Chief Officer will be initiated at the earliest opportunity and no longer than the next working day and updated or completed by 3 working days. If the incident has been classed as 'Red' or involved a patient safety incident, Root Cause Analysis techniques must be used as part of the investigation process.

The Chief Officer will decide if further investigation is required.

Report and action plan etc to be prepared as above and Chief Officer to determine the appropriate Committees to which the report will be presented.

This report and action plan will also be forwarded to the SHA within eight weeks of the SI.
Serious Incident Investigation Procedure

Serious Incidents (SI) are identified both internally and externally. Internally these are notified either by completion of an incident form, or notification through line management (including on call arrangements). External examples include information from HM Coroner to the Complaints Manager/ notification from GP practices, other providers and sometimes from the family’s of service users.

It is important that all incident(s) are managed/investigated equitably; by whatever means notification occurs.

Any Senior Manager undertaking SI investigations will be required to have had appropriate training in Root Cause Analysis.

This procedure should be read in conjunction with the relevant policies including Integrated Risk Management Framework Patient Safety Strategy and Incident Reporting policy.

If an SI is not declared the person who submitted the initial notification will be informed and the appropriate level of investigation will undertaken by the ‘Responsible Person’ within the business unit

The performance management of SIs reported by the BHNFT and SWYFT is delegated to NHS Barnsley Clinical Commissioning Group by Yorkshire & Humber Strategic Health Authority. It is NHS Barnsley Clinical Commissioning Group’s responsibility to ensure that they are satisfied that the investigation, report and action plan are adequate and that actions are complete

Performance management refers to Appendix 13 protocol for reporting and performance monitoring serious incidents occurring at any provider with NHS Barnsley as the commissioning PCT (this will be updated in the contracts for 2013/14 to reflect NHS Barnsley Clinical Commissioning Group)
Root Cause Analysis

Definition of Root Cause Analysis:

‘A structured investigation that aims to identify the true cause of a problem and the actions necessary to eliminate it’ (Anderson B, Fagerhaug T, 2000)

‘A methodology that enables you to ask the questions ‘How’ and ‘Why’ in a structured and objective way to reveal all the influencing and causal factors that have led to a patient safety incident. The aim is to learn how to prevent similar incidents happening again, not to apply blame.’ (NPSA)

Criteria for undertaking a Root Cause Analysis

Any incident which is graded as MAJOR or CATASTROPHIC must be considered for investigation using Root Cause Analysis. Where a decision is made not to use Root Cause Analysis the decision should be clearly documented.

Process for Undertaking a Root Cause Analysis

The Root Cause Analysis is best completed by a team approach with a nominated lead investigator. Membership/leadership of the team will be dependent upon the level of investigation required. The team will contain at least one person trained in Root Cause Analysis.

It is also important to consider how patients and their families may be involved in the process.

The following information will be included in the report

- Introduction
- Executive Summary
- Main Report to include
  - Incident Description and Consequences
  - Background Information
  - Description of the incident
  - Terms of reference
  - Investigation Team
  - Scope and level of Investigation
  - Investigation types, process and methods used
  - Involvement and support of patient and or family/significant others
  - Involvement and support provided to staff involved
  - Information and evidence gathered
- Findings to include the following
  - Chronology of events
  - Detection of incident
  - Notable good practice
  - Care and Service Delivery Issues
  - Contributory factors
  - Root Causes
• Lessons Learnt
• Recommendations
• Arrangements for sharing learning/Dissemination process
• Assurance
• Distribution list
• Signatories
• Action Plan

During the course of an investigation using Root Cause Analysis the following processes would normally occur to achieve the above requirements

• Form the investigation team
• Preserve direct evidence from the scene/visit the scene if appropriate/examine equipment
• Produce a time-line of events
• Chart the event with current knowledge
• Gather documentary evidence e.g. clinical notes, policies and procedures, training records, risk assessments and maintenance schedules
• Arrange and carry out interviews with those involved / witnesses and patients involved if appropriate
• Identify contributory factors see below
• Analyse contributory factors
• Ascertain root cause(s)
• Formulate recommendations and action plan
• Provide a report
• Hold a multi disciplinary learning event

Identifying and analysing contributory factors:

Examples of contributory factors are:

• Communication factors (includes verbal, written and non-verbal between individuals, teams and/or organizations)
• Education and training factors (e.g. availability of training)
Equipment and resource factors (e.g. ease of use, availability, placement and poor working order)

Medication factors (where one or more drugs directly contributed to the incident)

Organisation and strategic factors (e.g. organisational structure, contractor agency use and culture)

Patient factors (clinical condition, social/physical/psychological factors and relationships)

Task factors (includes work guidelines/procedures/policies/availability of decision making aids)

Team and social factors (includes role definitions, leadership, support and cultural factors)

Work and environment factors (e.g. poor/excess administration, physical environment workload and hours of work and time pressures)

Once the contributory factors have been identified these are then analysed to identify the root cause(s) behind the incident.

Making Action Plans – Key Points

Formulating action plans may require the involvement of other stakeholders.

Only those possessing budgetary responsibilities and an understanding of competing priorities will be able to formulate and sign up to action plans.

The person responsible for executing each point of the investigation action plan must be identified and formal instruction to proceed must be provided.

Time scales for the delivery of completed action points must be agreed.

Monitoring and review processes must be agreed and the Complaints/Serious Incidents and Claims Sub Group should monitor all progress. This will involve a review of progress 3 months from publication of the action plan.

Any new risks identified as a result of the actions taken must be assessed and reduced in accordance with the Integrated Risk Management Framework.

When considering Action Plans the following order of precedence must be kept in mind:

1. Hazard elimination (design improvements or change of process)
2. Substitution (replace a hazardous chemical with a less hazardous one)
3. Enclosure or use of barriers e.g. locked cupboards.
4. Use of procedures (safe systems of work/written procedures)
5. Adequate supervision and use of working systems (warning signs, instructions)
6. Use of personal protective equipment
**NB:** Information, Education and Training should be considered in the implementation of ALL risk treatment action plans.

**Investigation File**

For each investigation an Investigation File should be constructed. A structured format for Investigation Files will be developed. Investigation files will be used for all investigations whether initiated through incidents, complaints or claims. The file will contain all relevant and contemporary documentation and a record of all key decisions and actions taken from the outset of the incident.

There will be standardisation of incident files by using the following templates:

- File note standardised
- Standard template for the report
- Executive summary and template within the report
- Interview recording templates
- Timelines templates
- Fishbone diagrams template

All verbal and written communication with the patient and/or their relatives or the member of staff affected by the incident will be recorded with a short summary of any discussions and the date and time they took place.

The file will also include copies of any witness statements, transcripts of interviews, training records, sketches, photographs, risk assessments, maintenance records.

The file will finally contain the investigation report and copies of any subsequent action plan(s) review(s).

On closure of an investigation, an investigation file will be archived. NHS Barnsley Clinical Commissioning Group should ensure that all documentation is retained in line with the Department of Health ‘Records Management: NHS Code of Practice’.
Communications including “Being Open”

Effective communication with patients and their families begins at the start of their care and continues. This should be no different when a patient safety incident occurs. Discussing patient safety incidents promptly, fully and compassionately can help patients and families cope better with the after-effects. Patient safety incidents also incur extra costs through litigation and further treatment; openness and honesty can help prevent such events becoming formal complaints. Openness when things go wrong is fundamental to the partnership between patients, families and the staff who provide their care. The principles for communication for patient safety incident should also be used for complaints and claims and the following processes will also be used for these events, however for the sake of clarity the word incident has been used throughout. Further information is available from the NPSA Being Open Framework November 2009.

Communication involves:

- Acknowledging, apologising and explaining when things go wrong.
- Conducting a thorough investigation into the incident and reassuring patients and/or their carers that lessons learned will help prevent the incident recurring.
- Providing support to cope with the physical and psychological consequences of what happened.

For healthcare staff, Being Open has several benefits, including:

- Satisfaction that communication with patients and/or their carers following a patient safety incident has been handled in the most appropriate way.
- Improving the understanding of incidents from the perspective of the patient and/or their carers.
- The knowledge that lessons learned from incidents will help prevent them happening again.
- Having a good professional reputation for handling a difficult situation well and earning respect among peers and colleagues.

The following 10 principles should aid communication:

1. **Principle of Acknowledgement**

   All patient safety incidents should be acknowledged and reported as soon as they are identified. Any concerns should be treated with compassion and understanding by all healthcare staff.

2. **Principle of Truthfulness, Timeliness and Clarity of Communication**

   Information about a patient safety incident must be given to patients and/or their carers in a truthful and open manner by an appropriately nominated person. Communication should be timely and it is also essential that any information given is based solely on the facts known at the time. Healthcare staff should explain that new information may emerge as an incident investigation is undertaken, and patients and/or their carers should be kept up-to-date with the progress of an investigation.
3. **Principle of Apology**

Patients and/or their carers should receive a sincere expression of empathy and understanding for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded discussion, as early as possible.

Verbal discussions are essential because they allow face-to-face contact between the patient and/or their carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred.

4. **Principle of Recognising Patient and Carer Expectations**

Patients and/or their carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident and its consequences in a face-to-face meeting. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. When appropriate, information on accessing the Patient Advisory and Liaison Service (PALS) and other relevant support groups like Cruse Bereavement Care and Action against Medical Accidents (AvMA) should be given to the patient as soon as it is possible. Where a patient has died as a result of a patient safety incident a letter of condolence can be sent to the family if felt appropriate.

5. **Principle of Professional Support**

NHS Barnsley Clinical Commissioning Group Open and Fair Culture creates an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. Managers should ensure that staff feel supported throughout the incident investigation process as they too may have been traumatised by being involved. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.

6. **Principle of Risk Management and Systems Improvement**

Root cause analysis (RCA) should be used to uncover the underlying causes of a patient safety incident. Investigations should focus on improving systems of care, which will then be reviewed for their effectiveness.

7. **Principle of Multidisciplinary Responsibility**

Most healthcare provision involves multidisciplinary teams and communication with patients and/or their carers, following an incident that led to harm, should reflect this.

8. **Principle of Clinical Governance**

Communication has the support of patient safety and quality improvement processes through the clinical governance framework, in which patient safety incidents are investigated and analysed, to find out what can be done to prevent their recurrence.

Actions are monitored to ensure that the implementation and effects of changes in practice following a patient safety incident.
9. **Principle of Confidentiality**

Full respect should be given to the patient’s and/or their carer’s and staff’s privacy and confidentiality. Details of a patient safety incident should, at all times, be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient.

10. **Principle of Continuity of Care**

Patients are entitled to expect they will continue to receive all usual treatment and continue to be treated with respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere. Support should continue to be offered both to the patient and/or their carer’s as appropriate. In terms of an SUI a family liaison member of staff may be appointed by the service to offer additional support to the patient and/or carer.

The implementation of principles should be documented within the SI report or IR2. This means that when the patient and/or career has been informed, truthfully, about an incident an apology and an explanation given and the time this was done will be documented on the web form 2.

All SI reports will be performance managed for the principles of being open see Review of SI Inquiry/Investigation Report and action plan at Appendix and *.

**The healthcare professional who informs the patient and/or their carers about a patient safety incident**

This should be the most senior person responsible for the patient’s care and/or someone with experience and expertise in the type of incident that has occurred. They should:

- Be known to, and trusted by, the patient and/or their carers.
- Have a good grasp of the facts relevant to the incident.
- Be senior enough or have sufficient experience and expertise in relation to the type of patient safety incident to be credible to patients, carers and colleagues.
- Have excellent interpersonal skills, including being able to communicate with patients and/or their carers in a way they can understand and avoiding excessive use of medical jargon.
- Be willing and able to offer empathy, reassurance and feedback to patients and/or their carers.
- Be able to maintain a medium to long term relationship with the patient and/or their carers, where possible, and to provide continued support and information.
- Be culturally aware and informed about the specific needs of the patient and/or their carers.
- Document all communications.
Content of the initial discussion with the patient and/or their carers

With the patient’s agreement, carers and those close to the patient can be included in the discussions and decision making. If the patient is unable to participate or has died, then the carers or people closely involved with the patient may be provided with limited information in order to make decisions, but this should be done with regard to confidentiality and any patient instructions. Carers and people close to the patient can be referred to the HM Coroner for more information.
Incidents relating to Safeguarding Children

Incidents relating to safeguarding children should be reported if they fall within the criteria set below:

(a) Any case where there is *prima facie* evidence (i.e. initial indications) that a child has sustained a potentially life-threatening injury which may be through abuse or neglect or serious sexual abuse, or sustained serious and permanent impairment of health or development through abuse or neglect.

(b) A prima facie case where a child dies (including death by suicide) and abuse or neglect is known or suspected to be a factor in the child’s death and there will be a Serious Case Review (SCR). (‘Working Together to Safeguard Children’, 2006).

For safeguarding children incidents reported on the STEIS (UNIFY) system, a report should be submitted within one month.

The report should identify whether or not the case will proceed to a serious case review (SCR), whether or not any issues for action have been identified and details of action already taken/to be taken.

Where a SCR is undertaken, the investigation officer is required to submit an Internal Health Management Review (IHMR) to the serious case review panel chair or independent author within 4-6 weeks of the decision being made to hold the SCR, the aim of which is to openly and critically look at individual and organisational practice to see whether changes are required and to make recommendations for improvements. The SHA expects to receive a copy of the IHMR and action plan at the same time that it is submitted to the panel chair.

The lead coordinator may send a draft to the SHA clinical advisor for safeguarding children for their comments prior to final submission. The IMHR will be taken as the SI investigation report (a separate report is not required).

If it is not possible for the IHMR report to be completed within 12 weeks, this should be communicated to the SHA via incident.reporting@yorksandhumber.nhs.uk with the reasons for the delay and an estimated completion date.

NHS Barnsley Clinical Commissioning Group will update the SHA at least every twelve weeks and in between if necessary on developments pertaining to health services or health care that may occur during the course of the SCR, and following the SCR.
Appendix 9

The Memorandum of Understanding

NHS patient safety incidents involving unexpected death or serious untoward harm and requiring investigation by the police and/or the Health & Safety Executive (HSE) are rare. However, there has been an increase in the number reported in the past few years. Such incidents must be handled correctly, both for the sake of public safety as well as confidence in the NHS, police and HSE and in the interests of fairness and justice.

In the case of an incident that has caused unexpected death or serious untoward harm there may be, where criminal intent is suspected, the requirement to work with the Police and Health and Safety Executive. The following Protocol is in place, written in conjunction with all 3 agencies, to assist with the effective communication between agencies during investigation of the incident:

Memorandum of Understanding

Investigating patient safety incidents involving unexpected death or serious untoward harm: a protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and Health & Safety Executive

Foreword

This protocol coincides with a changing culture in the NHS. Public and patient safety is being put at the forefront of everyday practice. This requires openness on the part of the individuals working in the NHS in reporting errors, ensuring that lessons are learned for the future and that patients concerned receive proper treatment. It also requires fairness when considering whether action is to be taken against the individuals concerned.

Some patient safety incidents involve systems failures while others may also involve the failure of an individual or individuals. We recognise the important role of the NHS in investigating such failures using methods being developed by the Department of Health, the National Patient Safety Agency and the Health and Safety Executive.

The Department of Health is pursuing its commitment to patient safety among other things by encouraging a shift in the NHS from a prevailing culture of blame to one that is fair and just. All experience in other high risk industries shows that a culture in which blame predominates in the handling of errors and adverse incidents creates a climate of fear leading to concealment of safety problems. This can lead potentially to more, rather than fewer, incidents.

As a result, the police and HSE may conduct initial investigations into matters of concern reported to them and the threshold for taking these forward is usually set at a high level. This means that such investigations should take place only where there is clear evidence of a criminal offence having been committed or where a breach of health and safety requirements is the likely cause or a significant contributory factor.

In taking forward such investigations, we recognise that the safety of the public and of patients is our first priority and that this requires a collaborative approach. This protocol sets out our agreement as to how this should be achieved.
This protocol has been agreed between the Department of Health on behalf of the National Health Service, the Association of Chief Police Officers and the Health & Safety Executive. It will apply to patients receiving care and treatment from the NHS in England. It will also apply, with modifications, to Wales, where a separate memorandum will be issued. While the protocol does not apply in Scotland and Northern Ireland, the relevant bodies have been consulted informally about it.

The national group responsible for the work will monitor the use of the protocol so that it can be developed further in the light of experience. The first annual review will be preceded by a questionnaire to all three organisations.

We commend the protocol to you.

Signed

Sir Liam Donaldson
Chief Medical Officer
Department of Health

John Broughton
Assistant Chief Constable
Association of Chief Police Officers

Sandra Caldwell
Director of Field Operations
Health and Safety Executive

February 2006
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Introduction

1. NHS patient safety incidents involving unexpected death or serious untoward harm and requiring investigation by the police and/or the Health & Safety Executive (HSE) are rare. However, there has been an increase in the number reported in the past few years. Such incidents must be handled correctly, both for the sake of public safety as well as confidence in the NHS, police and HSE and in the interests of fairness and justice.

2. It is important that investigations into such incidents - be they conducted by the NHS, police and/or HSE - are carried out effectively and consistently. These investigations and any remedial actions need to ensure that:

   • public and patient safety is assured
   • patients, where appropriate their relatives, and NHS staff are informed, consulted and supported
   • health & safety in the NHS workplace are safeguarded
   • NHS services are maintained as far as possible
   • the NHS can learn effectively from the incident to reduce future risks to patients
   • the actions of NHS staff and services are properly and promptly examined where appropriate
   • criminal investigations that may be necessary are conducted promptly and effectively with appropriate support from the NHS, helping to expedite decisions on any prosecutions
   • links are made to investigations conducted by coroners to ensure coordination and minimise duplication
   • links are made to other types of reviews or investigations as appropriate, for example, serious case reviews on children who die or are seriously injured where abuse or neglect is the cause or a factor in the death or injury

3. To achieve these objectives it is important that the three organisations communicate and work with one another in a consistent and well-coordinated manner. This will include informed decision making about those incidents that require investigation by the police and/or the HSE, appropriate discussion and continued attention to the matter of safety. Sharing information and timely discussion are essential ingredients for such outcomes. Both need to be conducted in such a way that they do not impede the statutory responsibilities and duties of the three organisations or the coroner; or jeopardise any legal proceedings.

This protocol is intended to help the three agencies:

   • meet their responsibilities for the safety of patients and NHS staff
   • make clear to one another from the outset their particular statutory responsibilities
   • set out their own operational needs
   • prompt early decisions about the actions and investigation(s) thought to be necessary by all organisations and a dialogue about the implications of these
   • provide an efficient and effective approach to the management of the investigation(s)
   • develop and strengthen partnership working
   • prompt the identification of lead personnel to manage liaison between the three agencies
   • save time and other resources of all the agencies concerned.
4. In developing the protocol, the three signatory bodies have consulted widely, including publicly, and with a variety of organisations ranging from professional regulatory bodies to those representing victims. The views and opinions of NHS staff, police officers, HSE inspectors and others who have practical experience of these matters have also been sought. All have offered strong support for the development of the protocol.

5. Guidelines to the NHS, an additional chapter in the Police murder manual dealing with investigations in healthcare and internal guidance to HSE inspectors support the protocol. A joint training programme is also being commissioned to spur the development of good practice. This will be aimed at NHS staff, police officers and HSE inspectors. A list of documents relevant to the protocol appears in annex 1.

6. Criminal investigations into deaths at work are covered by an existing agreement between the Association of Chief Police Officers (ACPO), HSE, Crown Prosecution Service and local authorities known as the Work-related deaths protocol (WRDP, see annex 1 for details). This memorandum of understanding does not affect the operation of the WRDP but should be used in conjunction with it.

1. **Purpose**

1.1. The purpose of this protocol is to promote effective working relationships between the three organisations. The protocol will take effect in circumstances of unexpected death or serious untoward harm requiring investigation by the police, or the police and the HSE jointly. This will normally be the case if an incident has arisen from or involves criminal intent, recklessness and/or gross negligence or, in the context of health & safety, involves a work-related death or serious injury.

1.2. The protocol sets out the general principles for the NHS, police and HSE to observe when liaising with one another. It focuses on investigations in NHS Trusts, although the principles and practices it promotes should apply to other locations where healthcare is provided and the NHS is required to investigate under its performance management and other duties. For example, it should apply when considering an incident in the practice of a family doctor or dentist.

1.3. The protocol provides a framework for embarking on such liaison and is supplemented by detailed guidelines to the NHS. Police officers and HSE inspectors have their own guidelines.

**Circumstances in which the protocol will apply**

1.4. This protocol applies to those patient safety incidents involving unexpected death or serious untoward harm requiring investigation by the police or by the police and HSE jointly. By definition, these incidents will be serious and may have significant public safety implications.

1.5. All patient safety incidents should be investigated fully using existing NHS procedures, including those developed by the Department of Health and the National Patient Safety Agency. This includes using the services of such bodies as the Medicines and Healthcare products Regulatory Agency (MHRA) to investigate patient safety incidents involving devices or medicines. The majority of patient safety incidents can and should be dealt with by these means.
2. **Roles and responsibilities of the three organisations and other relevant bodies**

2.1. NHS bodies, the police and the HSE have various responsibilities in relation to investigating patient safety incidents in the NHS.

2.2. **NHS bodies** have a responsibility, among other things, to ensure the safety and well being of patients and staff and to investigate when things go wrong. This responsibility is placed upon every NHS chief executive and upon the board of their organisation and is a critical component of corporate and clinical governance. NHS organisations must conform to national and local policies and procedures in discharging this responsibility.

2.3. **The police**, who also have a duty to uphold public safety, may investigate all criminal offences and, in doing so, will seek to balance matters of public safety against the need to prosecute.

2.4. **The HSE** is responsible for the enforcement of the Health & Safety at Work etc Act 1974 (HSWA) throughout Great Britain. Its work includes ensuring that ‘risks to people’s health and safety from work activities are properly controlled’. The HSE does not normally seek to apply the HSWA to matters of clinical judgement or to the level of provision of care, although it is responsible for enforcing work-related health and safety legislation in a variety of settings including hospitals and nursing homes.

2.5. Other organisations may also have a role in investigating patient safety incidents. These include the coroner, Medicines and Healthcare products Regulatory Agency and the Healthcare Commission. (The associated guidelines contain more information about those organisations that may play a role in investigating patient safety incidents including the actions of the professional staff associated with the incident.) On occasions patient safety incidents may also result in other concerns coming to light e.g. fraud. In such instances, the NHS Counter Fraud and Security Management Service must be informed.

2.6. For the purposes of this protocol, an NHS patient is defined as: ‘A person receiving care or treatment under the NHS Act’.

**Patient safety incidents that may involve the police or the police and HSE**

2.7. The types of patient safety incident that may prompt an NHS Trust to involve the police are those that display one or more of the following characteristics:

- evidence or suspicion that the actions leading to harm were intended
- evidence or suspicion that adverse consequences were intended
- evidence or suspicion of gross negligence and/or recklessness in a serious safety incident, including as a result of failure to follow safe practice or procedure or protocols.

2.8. The police and/or HSE may also investigate an incident following contact by patients, relatives or, in the case of the death of a patient, by a coroner. Further information about the coroner is given in the NHS guidelines.

2.9. NHS guidelines contain general definitions of terms such as gross negligence, manslaughter, recklessness and corporate manslaughter.

2.10. Some accidents to patients must be reported to the HSE by NHS Trusts under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). HSE will normally investigate all fatal accidents reported under RIDDOR, but not accidents to patients that arise from medical treatment or diagnosis.
2.11. The police may decide either initially or later in their investigation that a death or serious
injury to a patient may have been caused by the use of unsafe equipment or procedures.
In such cases, they may consider referring the incident to HSE whether or not it was
reportable under RIDDOR. Given the potentially large number of such events, the HSE
will apply normal criteria in deciding whether it should investigate. General liaison
between the police, HSE, local authorities and the Crown Prosecution Service over
deaths in the workplace is covered by the Work-related deaths protocol.

3. Immediate action following the reporting of an incident

3.1. It will sometimes be immediately obvious to NHS Trusts that the police and/or the HSE
should be contacted, but in other cases the need may not come to light until the Trust,
Coroner or other body such as the Medicines and Healthcare products Regulatory
Agency has carried out its own investigations. The decision to report an incident to the
police should be made at a sufficiently senior level, for example, by either the chief
executive or another executive director.

3.2. Once such a decision has been taken, representatives of the Trust, police and, where
appropriate HSE, should arrange an initial meeting. The meeting of this ‘Incident
Coordination Group’ should be called as soon as practicable following the referral and, in
any case, the group should meet within five working days of the referral. All three
organisations are entitled to call an Incident Coordination Group, but responsibility for
organising the meeting rests with the NHS.

3.3. The police and/or the HSE may also call an Incident Coordination Group in response to
a complaint, referral from a coroner or in response to other concerns.

3.4. Until the first meeting of the Incident Coordination Group, the Trust should continue to
deal with concerns about patient safety but not undertake any activity that may
compromise any subsequent investigations conducted by the police and/or the HSE. If in
doubt about this matter, the Trust should seek legal advice and consult the police, the
HSE or where appropriate, other investigating bodies.

3.5. It is also critical that any relevant physical, scientific and documentary evidence is
secured and preserved.

3.6. It is important to recognise that some patient safety incidents may result in the police or
HSE investigating possible offences by individual NHS employees and / or the NHS
employer. Investigation of the NHS employer will normally involve the HSE because
health and safety legislation places the primary responsibility on the employer. In such
cases, it may not be appropriate for those who may be investigated or could be
defendants in a criminal case to be members of the Incident Coordination Group. When
this issue arises, it should normally be discussed at the outset by the agencies involved
and, if necessary, the strategic health authority should take on the role of liaising with the
police and HSE on behalf of the Trust. In the case of Foundation Trusts, this liaison may
be taken on by the appropriate Primary Care Trust.

4. The Incident Coordination Group

4.1. The purpose of the Incident Coordination Group is to provide strategic oversight of a
patient safety incident involving the NHS and the police and/or HSE. It is a forum for
communicating, exchanging information and coordinating multiple investigations. It
allows all three organisations to set out their needs so that actions can be agreed that do
not prejudice the work of each organisation e.g. legal proceedings, or the phasing,
extent and timing of further NHS investigations.
The Incident Coordination Group has no role in directing the investigations of the police and/or the HSE.

4.2. Those who attend on behalf of the three organisations should be sufficiently senior to take decisions concerning the management of the incident. They must also have sufficient skills, experience and training to deal with any immediate concerns. Police representation should normally be an accredited senior investigating officer at the level of inspector or above. HSE representation will normally be at main grade inspector level. NHS representation will normally be at executive director level. In instances of suspicious death, the Incident Coordination Group may ask the coroner if he or she wishes to send a representative to the meeting, in addition to the police. In instances of the unexpected death of a child where an investigation under child protection procedures might be appropriate, the Incident Coordination Group may want to ask children's social services if they want to send a representative to the meeting. The NHS should chair the first meeting of the group unless the circumstances preclude this.

4.3. The first meeting of the Incident Coordination Group should consider matters under the following headings (model documents for the Incident Coordination Group are provided in the associated NHS guidelines and include terms of reference, a draft agenda for the first meeting and responsibilities for action):

- nature of the incident(s)
- reasons for meeting, including an explanation from the organisation responsible for calling the meeting
- NHS actions to date, including the outcome of any internal or external investigation or root cause analysis
- public safety concerns
- safety of NHS systems and the need for continuity of patient care i.e. the need for remedial action, further investigation by the NHS or reporting to another safety body
- the extent of further, immediate NHS investigations and how these may need to be constrained in subject matter or format by the needs and requirements of the police and/or HSE
- role and responsibilities of the police and/or HSE and next steps to be taken (except where this would jeopardise any police/HSE investigations or subsequent legal proceedings)
- other statutory responsibilities e.g. safeguarding children
- need to inform professional regulatory bodies e.g. General Medical Council, General Dental Council, Nursing and Midwifery Council
- need to inform and involve other investigating bodies e.g. the Medicines and Healthcare products Regulatory Agency, Healthcare Commission
- securing and preserving evidence
- sharing information
- needs of and support to patients, relatives and NHS staff
- information to other interested parties e.g. the coroner
- handling communications/media
- future handling and coordination, including the appointment of a liaison officer from each organisation.

4.4. The precise nature of what is discussed at the first meeting of an Incident Coordination Group will be determined by local circumstances. However, all the above issues should be considered even if some are covered in more detail than others.
Responsibility for investigating

4.5. Where possible, the police and/or the HSE will come to an early view about the nature of the incident and where responsibility for any future investigation lies. For instance, the police and HSE may conclude that they have no further role in the matter. On some occasions, it may be decided that the Trust should investigate further and, if more information or evidence comes to light, convene another meeting of the Incident Coordination Group to discuss its findings. This will provide an opportunity for the police and/or HSE to decide if they need to conduct their own investigation or if some other course is appropriate.

4.6. There will be occasions when the incident may raise important concerns about wider patient safety. In such circumstances, the conduct of any further NHS investigations will need to be discussed by the Incident Coordination Group so that the necessary further investigation by the NHS can be conducted in such a way as to avoid the danger of prejudicing the police and/or HSE investigation, for example, by interviewing members of staff who may subsequently give evidence at court.

Documenting the Incident Coordination Group

4.7. A written record of each meeting of the Incident Coordination Group must be made. This should set out matters discussed, decisions reached and actions agreed by each agency. Where possible, objectives should be agreed and further meetings of the Incident Coordination Group scheduled to correspond with these. The NHS has responsibility for preparing the written record and for circulating it to other agencies. It is important that these meetings take place so as to ensure that all agencies remain up to date with one another’s actions and so that communications with other parties remain consistent.

4.8. A meeting of the Incident Coordination Group should take place also at the conclusion of any investigation into a patient safety incident. This should provide an opportunity to consider what went well and what could be improved. Learning from such de-briefings will allow the national and local arrangements to be improved.

5. Securing and preserving evidence

5.1. It is easy in the immediate aftermath of a patient safety incident to overlook the need to secure and preserve evidence. This may be particularly true of busy clinical areas that are in constant use by patients and staff and when people are following routine Trust operational practice e.g. sterilising a piece of equipment after a procedure or operation.

5.2. However, safeguarding physical, scientific and documentary evidence may be critical to understanding what has happened, thereby protecting public safety and ensuring the conduct of a satisfactory investigation by any agency. Destruction of evidence may also delay the introduction of safety measures. It may also lead to a more protracted and complex investigation than would otherwise have been necessary. For example, the absence of the packaging and batch number of a piece of equipment may lead to a delay in the Medicines and Healthcare products Regulatory Agency issuing a medical device alert to the NHS or instituting appropriate investigations into a device or medicine.

5.3. It is especially important that evidence is retained where a criminal offence is suspected, since failure to do so may undermine legal proceedings.
5.4. Even in incidents where concerns arise long after the event, it is important to make every effort to secure and preserve all available evidence.

5.5. A record must also be kept and receipts obtained wherever possible of any NHS documents, records or other items passed to other agencies.

6. Sharing information

6.1. The NHS, police and HSE have a duty to uphold the health and safety of patients and the public in addition to their responsibilities for investigation and enforcement. In discharging this duty, the three organisations will share all appropriate information where necessary to ensure patient safety. Such sharing should take account of the health and safety of patients and the public and the legal responsibilities and duties of the three organisations, in particular the limits on what information the organisations may disclose during criminal investigations.

6.2. The three organisations also need to share information to discharge their specific responsibilities.

**NHS**

- to ensure the safety of patients and wider NHS systems and processes
- to continue to manage health services in a timely and effective manner and ensure the delivery of services to patients

**Police/HSE**

- to conduct investigations in a way that helps maintain patient safety as a priority
- to conduct investigations in a timely and effective manner

6.3. Subject to legal requirements and safety concerns, there are a number of factors to bear in mind when making judgements about sharing information. These include:

- the nature and degree of risk associated with the incident itself and the circumstances and individuals involved
- the purpose for which any shared information is to be used and by whom
- whether consent to disclosure is necessary and, if so, whether it can be obtained
- current law and guidance e.g. the statutory requirement to provide information to the HSE and the obligations put upon different professionals by their individual codes of conduct
- confidentiality agreements with those with whom information is shared
- the justification for any necessary breach of patient confidentiality

6.4. Sharing information is an important matter for the Incident Coordination Group to consider. Where necessary, legal or other specialist advice e.g. from professional, regulatory or indemnifying bodies – including that of the Crown Prosecution Service – should be sought.

6.5. It may sometimes be necessary for the police and/or HSE to interview NHS staff. All efforts should be made following an incident to encourage NHS staff to make early, voluntary statements. Where necessary, NHS staff should be given access to legal representation for this purpose.
7. Supporting those harmed, patients, relatives and NHS staff

7.1. In the event of a patient safety incident it is important that the NHS, police and/or HSE work together to keep patients, relatives, injured parties and NHS staff informed and to provide support as appropriate. The organisations should therefore, as far as possible, agree and follow a liaison strategy for each incident. Such a strategy should be agreed at the first meeting of the Incident Coordination Group and as necessary at subsequent meetings.

8. Handling communications

8.1. A communications strategy needs to be agreed for dealing with patients, relatives, other organisations and the media. Where possible, the three organisations need to take a common approach to communications although in the event of legal proceedings this may not be practicable. Specialist help and advice should be sought as necessary.

9. Monitoring the implementation of the protocol

9.1. Good practice suggests that the protocol should be subject to regular review both locally and nationally and that the practical experience of liaising and working together should be evaluated and lessons learned. The three organisations will ensure that this happens and the national development group will review use of the protocol at the end of the first year.

Acknowledgements

The national development group is grateful to individuals and organisations that helped to develop this protocol and the associated guidelines.
Other related documents and websites

More information can be found in the following free publications or via the following web sites.

*Seven steps to patient safety – a guide for NHS staff SSG/2003/01 The National Patient Safety Agency*

*Decision making tool to reduce unnecessary suspensions and support a safety culture – The National Patient Safety Agency*  
[www.npsa.nhs.uk/idt](http://www.npsa.nhs.uk/idt)

*Maintaining high professional standards in a modern NHS: A framework for the initial handling of concerns about doctors and dentists in the NHS HSC 2003/012*

*Confidentiality: Code of Practice* Department of Health, November 2003


*Work related deaths protocol* MISC491 02/03 C140, Health & Safety Executive

Websites:

National Patient Safety Agency  
[www.npsa.nhs.uk](http://www.npsa.nhs.uk)

Department of Health  
[www.dh.gov.uk](http://www.dh.gov.uk)

Department for Education and Skills  
[www.everychildmatters.gov.uk](http://www.everychildmatters.gov.uk)

Health & Safety Executive  
[www.hse.gov.uk](http://www.hse.gov.uk)

NHS Counter Fraud & Security Management Service  
[www.cfs.nhs.uk/pub/sms/documents.html](http://www.cfs.nhs.uk/pub/sms/documents.html)

Healthcare Commission  
[www.chai.org.uk](http://www.chai.org.uk)

Medicines and Healthcare products Regulatory Agency  
[www.mhra.gov.uk](http://www.mhra.gov.uk)

Independent Healthcare Forum  
[www.ihf.org.uk](http://www.ihf.org.uk)
Membership of MOU national development group

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Annex 3

Organisations consulted when developing the MOU & those that responded to public consultation

Organisations consulted when developing the MOU

Commission for Health Improvement
Coroners’ Officers Association
Coroners’ Society
Crown Prosecution Service
General Dental Council
General Medical Council
Medicines & Healthcare products Regulatory Agency
National Clinical Assessment Authority
National Patient Safety Agency
Nursing & Midwifery Council

Organisations that responded to public consultation

Action against Medical Accidents
Addenbrooke’s Hospital
Bassetlaw PCT
Bedford Hospital
Birkenhead & Wallasey PCT
Bournemouth Teaching PCT
Bristol North PCT
Capsticks
Cardiff University
Christie Hospital, Manchester
Coroners’ Officers Association
County Durham and Darlington NHS Trust
County Durham and Tees Valley NHS Trust
Crown Prosecution Service
Department for Education and Skills
DHSSPS, Belfast (Dept. of Health, Social Security & Public Safety)
Derbyshire Constabulary
Devon & Cornwall Police
Doncaster and Bassetlaw Hospitals
Ealing Hospital PCT
Epping Forest PCT
Field Fisher Waterhouse
Five Boroughs Partnership
General Dental Council
General Infirmary at Leeds
Greater Manchester SHA
Guild of Healthcare Pharmacists
Gwent Community Health Council
Hartlepool PCT
Health and Safety Executive (internal consultation)
Healthcare Commission
Herefordshire PCT
Hertfordshire Constabulary
Home Office
Lancashire Teaching Hospitals
Leeds Teaching Hospitals NHS Trust
London Ambulance Service
Maidstone and Tunbridge Wells NHS Trust
Medical Defence Union
Medical Protection Society
Mentoring Associates Ltd
Mid Cheshire Hospital
Mid Yorkshire Hospitals
NACRO (National Association for Care & Resettlement of Offenders)
Newcastle Under Lyme
Bradwell Hospital, North Staffs NHS
North Middlesex Hospital
North Sheffield PCT
Northampton PCT
Nursing & Midwifery Council
Peterborough & Stamford Hospitals
Queens Mary’s Hospital, Sidcup NHS Trust
Rethink Severe Mental Illness
Royal College of General Practitioners
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics & Child Health
Royal College of Pathologists
Royal College of Physicians
Royal College of Physicians Edinburgh
Royal Pharmaceutical Society
School of Nursing & Midwifery, University of East Anglia
Sunderland Social Services Department
South Essex Partnership NHS Trust
South Warwickshire PCT
South Yorkshire Police
Staffordshire Moorlands PCT
Staffordshire Police
Suffolk Police
The Queen Victoria Hospital, NHS Foundation Trust, East Grinstead
The Royal College of Anaesthetists
The Royal College of Midwives
University Hospitals of Leicester
Victim Support
Wandsworth PCT
West Cumbria PCT
West Dorset General Hospitals
West Sussex Health and Social Care NHS Trust
West Yorkshire SHA
TERMS OF REFERENCE
MEMORANDUM OF UNDERSTANDING

Aim

To create a Memorandum of Understanding concerning the investigation of serious incidents affecting NHS Patients which require Police and/or the Health and Safety Executive (HSE) intervention. The Memorandum will be drawn up by the Department of Health, the Association of Chief Police Officers and the HSE, with the overriding objective of enhancing public safety. The Memorandum will:

- Agree on the role and responsibility of each agency when dealing with incidents involving NHS patients in England;
- Provide guidance to the NHS about identifying incidents which require, or may require, referral to the Police, HSE or other agencies, and then procedure to be followed;
- Determine and agree the process for the initial referral and response (the first 24 hours) by the relevant agency(s);
- Provide guidance for the NHS, the Police and others about working together effectively, including points of contact; and
- Determine the internal/external communication strategy for the work of the National MOU Group.

The memorandum will apply to serious incidents and those patients defined in the document, and will provide guidance for the investigation of other incidents involving the NHS, the Police and/or HSE. All of the above objectives will take account of national best practice from the respective organisations and other bodies.
Procedure for the Reporting of Injuries, Diseases and Dangerous Occurrences under RIDDOR Regulations

Types of Incident Requiring Reporting Under RIDDOR Regulations

For the purpose of reporting, the Regulations define major injuries, dangerous occurrences and diseases as below. Over 3 day (>3) injuries are also reportable.

**Major Injuries** are:

- Fracture other than to fingers, thumbs or toes
- Amputation
- Dislocation of the shoulder, hip, knee or spine
- Loss of sight (temporary or permanent)
- Chemical or hot metal burn to the eye or any penetrating injury to the eye
- Injury resulting from an electric shock or electrical burn leading to unconsciousness or requiring resuscitation or admittance to hospital for more than 24 hours
- Any other injury: leading to hypothermia, heat-induced illness or unconsciousness; or requiring resuscitation; or requiring admittance to hospital for more than 24 hours
- Unconsciousness caused by asphyxia or exposure to harmful substance or biological agent
- Acute illness requiring medical treatment, or loss of consciousness arising from absorption of any substance by inhalation, ingestion or through the skin
- Acute illness requiring medical treatment where there is reason to believe that this resulted from exposure to a biological agent or its toxins or infected material

**Examples:**

**Reportable Accidents**

- A confused client falls from a window on an upper floor and is badly injured.
- A hospital client is scalded by hot bath water and has to be moved to a burns unit for treatment.

**Not Reportable**

- A frail elderly woman falls and breaks her leg; there are no obstructions or defects in the premises which contributed to the fall.
- A client commits suicide.
Dangerous Occurrences are:

- Collapse, overturning or failure of load-bearing parts of lifts and lifting equipment
- Explosion, collapse or bursting of any closed vessel or associated pipe work
- Failure of any freight container in any of its load-bearing parts
- Plant or equipment coming into contact with overhead power lines
- Electrical short circuit or overload causing fire or explosion
- Any unintentional explosion, misfire, failure of demolition to cause the intended collapse, projection of material beyond a site boundary, injury caused by explosion
- Accidental release of a biological agent likely to cause severe human illness
- Failure of industrial radiography or irradiation equipment to de-energise or return to its safe position after the intended exposure period
- Malfunction of breathing apparatus while in use or during testing immediately before use
- Failure or endangering of diving equipment, the trapping of a diver, an explosion near a diver, or an uncontrolled ascent
- Collapse or partial collapse of a scaffold over five metres high, or erected near water where there could be a risk of drowning after a fall
- Unintended collision of a train with any vehicle
- Dangerous occurrence at a well (other than a water well)
- Dangerous occurrence at a pipeline
- Failure of any load-bearing fairground equipment, or derailment or unintended collision of cars or trains
- A road tanker carrying a dangerous substance overturns, suffers serious damage, catches fire or the substance is released

The following dangerous occurrences are reportable except in relation to offshore workplaces:

- Unintended collapse of: any building or structure under construction, alteration or demolition where over five tonnes of material falls; a wall or floor in a place of work; any false-work
- Explosion or fire causing suspension of normal work for over 24 hours
- Sudden, uncontrolled release in a building of: 100kg or more of flammable liquid; 10kg of flammable liquid above its boiling point; 10kg or more of flammable gas; or of 500kg of these substances if the release is in the open air
- Accidental release of any substance which may damage health.
Examples

Reportable Dangerous Occurrences

- A client hoists fails due to overload
- Asbestos is released from ducting during maintenance work
- A nurse suffers a needlestick injury from a needle and syringe known to contain Hepatitis B positive blood
- A laboratory worker spills a container of formaldehyde
- A container of TB culture is broken and releases its contents

Not Reportable

- A domestic suffers a needlestick injury; the source of the sharp is unknown.
- A urine specimen container is broken and the contents are spilled.
- A doctor is injured by a sharp containing a client’s blood. The client is not known to have any infection.

Reportable Diseases Include:

- Certain poisonings;
- Some skin disease such as occupational dermatitis, skin cancer, chrome ulcer, oil folliculitis/acne;
- Lung diseases including: occupational asthma, farmer's lung, pneumoconiosis, asbestosis, mesothelioma;
- Any infection reliability attributed to the performance of work activity which involved exposure to blood, body fluids or any potentially infected material either directly or indirectly whilst providing any treatment, service or conducting investigations with humans or animal.
- Other reportable infections include: leptospirosis; hepatitis; tuberculosis; anthrax; legionellosis and tetanus etc;
- Other conditions such as: occupational cancer; certain musculoskeletal disorders e.g. carpel tunnel and hand-arm vibration syndrome.

Examples:

Reportable Diseases

- A nurse contracts TB after nursing a client with TB
- A laboratory worker suffers from typhoid after working with specimens containing typhoid.
- A nurse suffers asthma and becomes sensitised to glutaraldehyde after working in a gastroenterology unit.
- A secretary suffers from work-related upper limb disorder.
- A surgeon suffers dermatitis associated with wearing latex gloves during surgery.
- A paramedic becomes Hepatitis B positive after contamination with blood from an infected client.

**Not Reportable**

- A nurse becomes colonised with MRSA after nursing clients infected with MRSA.
- A domestic catches chicken pox. Clients in areas where she has worked have chicken pox but so does her child.

For further information on diseases related to work activities you should contact the Health and Safety Department, the Infection Control Department, the Occupational Health Department or the Personnel Manager.

**Over 3 DAY (>3) Injuries**

As previously mentioned, accidents connected with work (including acts of physical violence), which result in an employee or a self-employed person being away from work or unable to do their normal duties for >3 days (not counting the day of the accident and including non-work days), must be reported to the HSE on F2508.

**Examples: >3 – day injuries**

- A porter suffers a back injury when lifting a heavy load and is unable to work for four days.
- A receptionist is punched by an angry client, suffers sever bruising and is off work for a week as a result of the injury and shock.
- A doctor’s finger is broken when it is trapped by a closing door; she is unable to do her normal work from Friday until Tuesday.
How To Report Injuries, Diseases And Dangerous Occurrences Under The (Riddor) Regulations

For an accident to be reportable it must arise ‘out of or in connection with work’. Accidents which arise solely from the condition of the injured person are not reportable, neither are suicides.

It is the responsibility of the relevant ‘Responsible Person’ in a given area/service to report personally to the Health and Safety Executive (HSE) under RIDDOR. The Health and Safety Executive must be notified immediately by phone, in the first instance, of the following:-

Any accident connected with the work of NHS Barnsley where:

- An employee, or self employed person working on NHS Barnsley’s premises is killed or suffers a major injury (including as a result of physical violence); or

- A member of the public is killed or requires hospital treatment;
  a) a member of the public slips on a mopped floor and is sent to A/E – RIDDOR reportable
  b) a member of the public walks snow in on their shoes, slips and is sent to A/E – NOT RIDDOR reportable

Any of the dangerous occurrences listed in the regulations.

In the case of serious accidents or dangerous occurrences which take place outside of normal working or office hours, i.e. during the night or at weekends, each Department will have available a flow chart and supporting documentation for the reporting procedure to be followed.

The ‘Responsible Person’ must also send a written report to the Health and Safety Executive within 10 days of any notifiable incident as outlined above and also of:

Any accident connected with work (including an act of physical violence) which leads to injury to an employee or self-employed person working on the NHS Barnsley’s premises which results in their absence from work or being unable to do their normal work for more than three days (including days which would not normally be working days).

Any of the cases of ill health/disease listed in the regulations.

RIDDOR does not require accidents to be reported if they arise directly from the conduct of an operation, examination or other medical treatment, carried out or supervised by a doctor or dentist. If in doubt, seek advice from Health and Safety.

Telephone number and address for reporting to Health and Safety Executive:

Incident Contact Centre
Caerphilly Business Park
Caerphilly
CF83 3GG

Website: www.riddor.gov.uk
Telephone: 0845 300 9923
Fax: 0845 300 9924
Email: riddor@natbrit.com
Appendix 11

Managing and Reporting of Incidents Involving Medical Devices (MDA/2004/001)

NHS Barnsley Clinical Commissioning Group requires incidents involving medical devices to be reported so that appropriate investigation/action can be taken to prevent recurrence. (Please refer to the Medical Devices Policy).

Incidents Involving Medical Devices May Arise Due To:

Shortcomings in the design or manufacture of the device itself;

- Inadequate instructions for use
- Locally initiated modifications or adjustments
- Inappropriate user practices (which may in turn result from inadequate training)
- Inappropriate management procedures
- The environment in which the device is used or stored
- Selection of the incorrect device for purpose

Conditions of use may also give rise to incidents:

- Environmental conditions (e.g. electromagnetic interference)
- Location (e.g. devices designed for hospitals may not be suitable for the community or ambulances)

What Is A Medical Device?

The Medicines and Healthcare Products Regulatory Agency (MHRA) defines a medical device as a piece of ‘equipment used for the diagnosis or treatment of disease, or for monitoring of patients.’ Medical Devices include computer software packages used to support diagnosis or clinical treatment.

What Is Not A Medical Device?

Medical devices do not include general workshop equipment such as power or machine tools or general purpose laboratory equipment. Pre-filled devices e.g. drug inhalers, syringes.

If in doubt as to whether a piece of equipment is a medical device contact the NHS Barnsley Clinical Commissioning Group’s’s Medical Devices Liaison Co-ordinator for advice. These may seek the advice as appropriate of the MHRA. The MHRA can also be contacted direct for advice on 020 7972 8080.

What Should Be Done With Medical Devices That Have Been Involved in Incidents?

Immediate Action and Evidence Collection

All items that have been involved in incidents should be taken out of use immediately.
The following information will be required for reporting to the Risk Management Department:

- Name of the equipment
- Model number and type
- Serial number
- Location of the equipment
- Incident report for. ‘IR1’ number
- Brief description of the incident

All material evidence should be labelled and kept secure. This includes the products themselves, their instructions for use, records of use, repair and maintenance records, and where appropriate packaging material or other means of batch identification. The evidence should not be interfered with in anyway except for safety reasons or to prevent its loss.

Records should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports.

UNDER NO CIRCUMSTANCES should devices be sent for repair (either in-house or by a third party), returned to the manufacturer/supplier (unless otherwise agreed with the MHRA), discarded or used again without prior consultation with NHS Barnsley Clinical Commissioning Group’s Medical Devices Liaison Officer (Head of Patient Safety/Deputy Chief Nurse). This officer will seek appropriate advice from the MHRA.

NB: In EXCEPTIONAL CIRCUMSTANCES, where devices cannot be removed from use because there is no alternative available, and where patient health would otherwise suffer, NHS Barnsley Clinical Commissioning Group Medical Devices Liaison Officer should be contacted for confirmation that the device may continue to be used or repaired and put back into use.

If a situation arises where this is not possible then MHRA should be contacted direct for advice. The MHRA’s adverse incident centre can be contacted on 020 7972 8080.

Contact with Manufacturer's/Suppliers

The Manufacturer/Supplier should be informed promptly, and allowed to inspect items if accompanied by the Medical Devices Co-ordinator (Head of Patient Safety/Deputy Chief Nurse).

To facilitate an investigation, it may be possible to provide the manufacturer with a sample of unused stock from a large batch.

Until advised to the contrary by NHS Barnsley’s Medical Devices Liaison Officer (Head of Patient Safety/Deputy Chief Nurse) who will seek the appropriate advice of the MHRA, the manufacturer/supplier must not be allowed to exchange, interfere with, or remove any part of the product implicated in the incident as this might prejudice any investigation(s).

Decontamination
The organisation has a legal requirement under the Health and Safety at Work etc Act 1974, The Management of Health and Safety at Work Regulations 1999, and Control of Substances Hazardous to Health (COSHH) Regulations 1999, to ensure that people (staff, patients, visitors, contractors) are not exposed to unnecessary risks through contaminated items.

Anyone who inspects, services, repairs or transports medical devices or equipment either on Trust premises or elsewhere has a right to expect that the equipment/devices have been appropriately treated so as to remove or minimise the risk of infection or other hazards e.g. chemical, radioactive.

However, in the case of a medical device involved in an incident, the process of decontamination may alter or influence the evidence available for investigation. Advice must be sought from the Medical Devices Liaison Officer ((Head of Patient Safety/Deputy Chief Nurse) who may take advice from the MHRA.

For further information on decontamination refer to NHS Barnsley Clinical Commissioning Group policy ‘Decontamination’ which can be found within NHS Barnsley Clinical Commissioning Group ‘s Infection Control Manual.’

What Should Be Reported?

Any incident involving a device or resulting from the use of its instructions should be reported, especially if the incident has led to or, were it to occur again, could lead to:

- Death, life threatening illness or injury
- Deterioration in health or permanent impairment of body structure or function
- The necessity for medical or surgical intervention (including implant revision)
- Hospitalisation or prolongation of existing hospitalisation
- Unreliable test results leading to inappropriate diagnosis or therapy
- Fetal distress, Fetal death or congenital abnormality or birth defect

Reports of adverse incidents that appear to be caused by human error are also helpful as:

- The error may be partly (or wholly) due to deficiencies in the design of the device or instructions for use;
- They will help to prevent repetition of mistakes, possibly by promulgation of advice or through improvements to the design of future devices.

How And When Should An Incident Involving A Medical Device Be Reported?

Incidents involving medical devices should be reported via web based form as soon as possible, usually within 24 hours.

The following information will be required:

- Name of the equipment
- Model number and type
• Serial number
• Location of the equipment
• Incident report form number
• Brief description of the incident
Appendix 12

Process for Other External Reporting Mechanisms

NHS Litigation Authority

Refer to Claims Policy for process of reporting to the NHSLA

National Patient Safety Agency (Risk Management Department Function)

The Head of Patient Safety/Deputy Chief Nurse will arrange for all patient safety incidents to be uploaded every 2 weeks to the National Reporting and Learning system via NHS Barnsley Clinical Commissioning Group electronic database
**NHS Barnsley CCG Serious Incident (SI) process**

Yorkshire & Humber Strategic Health Authority (Y&HSHA) have delegated the responsibility for performance managing SIs to PCT’s. Performance management responsibilities were allocated by Y&HSHA.

NHS Barnsley currently have responsibility for performance managing SIs reported by Barnsley Hospital NHS Foundation Trust (BHNFT) and South West Yorkshire Partnership Foundation Trust (SWYPFT) this is delegated to the NHS Barnsley Clinical Commissioning Group.

Yorkshire Ambulance Service NHS Trust (YAS) SI’s are performance managed by NHS Bradford and Airedale.

Y&HSHA – monitor this process requiring quarterly reporting of stats including assessment of the robustness of reports. They also undertake bi annual support/monitoring visits to each organisation.

<table>
<thead>
<tr>
<th>Originator</th>
<th>Reported to who in NHS Barnsley CCG</th>
<th>Circulation within NHS Barnsley CCG</th>
<th>Performance management responsibilities</th>
<th>Performance management process</th>
</tr>
</thead>
</table>
| BNHFT/SWYFT Report onto STEIS | STEIS alerts; Head of Patient Safety and Quality department. Both providers phone call to above as per protocol. Sometimes phone call to discuss appropriateness of making SI report, this to inform their SI committee where decision is made regarding SI reporting. | All reports; Chief officer (CO) Chief Nurse Medical Director As appropriate; Clinical Guardian Contract Manager | NHS Barnsley Clinical Commissioning Group | • NHSBCCG alerted when SI reported • Added to log, details checked on STEIS • Interim report submitted at 4 weeks if completed report expected to be delayed. • Completed report submitted - 12 weeks, to include action plans, chronology and learning to be shared. If post mortem (pm) to take place and this is delayed, performance management continues, keeping SI on log until PM details available. • Completed report discussed at SI }
May also be necessary to invite “specialist” to group for individual SI's.

- Robustness and appropriateness of investigation, report and actions considered. When satisfied SI group make decision to close or request further information, investigation or actions such as audit.
- It may be necessary to undertake further actions such as discuss with coroner.
- Actions will be monitored via Serious Incident and Complaints group.
- Summary to Quality and Patient Safety Committee, which reports to Governing Body.
- Monthly updates to the Governing Body to include, new incidents, ongoing incidents and recently closed incidents.

<table>
<thead>
<tr>
<th>RDaSH</th>
<th>NHS Doncaster CCG alerted.</th>
<th>As above</th>
<th>NHS Doncaster</th>
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<tbody>
<tr>
<td>Re Barnsley</td>
<td>NHS Doncaster alert</td>
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<tr>
<td>registered</td>
<td>HoPS/Deputy</td>
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<td>patients</td>
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<tr>
<td>Report onto</td>
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<td>STEIS</td>
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<tr>
<td>Role</td>
<td>Activity</td>
<td>Group</td>
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<td>--------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Chief Nurse</td>
<td>give brief details as per STEIS and as per responsibilities as detailed in Y&amp;H Procedure for the Management of Serious Incidents , Version 6 October 2010. (NHSB cannot access RDaSH details on STEIS)</td>
<td>All reports submitted by RDaSH to NHS Doncaster for performance management.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Interim reports passed to NHS Barnsley CCG HoPS by NHS Doncaster.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Completed reports performance managed by NHS Doncaster who make the decision to close on STEIS.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Reports forwarded on to NHS Barnsley (HoPS), together with performance management information.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Above info considered at SI group</td>
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</table>

**Safeguarding children**

If a safeguarding children issue must be reported by NHSB CCG as commissioner

<table>
<thead>
<tr>
<th>Designated Nurse</th>
<th>leads and follows set and combined Safeguarding and SUI procedures. This is a joint process between providers guided by legislation</th>
<th>Y&amp;H SHA</th>
</tr>
</thead>
</table>

**Sheffield Teaching Hospitals NHS Foundation Trust (STH)**

Sheffield Childrens NHS Foundation Trust (SCH)

Report onto STEIS

<table>
<thead>
<tr>
<th>NHS Sheffield</th>
<th>Standing agenda item at clinical quality review groups with commissioners</th>
<th>NHS Barnsley HoPSis a member of Clinical Quality Review Groups for SCH and STH together with other commissioners.</th>
</tr>
</thead>
</table>

**NHS Barnsley CCG**

Reported onto STEIS by NHS

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<th>As above</th>
<th>Y&amp;H SHA</th>
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<th>Each SI to be “project</th>
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<tr>
<td>Report onto STEIS</td>
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- HoPS has place on Clinical Quality Review Group, with other commissioners, at NHS Bradford & Airedale, with regard to sharing information about YAS. Overall SI information is a standing agenda item.
- HoPS is member of SI information sharing group, attendees; NHS Doncaster, NHS Barnsley, Doncaster & Bassetlaw Hospitals NHS Foundation Trust, NHS Lincolnshire, Bassetlaw PCT. (RFT invited, not yet attended)
- HoPs has regular meetings with Director of Quality BHNFT to discuss and review SI’s
- HoPs has regular meetings with Assistant Director Patient Safety SWYPFT to discuss and review SI’s
- Designated Nurse Safeguarding Children liaises with named support at Y&H SHA re safeguarding SI’s

National Patient Safety Agency (NPSA) have produced guidance and templates for reports and also provide support to the developing processes. Commissioners are united in requesting that reports are submitted using the NPSA templates.

Y&HSHA have allocated named support to PCT’s who undertake support/monitoring visits.

Y&H SHA Procedure for the Management of Serious Incidents (SI,) provides guidance for the local procedures.
Local procedures are updated to reflect changes and updates to the Y&HSHA procedures.
PROTOCOL FOR REPORTING AND PERFORMANCE MONITORING
SERIOUS INCIDENTS OCCURRING AT ANY PROVIDER
WITH NHS BARNSLY AS THE COMMISSIONING PCT
Currently part of contract with these providers
will be updated from 1 April 2013

1. Introduction

Under Section C Part 7.2, Safeguarding Policies or Section C Part 7.3, Incidents Requiring Reporting Procedure of the standard NHS Contract it states that providers will also report to the commissioner incidents as agreed through the SI protocol between commissioner and provider. This paper outlines the protocol for reporting and performance monitoring of serious untoward incidents occurring at any provider (where NHS Barnsley is the commissioning PCT) by NHS Barnsley (NHSB). It reiterates roles and responsibilities, including reporting lines, to ensure that the work in relating to serious incidents is properly co-ordinated.

2. Definitions of a Serious Untoward Incident

2.1 A serious incident requiring investigation is defined by the NPSA in the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation as an incident that occurred in relation to NHS-funded services and care resulting in one of the following:-

- **Unexpected or avoidable** death of one or more patients, staff, visitors or members of the public

- **Serious harm** to one or more patients, staff, visitors or members of the public or where the outcome requires life-threatening intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy or result in prolonged pain or psychological harm (this includes incidents graded under the NPSA definition of severe harm);

- A scenario that prevents or threatens to prevent a provider organisation’s ability to continue to deliver health care services, for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment, or IT failure.

- Allegations of abuse

- Adverse media coverage or public concern about the organisation or the wider NHS.

- One of the core set of **Never Events**. Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by providers. All Never Events should be reported as SIs.

*The Operating Framework for the NHS in England 2010/11* reaffirms that PCT’s should:
Use the national set of Never Events as part of their contract arrangements with providers.

Ensure that patient safety incidents which are Never Events are reported to the NPSA, and

Publish the numbers and types of events on an annual basis.

2.2 A full list of Never Events can be found at Appendix 2. NHS Barnsley expects that should a Never Event be reported that the provider will as part of their investigation consider any NPSA alerts that have been published in relation to the Never Event and their declaration of compliance around this alert. This is because there is existing national guidance and/or national safety recommendations on how these types of event can be prevented and support for implementation. The event is largely preventable if the guidance is implemented. Their occurrence is an indication that an organisation may have not put in place the right systems and processes to prevent the incidents from happening and thereby prevent harmful outcomes.

‘Near misses’ may also constitute Serious Incidents, where the contributory causes are serious and under different circumstances they may have led to serious injury, major permanent harm, or unexpected death, but no actual harm resulted on that occasion. A possible example is that of a system failure, the result of which is incorrect/delayed diagnosis. This may not have any serious consequences for some patients, but for others could lead to the wrong treatment/serious delay in treatment and ultimately to death.

Examples of other incidents which are reportable as Serious Incidents are shown at Appendix 1.

3. General principles and roles

3.1 Foundation Trusts – Barnsley Hospital NHS Foundation Trust & South West Yorkshire Partnership NHS Foundation Trust (SWYFT)

As part of the changes arising from the creation of Foundation Trusts, the responsibility for performance and monitoring of serious incidents (SI) rests with PCT’s. Under these arrangements all providers, where NHS Barnsley is the commissioning PCT, are required to report all serious incidents to the NHS Barnsley. This requirement covers all types of incidents. Examples of incidents are listed in Appendix 1. This procedure will also apply to all other providers

Continued participation of providers in UNIFY (formerly STEIS) reporting will also contribute to the sharing of learning arising from such incidents across Yorkshire and the Humber. On occasion a serious incident may arise which results from the actions of both the provider and NHS Barnsley. In such circumstances it may be inappropriate for NHS Barnsley to monitor the incident and NHS Barnsley and the provider may agree that the SHA is best placed to monitor the incident investigation and act as ‘honest broker’.

It is essential that clear local procedures are in place within providers for identifying and reporting serious untoward incidents. These arrangements do not replace the duty to inform the police and other authorities, such as social services, where appropriate. Nor do they affect the duties and responsibilities of the NHS in child protection cases or impinge on well established lines of accountability.
For example, the SHA’s Director of Finance will need to be informed of significant matters in relation to probity.

Local procedures for reporting managing and handling serious incidents will need to meet National Quality Standards including, but not exclusively statutory Care Quality Commission standards, National Patient Safety Agency voluntary NHS Litigation Authority standards and any subsequent published guidance. However in addition NHS Barnsley require the following additions to be included:

- Report the incident at the earliest opportunity to NHS Barnsley in the first instance by a telephone call to the Assistant Chief Operating Officer Patient Safety & Governance and subsequently via UNIFY (the SHA will also receive a copy for trend analysis to support shared learning in Yorkshire and the Humber). This should occur within 48 hours of the incident happening or the organisation becoming aware of the incident or by the next working day in instances of incidents occurring at weekends or bank holidays. If the facts are not clear within 48 hours then providers following a discussion with the Commissioner should log the SI onto UNIFY and the Commissioner will delog the SI if the facts determine the incident does not meet the criterion.

- All providers are required to log all serious incidents onto UNIFY. Initial information of new serious incidents together with any later investigation reports/action plans should also be sent the Assistant Chief Operating Officer Patient Safety & Governance at NHS Barnsley. All reports should be anonymised.

- If there is doubt as to whether the incident should be reported as an SI, then a discussion should be instigated with the Assistant Chief Operating Officer Patient Safety & Governance at NHSB to agree the way forward.

- Identify any involvement by other agencies and agree with them who is to take the lead responsibility;

- Consider the need for a short-and long-term communication/media handling strategy, liaising with NHS Barnsley as appropriate;

- Ensure the outcome of the investigation informs future practice;

- Consider whether it is appropriate to report the incident to the relevant professional body (eg General Medical Council, Nursing and Midwifery Council etc.) or ‘Confidential Enquiry’ e.g. maternal deaths, suicides and homicides.

Once a new incident has been entered onto UNIFY the system automatically notifies NHS Barnsley.

Providers should also report updates in the investigation of an incident on UNIFY and to NHS Barnsley by sending copies of investigation reports and action plans to the Assistant Chief Operating Officer, Patient Safety and Governance.

NHS Barnsley will expect to receive a copy of the Trust’s internal report and action plan within 12 weeks of the incident being reported, unless an extension to this timescale has been negotiated with NHS Barnsley. NHS Barnsley Commissioning Complaints/SI and Claims Sub Group will monitor these timescales. In addition this information is required by the SHA on a quarterly basis.
4. **Procedure for requesting an extension**

There will be relatively rare occasions when the provider is unable to complete the investigation within the 12 week deadline. The request for an extension should be seen as an exception rather than the norm as providers should have in place systems and processes to enable the current 12 week deadline to be achieved. Should it become apparent that the provider is not able to achieve this deadline then the provider should as soon as practicable request an extension from the Commissioner giving the rationale for the request and amount of time requested. NHS Barnsley would expect at this point to have sight of an interim report or be informed of the initial findings and any actions already taken to prevent recurrence. Given the importance of serious incident investigation to providers there is an expectation that the request should come via a senior manager with responsibility for the SI process.

The request should be made to the Assistant Chief Operating Officer Patient Safety & Governance for consideration and a response will be made as soon as practicable.

5. **Process for monitoring and closure of serious incidents**

NHS Barnsley Commissioning Complaints/SI and Claims Sub Group will monitor these reports/action plans and decide when to close the serious incident. This will be based on the criteria at Appendix 3. There is an expectation that reports and action plans must be graded as good before they are considered for closure. The Assistant Chief Operating Officer Patient Safety & Governance will arrange for the incident to be closed on UNIFY and inform the provider in writing within 7 working days of the incident being closed. Closed records can still be viewed on the system, but not edited.

NHS Barnsley will as part of its closure process send a copy of the RCA review to the provider.

NHS Barnsley will follow up non-receipt of expected reports with providers on a monthly basis.

It is important that providers complete as many parts of the UNIFY form as possible. It is particularly important that information is provided in the lessons learnt section. One of the key aims of the SI system is to allow easier dissemination of good practice, but this can only be achieved if sufficient information is provided on the UNIFY system. The SHA will continue to have access to all reports on UNIFY and will use this to produce a lessons learnt bulletin as appropriate.

6. **Role of NHS Barnsley**

The Assistant Chief Operating Officer Patient Safety & Governance is responsible for providing initial support and advice to the providers, liaising with NHS Barnsley Chief Executive and other NHS Barnsley Directors, South Yorkshire & Bassetlaw Cluster, the SHA and other bodies where appropriate.

The majority of serious untoward incidents will require little in the way of intervention or direct involvement by NHS Barnsley. However, in cases where there is evidence that the incident is part of a worrying trend or where the circumstances or consequences of the incident are exceptionally serious, NHS Barnsley may need to instigate a wider investigation. The extent of that investigation will depend on the nature of the incident and it is difficult to be prescriptive. For some incidents, it may be that NHS Barnsley will ask the provider to undertake further inquiries or suggest a particular course of action.
In more serious cases, NHS Barnsley may decide that a more independent investigation of the incident is required and would liaise with the provider on the arrangements for this at senior level. In addition, NHS Barnsley would expect to be notified if the Trust itself decided that it wished to involve colleagues independent of the Trust in any investigation and to have sight of the terms of reference.

7. **Safeguarding Children**

In line with the Yorkshire and Humber procedure for management of serious incidents, NHS Barnsley has a specific role in relation to Serious Incidents and Safeguarding Children in relation to their lead role. Providers should ensure they comply with the principles in the policy above, including the provision of information to ensure the PCT is able to complete a 72 hour initial management report.

8. **Safeguarding Adults**

Where it is identified that the incident meets the thresholds of the South Yorkshire Safeguarding Adults Multi Agency Procedures, the provider will be asked to instigate these in collaboration with the Local Authority.

9. **Other specific Incidents**

There will be specific incidents that also require the PCT to complete a 72 hour initial management report. Providers will be expected to provide as much information as practicable to ensure the PCT can fulfil its responsibilities

**Author** – Assistant Chief Operating Officer Patient Safety & Governance  
**Protocol updated** March 2012  
**Review date** – March 2013
APPENDIX 1

Examples of Serious Untoward Incidents

It is difficult to be prescriptive, but the following are examples of events that would warrant reporting to NHS Barnsley Clinical Commissioning Group

- Death or serious injury to a patient or member of the public which is alleged to be at the hands of another patient or member of the public while on NHS premises;

- Suspected homicide by a person currently in receipt of mental health services (or within the last six months);

- Suicide/suspected suicide of a person currently in receipt of NHS mental health services (both out-patients and in-patients) or who have received NHS mental health services in the last six months;

- Serious injury of a person currently in receipt of NHS care (or within the last six months) as a result of deliberate self-harm (e.g. attempted suicide) or accidental injury;

- Patients detained under the Mental Health Act who abscond from NHS care and who present a serious risk to themselves and/or others. Of particular concern would be those patients who abscond from medium secure or specialist forensic services, those who are likely to pose a risk to the public, attract media attention and/or who commit an offence in the community;

- Any death on GP premises (in line with Shipman recommendations);

- Safeguarding incidents meeting the criteria specified below:

  Incidents relating to safeguarding children should be reported if they fall within the criteria set below:

  (a) Any case where there is prima facie evidence (i.e. initial indications) that a child has sustained a potentially life-threatening injury which may be through abuse or neglect or serious sexual abuse, or sustained serious and permanent impairment of health or development through abuse or neglect.

  (b) A prima facie case where a child dies (including death by suicide) and abuse or neglect is known or suspected to be a factor in the child’s death and there will be a Serious Case Review (SCR). (‘Working Together’, 2006).

- Death or serious injury to a member of staff (including independent contractors e.g. GPs, dentists, opticians, pharmacists) in the course of their NHS duties;

- Medication incidents resulting in death/serious injury eg incorrect medication dispensed to patient; drugs given to patients with known allergy;

- Failure of medical equipment resulting in death/major injury;
- Clinical incidents resulting in death/serious injury e.g. surgery performed on wrong patient, wrong site, etc;

- Serious fires or other serious damage, which occurs on NHS/Independent contractor premises. Of particular concern would be any fire which resulted in casualties or major disruption to services;

- Serious or unexplained outbreaks of infection or disease in hospital or the wider community (e.g. food poisoning, Legionnaire’s Disease) or the confirmed transmission of serious infectious disease between an NHS staff member and a patient (e.g. HIV/Hepatitis B);

- Major system failure e.g. failure of laboratory services to provide accurate screening results; patient referral system failure for further consultation/treatment;

- Major environmental incident (e.g. release of gas/chemicals, inappropriate disposal of clinical waste) which has or could have harmed the public;

- Major service disruption e.g. due to power failure, flooding, etc;

- Major breach of patient confidentiality e.g. theft of patient notes or computers/laptops containing patient information; discovery of patient records in public area;

- Incidents/concerns regarding the actions of NHS staff (including independent contractors). Examples include fraudulent behaviour, gross misconduct and actions resulting in harm to patients. This could lead to suspension/summary dismissal, media interest and the involvement of the criminal justice system;

- A pattern emerging that is causing concern such as a high number of complaints regarding a member of staff (including independent contractors), a particular service and/or hospital that may warrant further investigation and action;

- Only certain HCAI incidents should be reported as SI’s where a HCAI has been confirmed as the primary care of death. Other cases which should be reported as SI’s include:- clusters of HCAI, such as those that result in ward closures, recurrent incidences within the same unit and those which result in adverse media interest;

This list is not exhaustive but should help in clarifying under what circumstances an incident should be reported. Chief Executives or their nominated leads officers will need to exercise personal judgement when considering whether or not a Serious Incident needs to be reported. Chief Executives will also need to make the final decision about whether or not the incident is of sufficient severity and/or focus of public concern to warrant reporting to the NHS Barnsley.
**Never Events**
The "Never Events" list 2012/13 policy framework for use in the NHS Department of Health 2012

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<tr>
<td><strong>SURGICAL</strong></td>
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</tr>
<tr>
<td>1</td>
<td>Wrong site surgery</td>
</tr>
<tr>
<td>2</td>
<td>Wrong Implant/prosthesis</td>
</tr>
<tr>
<td>3</td>
<td>Retained foreign object post-operation</td>
</tr>
<tr>
<td><strong>MEDICATION EVENTS</strong></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Wrongly prepared high-risk injectable medication</td>
</tr>
<tr>
<td>5</td>
<td>Maladministration of potassium-containing solutions</td>
</tr>
<tr>
<td>6</td>
<td>Wrong route administration of chemotherapy</td>
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<tr>
<td>7</td>
<td>Wrong route administration of oral/enteral treatment</td>
</tr>
<tr>
<td>8</td>
<td>Intravenous administration of epidural medication</td>
</tr>
<tr>
<td>9</td>
<td>Maladministration of Insulin</td>
</tr>
<tr>
<td>10</td>
<td>Overdose of midazolam during conscious sedation</td>
</tr>
<tr>
<td>11</td>
<td>Opioid overdose of an opioid-naïve patient</td>
</tr>
<tr>
<td>12</td>
<td>Inappropriate administration of daily oral methotrexate</td>
</tr>
<tr>
<td><strong>MENTAL HEALTH</strong></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Suicide using non collapsible rails</td>
</tr>
<tr>
<td>14</td>
<td>Escape of a transferred prisoner</td>
</tr>
<tr>
<td><strong>GENERAL HEALTHCARE</strong></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Falls from unrestricted windows</td>
</tr>
<tr>
<td>16</td>
<td>Entrapment in bedrails</td>
</tr>
<tr>
<td>17</td>
<td>Transfusion of ABO-incompatible blood components</td>
</tr>
<tr>
<td>18</td>
<td>Transplantation of ABO incompatible organs as a result of error</td>
</tr>
<tr>
<td>19</td>
<td>Misplaced naso- or orogastric tubes</td>
</tr>
<tr>
<td>20</td>
<td>Wrong gas administered</td>
</tr>
<tr>
<td>21</td>
<td>Failure to monitor and respond to oxygen saturation</td>
</tr>
<tr>
<td>22</td>
<td>Air Embolism</td>
</tr>
<tr>
<td>23</td>
<td>Misidentification of patients</td>
</tr>
<tr>
<td>24</td>
<td>Severe Scalding of patients</td>
</tr>
<tr>
<td><strong>MATERNITY</strong></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Maternal death due to post partum hemorrhage after elective Caesarean section</td>
</tr>
</tbody>
</table>

Further details can be found at:
## NHS Barnsley Clinical Commissioning Group
### Review of SI inquiry/investigation report and action plan

Name of Organisation:  
Date:  
SI Number:  
NHS Reviewer/Clinical Adviser:  

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>CRITERIA</th>
<th>YES/NO</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Does the report identify the SI reference number, author and date of report?</td>
<td></td>
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<tr>
<td>2</td>
<td>What was the date of the incident</td>
<td></td>
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<tr>
<td>3</td>
<td>Was there telephone notification to the organisation</td>
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<tr>
<td>4</td>
<td>When was the incident reported on STEIS (within 24 hours)</td>
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<td>5</td>
<td>Quality of the information of STEIS</td>
<td></td>
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<tr>
<td>6</td>
<td>Is the incident coded correctly on STEIS (based on the information available at the time)</td>
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</tr>
</tbody>
</table>
| 7      | Has the report been submitted within twelve weeks from the date the incident was notified to the SHA? |  | Date of incident:  
Date reported to NHS Barnsley CCG:  
Date report due to NHS Barnsley CCG:  
Final Report submitted **** weeks after reporting the incident to CCG.  |
| 8      | Has the provider requested any extensions and if so how many and what time frames and the rationale |  |  |
| 9      | Does the report have Chief Executive or delegated Director sign off? |  |  |
| 10     | Does the report give a factual description of the incident, covering the following:  
- Who or what was involved?  
- What happened?  
- When did it happen?  
- Where did it happen?  
- How did it happen? |  |  |
<table>
<thead>
<tr>
<th>NUMBER</th>
<th>CRITERIA</th>
<th>YES/NO</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Does the report detail the immediate actions taken, including support to carers/staff, contact with the media and notification to external bodies?</td>
<td></td>
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<tr>
<td>12</td>
<td>Was the investigation sufficiently robust and proportionate to the scale and complexity of the incident?</td>
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<tr>
<td>13</td>
<td>Where appropriate, has a coroner's inquest been held? If so what was the outcome?</td>
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<tr>
<td>14</td>
<td>Does the report identify all root causes of the incident through Systematic analysis? (There may be more than one root cause)</td>
<td></td>
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<tr>
<td></td>
<td>These may include:</td>
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<td></td>
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<tr>
<td></td>
<td>- Organisational &amp; management factors</td>
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<td></td>
<td>- Work environment factors</td>
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<td>- Team factors</td>
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<td>- Individual factors</td>
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<td></td>
<td>- Task factors</td>
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<td></td>
<td>- Patient factors</td>
<td></td>
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<tr>
<td>15</td>
<td>Does the report make robust recommendations to minimise risk of recurrence?</td>
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<tr>
<td>16</td>
<td>Has the Trust developed an action plan to implement these recommendations?</td>
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<tr>
<td>17</td>
<td>Are the identified actions clear and specific and resources identified where appropriate?</td>
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<tr>
<td>18</td>
<td>Are there timescales set for each action? And are they reasonable?</td>
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<tr>
<td>19</td>
<td>Does the report indicate the name and job title of the individual(s) responsible for each action?</td>
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<tr>
<td>20</td>
<td>Are there arrangements in place to audit implementation and effectiveness of action plans?</td>
<td></td>
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</tr>
<tr>
<td>21</td>
<td>When any new changes are made, new risks are often introduced (e.g. bedside alcohol gel → accidental ingestion). Have action plans been risk assessed so that any downside of the recommendations are minimised?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NUMBER</td>
<td>CRITERIA</td>
<td>YES/NO</td>
<td>COMMENT</td>
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<td>---------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>22</td>
<td>Are there any areas of good practice which have been highlighted as part of this investigation?</td>
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<tr>
<td>23</td>
<td>Does the report indicate how the learning from the incident will be shared across the Trust?</td>
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<tr>
<td>24</td>
<td>Is this report suitable to be shared with colleagues in an anonymised way as an exemplary report?</td>
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</tr>
</tbody>
</table>

Comments:
Grading of Investigation Report
Please tick the appropriate box

- Excellent
- Good
- Fair
- Weak

Grading of Action Plan
Please tick the appropriate box

- Excellent
- Good
- Fair
- Weak

The report and action plan should be graded individually.

<table>
<thead>
<tr>
<th>Rating</th>
<th>Examples of criteria</th>
</tr>
</thead>
</table>
| Excellent | • Report subject to a comprehensive root cause analysis  
|           | • Terms of reference are clearly identified and the report follows these  
|           | • Root causes and contributory factors are identified  
|           | • Report contains robust recommendations and an action plan has been developed from these  
|           | • Action plan contains named leads and timescales with a process in place for monitoring to ensure effective risk reduction  
|           | • Evidence based practice is detailed within the report  
|           | • Details of how the learning is to be shared is contained within the report  
|           | • Staff and relatives contribute to incidents where appropriate  
|           | • No additional information required  |
| Good      | • Report is subject to a detailed root cause analysis investigation  
|           | • Terms of reference are identified  
|           | • Root causes and contributory factors are identified  
|           | • Recommendations and action plans are robust  
|           | • Action plan has a named lead and timescale is provided, process is in place for monitoring or audit of the action plan  
|           | • Report needs minor additional information prior to closure  |
| Fair | • Root causes not identified but contributory factors are detailed  
|      | • Recommendations and/or action plans are in place but named leads and/or timescales are not identified  
|      | • There is no/limited monitoring/audit of actions  
|      | • Report needs to be returned for additional information prior to closure  |
| Weak | • Not subject to a RCA investigation  
|      | • No terms of reference  
|      | • Recommendations/action plan are not in place or weak  
|      | • No monitoring of action plan detailed  
|      | • Report needs to be returned for substantial additional information |