NHS
Bolton Clinical Commissioning Group

Operational Policy for the Performance Management of Serious Incidents
V 1.3

May 2017

Document Control

Doc. Ref. No.	QS003
Title of document	Operational Policy for the Performance Management of Serious Incidents
Author's name	Sue Mackie
Author's job title	Lead Nurse for Quality & Safety
Dept / Service	Integrated Governance & Quality
Doc. Status	DRAFT
Based on	▪ Bolton PCT StEIS Operational Policy (2010) ▪ NHSE. (March 2015) Serious Incident Framework. Supporting learning to prevent recurrence. ▪ Tissue Viability (Pressure Ulcer) Guidance for Reporting and Safeguarding (2012) ▪ NHSE. (March, 2015) Never Events List 2015/2016 ▪ Tissue Viability (Pressure Ulcer) Guidance for Reporting and Safeguarding DRAFT ▪ Introducing the Statutory Duty of Candour (2014) ▪ NHS Standard Contract 2014/2015 ▪ Annex A – Final regulations. Draft statutory instruments. Health & Social Care Act 2008 (Regulated Activities) Regulations 2014 ▪ National Guidance on Learning from Deaths – National Quality Board (2017)
Signed off by	Quality & Safety Committee
Publication Date	May 2017
Next review date	May 2019
Distribution	Health Economy Wide
Has an Equality & Diversity Impact Assessment been completed?	In progress

Consultation

Version	Date	Reviewed by	Comments
V1.0	12/10/2015	Michael Robinson	
	11/11/2015	Quality & Safety Committee	
V1.1	9/12//2015	Quality & Safety Committee - Approved	
V 1.2	9/3/2016	Quality & Safety Committee – Approved	Minor alteration to policy to clarify that serious incidents need to be reported to the CCG and on the StEIS system within 2 working days (48 hours) of the incident being identified, not the incident occurring. No other amendments made.
V 1.3	10/5/2017	Quality & Safety Committee - Approved.	Minor alterations to terminology in relation to the safeguarding aspects of the policy. Reference to the National Guidance on Learning from Deaths NQB paper

In considering the application of this policy, procedure or function NHS Bolton CCG will ensure that staff or patients will not be discriminated against or treated differently on account of any subjective bias in relation to the six pillars of equality and diversity: race, disability, gender, age, sexual orientation, religion/belief.

This document can only be considered valid when viewed via the NHS Bolton CCG website or Department Policy Folder. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one online.

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1. INTRODUCTION

Within the Bolton health economy the performance management of Serious Incidents (SI) that occur within commissioned services is managed by NHS Bolton CCG under the direction of the Greater Manchester Health & Social Care Partnership, part of NHS England.

This policy outlines the responsibilities of NHS Bolton CCG in relation to the performance management of Serious Incidents and the expectations of its commissioned and contracted NHS services, and should be read in conjunction with the related documents listed below.

Related documents:

- HSG (94) 27 (revised June 2005)
- NHSE. (2015) Serious Incident Framework. Supporting learning to prevent recurrence.
- NHSE. (2015) Never Events 2015/2016
- Tissue Viability (Pressure Ulcer) Guidance for Reporting
- Bolton CCG Safeguarding policy
- Working Together to Safeguard Children (2013) HM Government
- Department of Health (2011) Defining Avoidable and Unavoidable Pressure Ulcers, DH, London.
- National Quality Board (2017) National Guidance on Learning from Deaths

NB: ***this policy <u>does not</u> replace the systems and processes associated with a Serious Case Review in the event of a death of a child, young person below the age of 18, an adult at risk or a Domestic Homicide Review (DHR), although it would be expected that these reviews are reported on StEIS.***

2. PURPOSE

The purpose of this policy is to outline NHS Bolton CCG's governance arrangements for the performance management of Serious Incidents and to ensure that patient safety and other reportable incidents are appropriately managed within our commissioned services in order to address the concerns of patients and promote public confidence. We will quality assure the robustness of serious incident investigations and hold providers to account for their responses and related action plans. When appropriate, information may also be shared with relevant regulatory and partner organisations.

This policy describes the requirements for the reporting and management of serious incidents within the Greater Manchester Health & Social Care Partnership of NHS England and is in line with *NHSE Serious Incident Framework. Supporting learning to prevent recurrence* (2015). Providers should also be familiar with the NPSA/NRLS document *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation* (January 2010).

The role of the Greater Manchester Health & Social Care Partnership and NHS Bolton CCG is to ensure incidents are investigated properly, action is taken to improve clinical quality and lessons are learned in order to minimise the risk of similar incidents occurring in the future. NHS Bolton CCG's Board will be appraised of incidents via the Quality and Safety Committee and the monthly serious incident update.

NHS Bolton CCG will utilise this policy to make explicit in provider contracts their expectations regarding serious incident reporting and their management, and the indicators and processes for performance management.

NHS Bolton CCG will triangulate data, for example patient safety intelligence, provider performance knowledge and lessons learned to inform a commissioning process that actively reduces the risk of harm to patients. As such, NHS Bolton CCG will quality assure the robustness of their providers' serious incident investigation reports and related action plans produced by their providers to seek assurance that the processes and outcomes of investigations include identification and implementation of improvements that will prevent recurrence of serious incidents.

3. DEFINITION OF A SERIOUS INCIDENT

In broad terms, serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver on-going healthcare.

The occurrence of a serious incident demonstrates weaknesses in a system or process that needs to be addressed to prevent future incidents leading to avoidable death or serious harm.

There is no definitive list of events or incidents that constitute a serious incident; instead a definition has been produced by NHS England which describes circumstances that must be declared as serious incidents.

Serious Incidents in the NHS include:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
    - Unexpected or avoidable death of one or more people. This includes;
        - suicide/self-inflicted death; and
        - homicide by a person in receipt of mental health care within the recent past;

- Unexpected or avoidable injury to one or more people that has resulted in serious harm;

- Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
  - the death of the service user; or
  - serious harm;

- Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
  - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
  - where abuse occurred during the provision of NHS-funded care.

This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident.

- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See Never Events Policy and Framework for the national definition and further information;

- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:

  - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues;

  - Property damage;

  - Security breach/concern;

  - Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;

  - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);

  - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or

  - Activation of Major Incident Plan (by provider, commissioner or relevant agency)

- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

Serious Incident Framework. Supporting learning to prevent recurrence (2015) NHSE

Adverse outcomes reasonably associated with routine NHS activity such as major surgical procedures, trauma interventions etc are excluded from the above list. This does not relate to Never Events which are specified in *Appendix 1.*

It may sometimes be appropriate to report a "near miss" as a serious incident as the actual outcome does not always reflect the degree of potential harm that could have occurred should a similar incident happen again. Deciding whether to report a "near miss" as a serious incident depends upon the likelihood of the incident occurring again and the potential for harm.

Whilst it is acknowledged that many deaths occur where there are no concerns in the care delivery, following the publication of the National Quality Board's paper – National Guidance on Learning from Deaths (NQB, 2017), acute, mental health and community NHS Trusts and Foundation Trusts are required to review, investigate and report all deaths, including those that are determined more likely than not to have resulted in problems in care. Although there is an expectation for providers to review all deaths, only ones that fulfil the definition of a serious incident will be required to proceed to a full investigation and be reported as a Serious Incident. For further clarification please refer to the National Guidance on Learning from Deaths (NQB 2017).

When it is not clear if an incident fulfils the criteria for a serious incident, providers and commissioners must engage in open and transparent discussion to agree on the most appropriate and proportionate response. Further advice may be sought from the Greater Manchester Health & Social Care partnership.

4. SAFEGUARDING AND SERIOUS INCIDENTS

All serious incidents must be reported in line with the serious incident reporting principles. Where a serious incident is identified in NHS funded care there must be immediate consideration relating to whether or not the incident should be escalated as a safeguarding concern.

The Local Authority, via the Local Safeguarding Children Board (LSCB) or Local Safeguarding Adult Board (LSAB) has a statutory duty to investigate certain types of safeguarding incidents / concerns. Where appropriate a Serious Case Review or a Safeguarding Adult Review may be commissioned. Healthcare providers must contribute towards safeguarding reviews and when an incident has occurred that meets the definition of a serious incident then this must also be reported as a Serious Incident.

In addition there may be occasions when a domestic homicide review is undertaken. The Domestic Violence, Crime and Victims Act 2004 sets out the statutory obligations that relate to provider and commissioner organisations. For more detailed information please refer to the NHS England Serious Incident Framework (2015)

See:

- *Appendix 2: Safeguarding Concerns: Definitions and Indicators NHS Serious Incident Management (2014)*
- *Appendix 3: Serious Incidents involving Children & Young Persons under the age of 18: statutory processes and/or*
- *Appendix 4: Serious Incidents involving Adults at Risk: statutory processes*

5. MANAGEMENT OF SERIOUS INCIDENTS

The needs of those affected should be a primary concern for those involved in the response to and the investigation of serious incidents. It is important that affected patients, staff, victims, perpetrators, patients/victims' families and carers are involved and supported throughout the investigation.

The NHSE framework for the management of Serious Incidents endorses the application of 7 key principles in the management of all serious incidents - *see Table 1*

Table 1

Key Principle	Supporting Information
Open and transparent	The needs of those affected should be the primary concern of those involved in the response to and the investigation of serious incidents. The principles of openness and honesty as outlined in the NHS Being Open guidance and the NHS contractual Duty of Candour must be applied in discussions with those involved. This includes staff and patients, victims and perpetrators, and their families and carers. Openness and transparency (as described in 'Being Open') means: • Acknowledging, sincerely apologising and explaining when things have gone wrong; • Conducting a thorough investigation into the incident, ensuring patients, their families and carers are satisfied that lessons learned will help prevent the incident recurring; • Providing support for those involved to cope with the physical and psychological consequences of what happened Saying sorry is not an admission of liability and is the right thing to do. Healthcare organisations should decide on the most appropriate members of staff to give both verbal and written apologies and information to those involved. This must be done as early as possible and then on an ongoing basis as appropriate. The NHS Litigation Authority provides advice on saying sorry available online from: http://www.nhsla.com/claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf

Preventative	Investigations of serious incidents are undertaken to ensure that weaknesses in a system and/or process are identified and analysed to understand what went wrong, how it went wrong and what can be done to prevent similar incidents occurring again. Investigations carried out under this Framework are conducted for the purposes of learning to prevent recurrence. They are not inquiries into how a person died (where applicable) as this is a matter for Coroners. Neither are they conducted to hold any individual or organisation to account. Other processes exist for that purpose including: criminal or civil proceedings, disciplinary procedures, employment law and systems of service and professional regulation, such as the Care Quality Commission and the Nursing and Midwifery Council, the Health and Care Professions Council, and the General Medical Council. In circumstances where the actions of other agencies are required then those agencies must be appropriately informed and relevant protocols, outside the scope of this Framework, must be followed. Organisations must advocate justifiable accountability and a zero tolerance for inappropriate blame. The Incident Decision Tree should be used to promote fair and consistent staff treatment within and between healthcare organisations.
Objective	Those involved in the investigation process must not be involved in the direct care of those patients affected nor should they work directly with those involved in the delivery of that care. Those working within the same team may have a shared perception of appropriate/safe care that is influenced by the culture and environment in which they work. As a result, they may fail to challenge the 'status quo' which is critical for identifying system weaknesses and opportunities for learning. Demonstrating that an investigation will be undertaken objectively will also help to provide those affected (including families/carers) with confidence that the findings of the investigation will be robust, meaningful and fairly presented. To fulfil the requirements for an independent investigation, the investigation must be both commissioned and undertaken independently of the care that the investigation is considering.
Timely and responsive	Serious incidents must be reported via the StEIS system without delay and no longer than 2 working days after the incident is identified. Every case is unique, including: the people/organisations that need to be involved, how they should be informed, the requirements/needs to support/facilitate their involvement and the actions that are required in the immediate, intermediate and long term management of the case. Those managing serious incidents must be able to recognise and respond appropriately to the needs of each individual case.
Systems based	The investigation must be conducted using a recognised systems-based investigation methodology that identifies: • The problems (the what?); • The contributory factors that led to the problems (the how?) taking into

	account the environmental and human factors; and • The fundamental issues/root cause (the why?) that need to be addressed. Within the NHS, the recognised approach is commonly termed Root Cause Analysis (RCA) investigation. The investigation must be undertaken by those with appropriate skills, training and capacity.
Proportionate	The scale and scope of the investigation should be proportionate to the incident to ensure resources are effectively used. Incidents which indicate the most significant need for learning to prevent serious harm should be prioritised. Determining incidents which require a full investigation is an important part of the process and ensures that organisations are focusing resources in an appropriate way. Typically, serious incidents require a comprehensive investigation, but the scale and scope (and required resources) should be considered on a case by-case-basis. Some incidents may be managed by an individual (with support from others as required) whereas others will require a team effort and this may include members from various organisations and/or experts in certain fields. In many cases an internally managed investigation can fulfil the requirements for an effective investigation. In some circumstances (e.g. very complex or catastrophic incidents spanning multiple organisations and/or where the integrity of the investigation would be challenged / undermined if managed internally) an independent investigation may be required. In exceptional circumstances a regional or centrally-led response may be required.
Collaborative	Serious incidents often involve several organisations. Organisations must work in partnership to ensure incidents are effectively managed. There must be clear arrangements in place relating to the roles and responsibilities of those involved. Wherever possible partners should work collaboratively to avoid duplication and confusion. There should be a shared understanding of how the incident will be managed and investigated and this should be described in jointly agreed policies/procedures for multi-agency working.

Each NHS organisation, or organisations providing NHS funded care, should have an authorised named person who is responsible for deciding when an incident should trigger the serious incident procedure – in Bolton CCG this is the Assistant Director of Integrated Governance and Policy. Chief Executives or Managers in provider organisations must ensure that local procedures are in place so that all staff know how to identify and report a serious incident as outlined in this document. Arrangements must be in place to ensure responsibilities remain clear throughout any organisational changes.

The named person should involve their Communications Lead in the assessment of incidents for potential media impact. The NHS provider organisation or CCG should prepare a press release to respond to media enquiries where media interest is anticipated. Where required the Lancashire & Greater Manchester Area Team

Communications team is available for advice and will offer support in media handling for high profile incidents.

The national guidance contained in HSG (94) 27 (revised June 2005) should be followed for mental health incidents.

When a child or young person under the age of 18 has died or is seriously injured and non-accidental injury, abuse or neglect is suspected then all local child protection procedures **must** be followed and the Designated Nurse for Bolton Local Safeguarding Children Team **must** be informed immediately the incident is identified. When cases fall under the authority of the Local Safeguarding Children Board (LSCB), it will be the responsibility of the LSCB to determine the strategy for managing the incident.

More information regarding provider responsibilities in managing serious incidents can be found in the NHS England Serious Incident Framework (2015).

6. REPORTING SERIOUS INCIDENTS

Serious incident management is a critical component of corporate and clinical governance. NHS organisations, provider and commissioning, are responsible for identifying serious incidents and taking effective action in each instance. It is expected that clear local operational procedures are in place at each NHS organisation, or organisations providing NHS funded care for identifying, reporting, investigating, learning and sharing the outcome of serious incidents.

Provider organisations should treat an incident as a serious incident even if there is a possibility that it is not. If it is identified that the incident is not a serious incident, then reporting logs / entries on StEIS can be amended. If in doubt, organisations are advised to contact the Integrated Governance Directorate at NHS Bolton CCG (please see page 18 of this policy for contact details).

This policy must not interfere with existing lines of accountability nor replace the duty to inform the Police and / or other organisations or agencies as required. Please refer to the joint publication 'Memorandum of Understanding – Investigating Patient Safety Incidents (2013) issued by the Department of Health, the Health and Safety Executive and Association of Chief Police Officers and 'Guidance for the NHS in support of the Memorandum of Understanding' (2006) for further guidance. For serious incidents involving children and young persons under the age of 18, refer to Bolton Local Safeguarding Children Board Procedures, and the statutory guidance 'Working Together to Safeguard Children' (2013).

NHS provider organisations are required to report serious incidents via the Strategic Executive Information System (StEIS) as well as notifying NHS Bolton CCG. For non-NHS organisations, the incident will be reported on the StEIS system by the CCG upon receipt of the appropriate information into the CCG.

As soon as a serious incident is identified, a senior manager or clinician should be identified by the health care provider organisations chief executive or equivalent, or the officer with relevant delegated authority, to undertake the following:

- Arrange for any immediate actions required to ensure the safety of the patient(s), other service users and staff.
- Obtain all relevant physical, scientific and documentary evidence, and make sure it is secure and preserved. Initial actions of local managers in the collection and retention of information are important for the overall integrity of the investigation process.
- Identify witnesses, including staff, and other service users, to ensure they receive effective support.
- Identify an appropriate specialist / clinician to conduct an initial incident review (72 hour review) to confirm whether a serious incident has occurred and the level of investigation required.
- Ensure commissioners and other relevant parties (for example, police, Safeguarding Professionals, the Information Commissioners) are informed at the earliest opportunity and within 2 working days of a serious incident being identified. During Out of Hours contact the CCG Director on Call (*see Appendix 5*)
- Agree who will make the initial contact with those involved, or their family/carer(s). Where an individual has been harmed by the actions of a patient, particular thought should be given as to who is the best person to contact the victim(s), their family, carer(s) and / or the perpetrators family. Those involved should have a single point of contact within the provider organisation.
- Ensure the serious incident is logged on the serious incident management system StEIS (Strategic Executive Information System, NHS England's web-based serious incident management system) or successor system within a maximum of 2 working days of the incident being identified. Care should be taken to ensure that ***all sections are completed and as much detail as possible is included in the initial StEIS report***. Information should be provided in a manner which maintains the anonymity of patients and staff involved in line with Caldicott principles. In the event of the StEIS reporting system being unavailable, contact with NHS Bolton CCG should be made via telephone (see *Appendix 5 for a flow chart of the process),* and the incident entered onto StEIS once the system is back online. For non-NHS organisations the CCG will report the incident on StEIS.
- Having completed the initial StEIS report, an initial review (72 hour report - see Appendix 6 for an example template) should be undertaken and submitted by the provider to the commissioner within 72 hours of the incident being identified. The aim of the review is:
    - identify and provide assurance that any necessary immediate action to ensure the safety of staff, patients and the public is in place;

- assess the incident in more detail to determine if it may or does meet the criteria for a serious incident; and
- propose the appropriate level of investigation.

Information contained within the initial review should also be uploaded into StEIS by the provider for completeness. The initial review should also be made available to the patient, their family or carer(s) as part of an appropriately and sensitively managed process of disclosure according to the principles in *Being Open* and the statutory Duty of Candour as soon as possible.

The reporting organisation must then take appropriate measures to investigate the Serious Incident. The onus of responsibility lies with the reporting organisation to inform NHS Bolton CCG of any problems or delays.

In addition to reporting serious incidents on StEIS, provider and commissioning organisations need to ensure that other regulatory, statutory, advisory and professional bodies are also informed dependent upon the nature and circumstances of the incident. *Appendix 7* is a list of other organisations which may need to be considered.

Pressure Ulcers

Category 3 and 4 pressure ulcers are considered serious incidents and as such subject to the same reporting process outlined in this policy, with the exception that initial reviews (72 hour reports) will not be expected, however completed reports will be expected within 30 working days following identification of a pressure ulcer, as opposed to the 60 working days allowed for all other serious incidents.

Following review, all pressure ulcers will be classified as either:

- **Avoidable** – where the person receiving care developed a pressure ulcer and the provider of care did not do one or more of the following; evaluate the person's clinical condition and pressure ulcer risk factors; plan and implement interventions that are consistent with the person's needs and goals, and recognise standards of practice; monitor and evaluate the impact of interventions; or revise the intervention as appropriate.
- **Unavoidable** – where the person receiving care developed a pressure ulcer even though the provider of care had evaluated the person's clinical condition and pressure ulcer risk factors; planned and implemented interventions that are consistent with the person's goals; and recognised standards of practice; monitored and evaluated the impact of interventions; and revised the approaches as appropriate; or the individual person refused to adhere to prevention strategies in spite of education of the consequence of non-adherence.

DH (2011)

N.B. A RCA will be used to establish whether the pressure ulcer was avoidable or unavoidable. Commissioners, regulators or others could request to see evidence demonstrating the actions outlined in the "avoidable" definition are demonstrated. Commissioners may also seek assurance of compliance with action plans to evidence learning from incidents.

Tissue Viability (Pressure Ulcers) Guidance for Reporting and Safeguarding (2012)

Serious Incidents external to the provider organisation.

In certain circumstances, serious incidents may be identified by providers who had no previous involvement in the incident or by other parties. For example a patient may be admitted to a secondary care setting with a grade 4 pressure ulcer due to omissions in the care provided within a community setting. In such circumstances, the provider identifying the incident should raise their concerns with the relevant provider (with support from their commissioner where required) to ensure the incident is reported, investigated and learned from by the provider where the incident occurred to prevent reoccurrence. The provider that identifies the incident should record the incident via their local risk management system according to local policy and share this information with NHS Bolton CCG. However, where the provider has no involvement in the incident or investigation, providers are not expected to report via the serious incident management system.

Duty of Candour

The statutory Duty of Candour, introduced following the Francis Report (2013), applies when a patient has experienced moderate or severe harm, or prolonged psychological harm. The Duty of Candour places a requirement on all providers to be open with patients when things go wrong. The principles of honesty and openness as out lined in the NHS Being Open (2009) guidance must be applied in discussions with victims, perpetrators, families and carers when any harm occurs.

Contractual requirements in relation to the Duty of Candour are outlined in the NHS Standard Contract and can be summarised as:

- The patient or their family/carer must be informed that a suspected or actual patient safety incident has occurred within at most 10 working days of the incident being reported to local systems, and sooner where possible.
- The initial notification must be verbal (face to face where possible) unless the patient cannot be contacted in person or declines notification.
- It may initially be unclear whether a patient safety incident has occurred, or what degree of harm was caused. This is not a reason to avoid disclosure. Patients or their carers/families must be told if there is a suspected patient safety incident that might involve moderate or severe harm or death within 10 working days of the incident being reported.

- An apology must be provided - a sincere expression of sorrow or regret for the harm caused must be provided verbally and in writing.

NHS Standard Contract 2014/2015 – NHS England.

Fundamentally this means:

- acknowledging, sincerely apologising and explaining when things have gone wrong;
- conducting a thorough investigation into the incident, ensuring patients, their families and carers are satisfied that lessons learned will help prevent the incident recurring;
- providing support for those involved to cope with the physical and psychological consequences of what happened.

NHS England's Role.

NHS England has a direct commissioning role as well as a role in supporting the commissioning system. NHS England maintains oversight and surveillance of the serious incident management system and assures that CCGs have systems in place to appropriately manage serious incidents.

7. SERIOUS INCIDENT INVESTIGATIONS

Serious incident investigations are conducted to ensure that the root cause of the incident is identified and to ensure that lessons can be learned and applied to prevent similar harm from occurring again. The provider declaring an incident must ensure that an investigation team is established with appropriate knowledge, skills and experience to lead the investigation.

All serious incidents reported to NHS Bolton CCG should be subject to a comprehensive Root Cause Analysis by the provider organisation which identifies the root cause of the incident. NHS England's Serious Incident Framework (2015) recommends the NHS Patient Safety's RCA investigation template to be used to aid the investigation of all serious incidents. More information on the NHS Patient Safety RCA tools can be accessed here:

http://www.nrls.npsa.nhs.uk/resources/?entryid45=59847

Upon completion of the review a report should be completed and submitted to NHS Bolton CCG within 60 days. Reports should not contain confidential personal information unless consent has been obtained or there is an overriding public interest. *Appendix 8* is an example of the information required.

Agreeing the level of investigation

The nature, severity and complexity of serious incidents varies on a case by case basis and therefore the level of response should be dependent on and proportionate to the circumstances of each specific incident. The appropriate level of investigation should be proposed by the provider as informed by the initial review (72 hour review). The investigations team and where applicable other stakeholders will use the information within the initial review to inform the level of investigation. It is however acknowledged that the level of investigation may need to be reviewed and changed as new information or evidence emerges as part of the investigation process.

Within the NHS there are three recognised levels of investigation which apply root cause analysis (RCA) methodology – see *Appendix 9.*

8. ESCALATION AND INFORMATION SHARING

Where a serious incident may cause widespread concern to the public or healthcare system, NHS Bolton CCG may need to share information throughout the system. This is a judgement call depending on the nature of the incident, although the likelihood of national media attention will be a significant factor in deciding to share information. Where incidents are needed to be shared, information about the serious incident will be shared directly with the appropriate Lead at the Area Team, which will subsequently and where necessary be shared with the Regional Team. The Regional Team can then make an informed decision about whether or not to inform directorate leads within National Support Centre of NHS England.

9. NHS BOLTON CCG's ROLE AND RESPONSIBILITIES

Commissioning Responsibilities

NHS Bolton CCG is the Lead Commissioner for:

- Bolton NHS Foundation Trust
- BMI The Beaumont

NHS Bolton CCG is responsible for holding their provider organisations to account to serious incidents that occur in care commissioned by the CCG. On receipt of a notification of a serious incident, NHS Bolton CCG will seek further information pertaining to the incident and seek assurance that initial measures have been put in place to manage the incident and to prevent any further concerns.

NHS Bolton CCG will oversee investigations and review reports produced by the provider organisation and seek to challenge any areas as appropriate to gain further assurance. In addition NHS Bolton CCG will expect providers to report incidents in a timely manner, expect incidents to be appropriately and effectively investigated – showing evidence of wider triangulation and for robust action plans to be produced and implemented to minimise the risk of similar occurrences from happening in the future. Where this does not occur, NHS Bolton CCG reserves the right to take

regulatory / contractual action or performance manage the organisation as appropriate.

NHS Bolton CCG will also investigate and respond to any internal serious incidents, sharing information with any external regulatory bodies as required.

Executive Responsibilities

The Chief Officer has overarching responsibility for the management of the StEIS system and has delegated responsibility for the performance management of serious incidents to the Associate Director of Integrated Governance and Policy.

A core team of individuals have been established as initial contacts during office hours for the notification of a SI and can be contacted as below;

Associate Director of Integrated Governance and Policy Governance
Tel: 01204 462398

Risk and Complaints Manager
Tel: 01204 462023

Lead Nurse for Quality & Safety
Tel: 01204 462132

Directorate PA
Tel: 01204 462032

For SIs involving children, young persons under the age of 18 and adults at risk, which may fall under local Safeguarding Board Procedures, contact the Bolton CCG's Safeguarding Team.

Associate Director for Safeguarding
Tel: 01204 463389

Safeguarding Adult Lead
Tel: 01204 462204

Admin -Tel: 01204 463390

10. QUALITY ASSURANCE OF THE REVIEW PROCESS

Notification & Initial Review

Following notification of an SI and upon receipt of the initial review (72 hour report), NHS Bolton CCG will liaise with the reporting organisation to confirm the appropriate level of investigation and the reports required. If the provider organisation faces unavoidable delays in its investigation of an incident e.g. police investigation, the

provider must formally contact the CCG and request an extension, detailing the reason for the delay. If an extension is approved by the CCG a new reporting timescale will be negotiated on a case by case basis as required. The reason for the delay and the agreed extension must be uploaded into StEIS by the provider organisation.

NHS Bolton CCG will accept draft investigation reports during the provider's consultation phase, with the final report being produced and shared with the CCG within the 60 day timescale unless an extension has been granted. All reports received will be reviewed by NHS Bolton CCG's Serious Incident Review Group.

NHS Bolton CCG's Serious Incident Review Group

NHS Bolton CCG has established a Serious Incident Review Group, consisting of key members from within the CCG, who will meet monthly to discuss any incidents and also to review any post investigation reports. Relevant expertise, knowledge and experience within the organisation will be utilised dependent upon the type of incident being reported. NHS Bolton CCG will ensure that the group has sufficient knowledge and experience of the subject matter to enable an objective assessment of the adequacy of the scope of the review, the subsequent review report and any recommendations made and facilitate incident closure on receipt of assurance that recommendations have been implemented.

The Terms of reference for NHS Bolton CCG's Serious Incident Group can be found in *Appendix 10.*

11. CRITERIA FOR ASSESSING THE 60 WORKING DAY INVESTIGATION REPORTS

The following criteria are used when appraising the Internal Investigation reports:

- Has the report examined the workings of the risk management (including incident reporting and the related incident management systems) and clinical governance arrangements at the provider organisation? Has the report assessed whether these systems are fit for purpose;
- Is a "Duty of Candour" evidenced within the report;
- Is there evidence of wider triangulation – taking into account other complaints, incidents, staffing and sickness levels, levels of training compliance etc.;
- Have the authors of the report interviewed / sought information / statements from the key workers / managers involved in the case (please note care should be taken to ensure staff do not feel intimidated if interviewed);
- Has the report adequately addressed all of the investigations terms of reference;
- Is the report internally consistent i.e. do the main conclusions follow from the body of the report;

- Are the main recommendations directed at the appropriate sector of the health community – i.e. primary care, secondary care, local authority;
- Is there a robust action plan in place to meet the report's recommendations;
- Do the recommendations address the root causes of the incident.

Appendix 11 is an example of a StEIS Investigation Evaluation template which may be used to evaluate the report.

Any further action will be agreed with the Provider organisation on a case by case basis as required. Once completed the incident may be recommended for closure by NHS Bolton CCG Serious Incident Review Group.

12. CRITERIA FOR INCIDENT CLOSURE

Closure of incidents reported on StEIS will be considered after submission of the internal investigation report and action plan (if appropriate) to NHS Bolton CCG and following review by NHS Bolton CCG's Serious Incident Review Group. NHS Bolton CCG's Serious Incident Review Group meets on a monthly basis so any reports received into the CCG will be reviewed at the next diarised meeting. Lessons learned and any actions must be uploaded into StEIS by the provider upon completion of the review, prior to the incident being closed by the CCG. However if there are significant recommendations closure may be delayed until these recommendations have been addressed or the associated action plan has been implemented.

There may be occasions where the NHS Bolton CCG requests a separate commissioning organisation to undertake an additional quality assurance review, if there is considered to be a conflict of interest.

Closure of a serious incident will depend on the severity of the incident and will be decided on a case by case basis. NHS Bolton CCG will confirm via email the closure of a serious incident with the provider organisation. In general, NHS Bolton CCG will look to ensure;

- There is evidence of adherence to the duty of candour
- A robust root, cause, analysis has been conducted with evidence of wider triangulation of relevant information (including recent complaints, similar incidents, staffing levels etc) and that the report has fulfilled the terms of reference
- An action plan has been agreed, which addresses the recommendations and has been ratified by the NHS provider organisations board.
- There is evidence to suggest that significant recommendations have been implemented, that learning has occurred and where appropriate practice/ processes changed.
- That the learning from the incident has been uploaded into StEIS.

*Figure 1 – an overview of the responsibilities and relationships between **NHS** Provider Organisations / NHS Bolton CCG and the Lancashire & Greater Manchester Area Team in relation to the management of Serious Incidents*

Figure 2 - *an overview of the responsibilities and relationships between **non NHS** Provider Organisations / NHS Bolton CCG and the Lancashire & Greater Manchester Area Team in relation to the management of Serious Incidents*

Figure 3 - *an overview of the responsibilities and relationships between **Nursing Home Providers** / NHS Bolton CCG and the Lancashire & Greater Manchester Area Team in relation to the management of Category 3 and Category 4 Pressure Ulcer Serious Incidents.*

13. DATA COLLECTION AND ANALYSIS

The Associate Director of Integrated Governance and Policy will have responsibility for maintaining accurate electronic records through the StEIS database.

The StEIS database will assist the Associate Director of Integrated Governance and Policy in providing relevant and timely information as required by NHS Bolton CCG's Quality and Safety Committee and Serious Incident Review Group.

The Associate Director of Integrated Governance and Policy will provide reports to the Quality & Safety Committee according to the meeting schedule, and the Trust Board as requested.

14. LEARNING FROM EXPERIENCE

NHS Bolton CCG is committed to assuring the quality and safety in commissioned services.

A systematic approach to the analysis of patient safety intelligence will be developed which supports the commissioning of safe services which meet the clinical quality requirements.

Through a robust governance process, provider organisations will be required to demonstrate to their Board that any actions or learning from serious incidents has been fully implemented and embedded and internal systems are in place to provide any necessary on-going monitoring or audit.

NHS Bolton CCG will make explicit reference within contracts as to its expectation regarding serious incident reporting and management. The clinical quality reviews with provider services will enable local discussions on areas of concern or provide an opportunity to facilitate the sharing of good practice.

It is acknowledged that providers will invoke their own arrangements for instigating remedial action following a Serious Incident.

This review does not replace any internal mechanisms for review a provider organisation may have. The spirit of the review must be one of openness and learning – it is not about the allocation of blame. In the interest of wider participation and the sharing of lessons, NHS Bolton CCG will share and disseminate learning as appropriate with all involved. This may be through a variety of methods:

- NHS Bolton CCG's Learning and Development Newsletter
- NHS Bolton CCG's Quality & Safety Committee
- NHS Bolton CCG's Board
- Lancashire & Greater Manchester Area Team Quality & Safety Collaborative

15. MONITORING REVIEW AND REVISION ARRANGEMENTS

This policy will be reviewed by NHS Bolton CCG on two yearly basis.

FIGURE 1 - Overview of Responsibilities and Relationships NHS PROVIDER / NHS BOLTON CCG / L&GMAT in relation to SI's

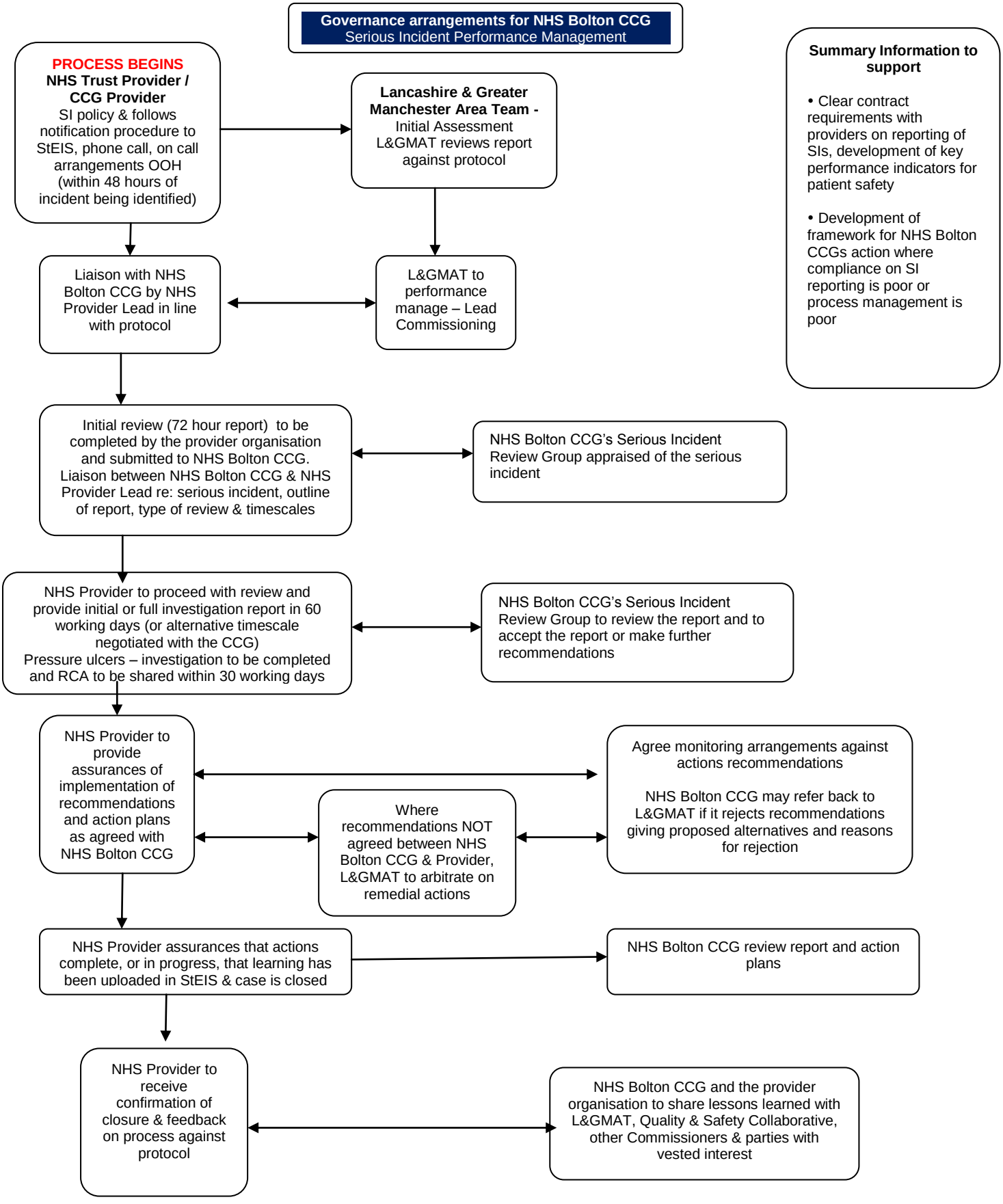


FIGURE 2 - Overview of Responsibilities and Relationships Non- NHS PROVIDER / NHS BOLTON CCG / L&GMAT in relation to SI's

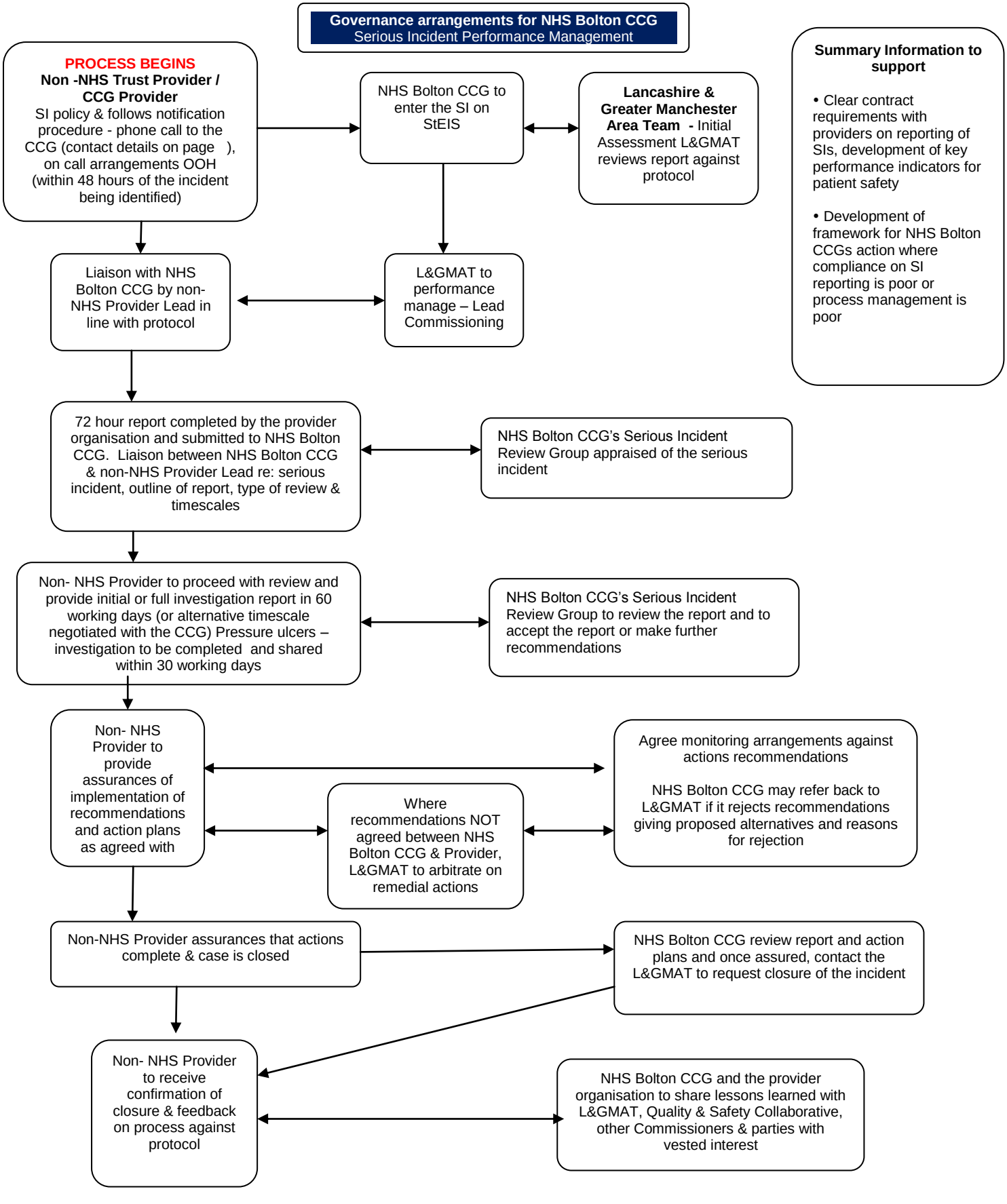
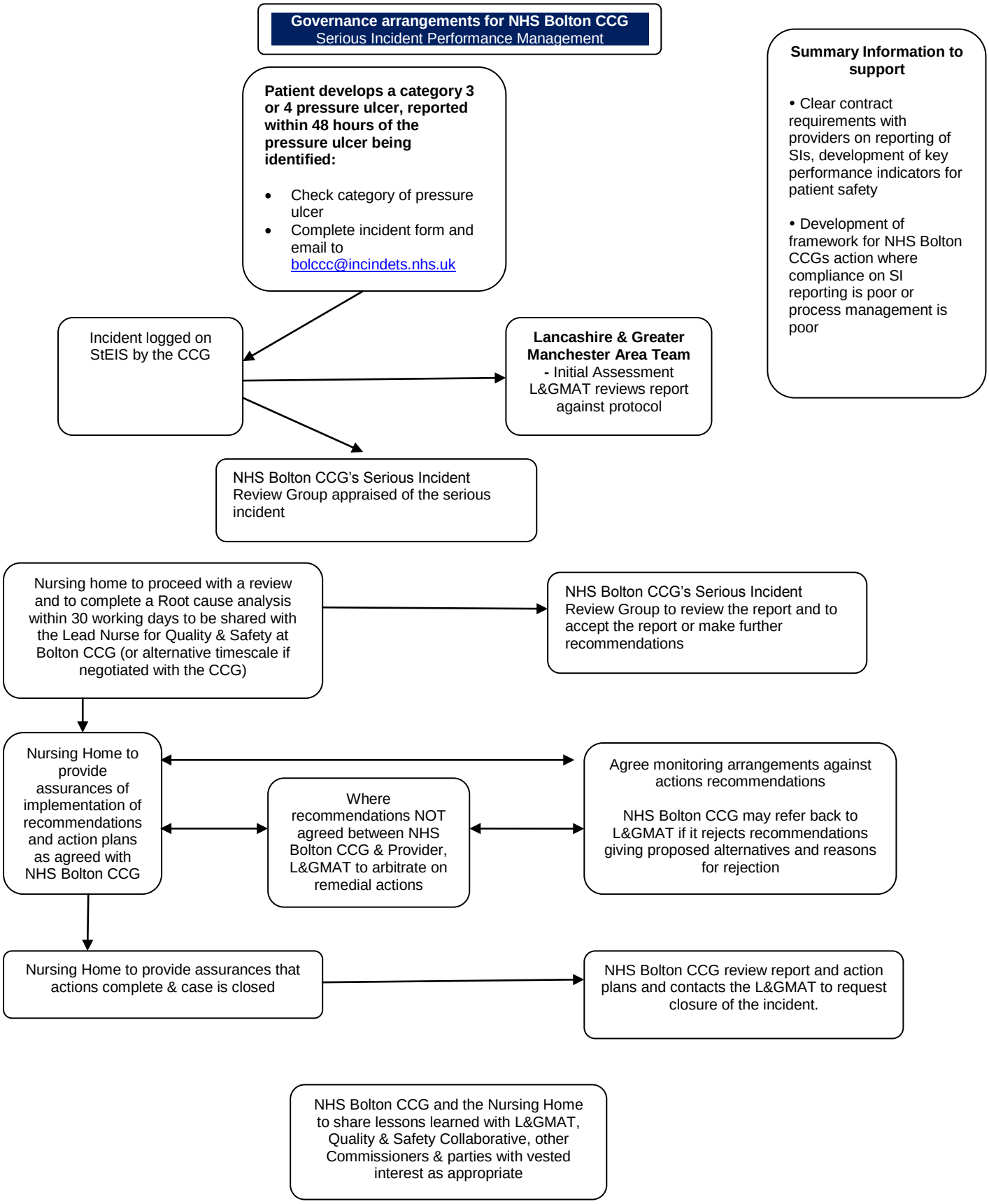


FIGURE 3 - Overview of Responsibilities and Relationships Nursing Home Providers / NHS BOLTON CCG / L&GMAT in relation to Category 3 &4 pressure ulcer SI's



Appendix 1

Never Events list
NHSE Patient Safety 2015/2016

SURGICAL

1. Wrong site surgery

2. Wrong implant / prosthesis

3. Retained foreign object post procedure

MEDICATION

4. Mis-selection of a strong potassium containing solution

5. Wrong route administration of medication

6. Overdose of insulin due to abbreviations or incorrect device

7. Overdose of methotrexate for non-cancer patient

8. Mis-selection of high strength midazolam during conscious sedation

MENTAL HEALTH

9. Failure to install functional collapsible shower or curtain rails

GENERAL HEALTH

10. Falls from poorly restricted windows

11. Chest or neck entrapment in bedrails

12. Transfusion or transplantation of ABO-incompatible blood components or organs

13. Misplaced naso- or oro-gastric tubes

14. Scalding of patients

For more information see the full document:
http://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/03/never-evnts-list-15-162.pdf

Appendix 2

Safeguarding Concerns: Definitions and Indicators
NHS Serious Incident Management (2014)

Abuse and Neglect in relation to Adult Safeguarding Concerns in line with the Care and Support Statutory Guidance underpinned by the Care Act 2014	
Physical abuse	Hitting, slapping, pushing, misuse of medication, restraint or inappropriate physical sanctions
Domestic violence	including psychological, physical, sexual, financial, emotional abuse; so called 'honour' based violence.
Sexual abuse	Including rape, indecent exposure, sexual harassment, inappropriate looking or touching, sexual teasing or innuendo, sexual photography, subjection to pornography or witnessing sexual acts, indecent exposure and sexual assault or sexual acts to which the adult has not consented or was pressured into consenting.
Psychological abuse	including emotional abuse, threats of harm or abandonment, deprivation of contact, humiliation, blaming, controlling, intimidation, coercion, harassment, verbal abuse, cyber bullying, isolation or unreasonable and unjustified withdrawal of services or supportive
Exploitation	Either opportunistically or premeditated, unfairly manipulating someone for profit or personal gain
Financial or material abuse	including theft, fraud, internet scamming, coercion in relation to an adult's financial affairs or arrangements, including in connection with wills, property, inheritance or financial transactions, or the misuse or misappropriation of property, possessions or benefits
Modern slavery	Encompasses slavery, human trafficking, forced labour and domestic servitude. Traffickers and slave masters use whatever means they have at their disposal to coerce, deceive and force individuals into a life of abuse, servitude and inhumane treatment.
Discriminatory abuse	including forms of harassment, slurs or similar treatment; because of race, gender and gender identity, age, disability, sexual orientation or religion.
Organisational abuse	including neglect and poor care practice within an institution or specific care setting such as a hospital or care home, for example, or in relation to care provided in one's own home. This may range from one off incidents to on-going ill-treatment. It can be through neglect or poor professional practice as a result of the structure, policies, processes and practices within an organisation.
Neglect and acts of omission	– including ignoring medical, emotional or physical care needs, failure to provide access to appropriate health, care and support or educational services, the withholding of the necessities of life, such as medication, adequate nutrition and heating.
Self-neglect	this covers a wide range of behaviour neglecting to care for one's personal hygiene, health or surroundings and includes behaviour such as hoarding.

Abuse and Neglect in relation to Children and Young People (who have not reached their 18th Birthday)	
Abuse	A form of maltreatment of a child. Somebody may abuse or neglect a child by inflicting harm, or by failing to act to prevent harm. Children may be abused in a family or in an institutional or community setting by those known to them or, more rarely, by others (e.g. via the internet). They may be abused by an adult or adults, or another child or children.
Physical abuse	A form of abuse which may involve hitting, shaking, throwing, poisoning, burning or scalding, drowning, suffocating or otherwise causing physical harm to a child. Physical harm may also be caused when a parent or carer fabricates the symptoms of, or deliberately induces, illness in a child.
Emotional abuse	The persistent emotional maltreatment of a child such as to cause severe and persistent adverse effects on the child's emotional development. It may involve conveying to a child that they are worthless or unloved, inadequate, or valued only insofar as they meet the needs of another person. It may include not giving the child opportunities to express their views, deliberately silencing them or 'making fun' of what they say or how they communicate. It may feature age or developmentally inappropriate expectations being imposed on children. These may include interactions that are beyond a child's developmental capability, as well as overprotection and limitation of exploration and learning, or preventing the child participating in normal social interaction. It may involve seeing or hearing the ill-treatment of another. It may involve serious bullying (including cyber bullying), causing children frequently to feel frightened or in danger, or the exploitation or corruption of children. Some level of emotional abuse is involved in all types of maltreatment of a child, though it may occur alone.
Sexual abuse	Involves forcing or enticing a child or young person to take part in sexual activities, not necessarily involving a high level of violence, whether or not the child is aware of what is happening. The activities may involve physical contact, including assault by penetration (for example, rape or oral sex) or non-penetrative acts such as masturbation, kissing, rubbing and touching outside of clothing. They may also include non-contact activities, such as involving children in looking at, or in the production of, sexual images, watching sexual activities, encouraging children to behave in sexually inappropriate ways, or grooming a child in preparation for abuse (including via the internet). Sexual abuse is not solely perpetrated by adult males. Women can also commit acts of sexual abuse, as can other children. Also includes – Child Sexual Exploitation:

	Child sexual exploitation is a form of child sexual abuse. It occurs where an individual or group takes advantage of an imbalance of power to coerce, manipulate or deceive a child or young person under the age of 18 into sexual activity (a) in exchange for something the victim needs or wants, and/or (b) for the financial advantage or increased status of the perpetrator or facilitator. The victim may have been sexually exploited even if the sexual activity appears consensual. Child sexual exploitation does not always involve physical contact; it can also occur through the use of technology.
Neglect	The persistent failure to meet a child's basic physical and/or psychological needs, likely to result in the serious impairment of the child's health or development. Neglect may occur during pregnancy as a result of maternal substance abuse. Once a child is born, neglect may involve a parent or carer failing to: - provide adequate food, clothing and shelter (including exclusion from home or abandonment); - protect a child from physical and emotional harm or danger; - ensure adequate supervision (including the use of inadequate care-givers); or - ensure access to appropriate medical care or treatment. It may also include neglect of, or unresponsiveness to, a child's basic emotional needs.

Appendix 3

Serious Incidents involving Children & Young Persons under the age of 18 : Statutory Processes

The following reviews/referrals need to be reported on StEIS.

Child Death Review Processes

- The statutory requirement for Local Safeguarding Children Boards (LSCBs) to undertake the functions relating to child deaths is set out in Working Together to Safeguard Children (HM Government, 2015)

- Further local information can be found on Bolton Safeguarding Children Board website

- The different types of review include:
    - Serious Case Review (see Working Together to Safeguard Children: Learning and Improvement Framework, chapter 4): for every case where abuse or neglect is known or suspected and either:
        - a child dies; or
        - a child is seriously harmed **and** there are concerns about how organisations or professionals worked together to safeguard the child;
    - review of a child protection incident which falls below the threshold for an SCR;
    - child death review (see Working Together to Safeguard Children: Learning and Improvement Framework, chapter 5): a review of all child deaths up to the age of 18; and
    - review or audit of practice in one or more agencies.

Managing Allegations Made Against Staff in Respect of Children and Young People

Working Together to Safeguard Children 2015 (Chapter 2) places an explicit duty on agencies to have clear policies in line with those from the Local Safeguarding Children Boards (LSCBs) for dealing with allegations against people who work with children. Please refer to Bolton CCG's Safeguarding Policy section 2.

Such procedures should be applied when there is an allegation or concern that any person employed (or service commissioned) by the CCG who works with children, in connection with his/her employment or voluntary activity, has:

- behaved in a way that has harmed a child, or may have harmed a child;

- possibly committed a criminal offence against or related to a child; or

- behaved towards a child or children in a way that indicates they may pose a risk of harm to children

If concerns arise about a person's behaviour in regard to his/her own children, the police and/or social care need to consider informing the person's employer in order to assess whether there may be implications for children with whom the person has contact at work.

For any such incident the Designated Nurse, as Senior Nominated Officer, must be notified immediately.

To contact the Safeguarding Team, Bolton CCG:

Name	Title	Contact
Pam Jones	Associate Director Safeguarding /Designated Nurse Safeguarding Children	pam.jones8@nhs.net 01204 463389 07920 478715
Kaleel Khan	Specialist Safeguarding Adult's Practitioner	kaleelkhan@nhs.net 01204 462204
Helen Bolton	Specialist Safeguarding Children's Practitioner	Helen.bolton2@nhs.net 01204 463390
Charlotte McManus	Safeguarding Team Administrative Support/PA to Designated Nurse	charlottemcmanus@nhs.net 01204 463390

Appendix 4

Serious Incidents involving Adults at Risk: Statutory Processes

The following reviews/referrals need to be reported on StEIS.

Domestic Homicide Reviews

Domestic Homicide Reviews (DHRs) were established on a statutory basis under section 9 of the Domestic Violence, Crime and Victims Act (2004). This provision came into force on 13th April 2011.

Guidance can be found within "Multi-agency Statutory Guidance for the Conduct of Domestic Homicide Reviews" (Revised – applicable to all notifications made from and including 1 August 2013).

They are a review of the circumstances in which the death of a person aged 16 or over has, or appears to have, resulted from violence, abuse or neglect by:

- a person to whom the victim was related or with whom they were or had been in an intimate personal relationship, or
- a member of the same household as the victim

Safeguarding Adult Reviews

The Care Act (2014) says that Local Safeguarding Adults Boards must arrange a Safeguarding Adults Review in certain circumstance, including if an adult with care and support needs dies as a result of abuse or neglect and there is concern about how one of the members of the Safeguarding Adults Board acted.

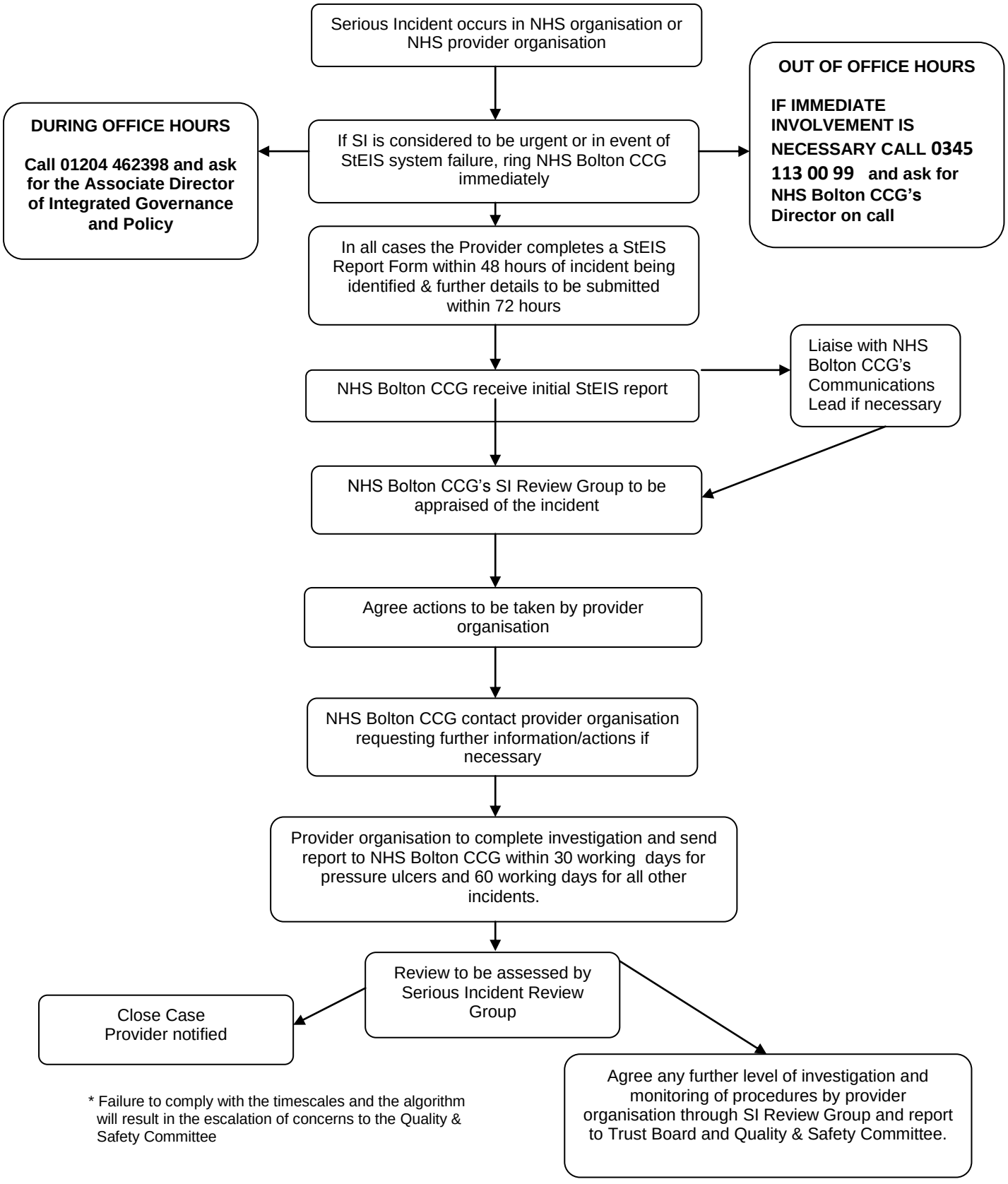
At present work is being undertaken locally to meet the requirements of the Care Act by the subgroups of the Bolton Safeguarding Adults Board. Guidance will be added as this becomes available.

To contact the Safeguarding Team, Bolton CCG:

Name	Title	Contact
Pam Jones	Associate Director Safeguarding /Designated Nurse Safeguarding Children	pam.jones8@nhs.net 01204 463389 07920 478715
Kaleel Khan	Specialist Safeguarding Adult's Practitioner	kaleelkhan@nhs.net 01204 462204
Helen Bolton	Specialist Safeguarding Children's Practitioner	Helen.bolton2@nhs.net 01204 463390
Charlotte McManus	Safeguarding Team Administrative Support/PA to Designated Nurse	charlottemcmanus@nhs.net 01204 463390

Appendix 5

Flow Chart for Reporting Serious Incidents to NHS Bolton CCG



* Failure to comply with the timescales and the algorithm will result in the escalation of concerns to the Quality & Safety Committee

Appendix 6

Example of an initial review reporting template (72 hour report)

StEIS Number			
CCG Area			
Reporting organisation			
Reporter Details			
Reporter name		**Reporter Job Title**	
Reporter Tel. no		**Reporter E-mail**	
Incident Details			
Date of incident?		**Date Incident Identified?**	
Incident Site? (if other than reporting org)		**Incident Location?**	
Who Was Involved			
Type of Patient?			
GP Practice?			
Gender?	**Male** ☐ **Female** ☐		
Date Of Birth? (dd/mm/yyyy or N/A)			
Ethnic Group?			
Persons Notified?	**Patient** ☐ **Family** ☐ **Carer** ☐		
Degree of Harm	**None** ☐ **Low** ☐ **Moderate** ☐ **Severe** ☐ **Death** ☐		
Junior Doctor Involvement?	**Include Specialty and Grade**		
What Happened			
Type of Incident			
Actual/Near Miss?			
Never Event?	**Yes** ☐	**Expected level of investigation**	

Description of Incident

Immediate Action Taken

Media Interest?	**Yes** ☐ **No** ☐	**Comms informed?**	**Yes** ☐ **No** ☐
Externally reportable?	**Yes** ☐ **No** ☐	**Externally reported to?**	

Any Other Comments: e.g. multiagency incident, police and /or HSE investigation, Coroner's inquest, CQC involvement.

Appendix 7

Notification of Interested Bodies – Brief guidance

Serious incidents must be notified without delay (or within specified timescales) to all relevant bodies via the appropriate routes. Guidance produced by specific bodies should be referred to in order to ensure compliance with their requirements. Commissioners should be notified of serious incidents no later than 2 working days after the incident is identified.

CQC – Health and Social Care Act (HSCA) notifications must be made by all services registered under the Act

Controlled Drugs – serious incidents relating to controlled drugs must be reported to the provider's accountable officer.

Coroner – An unexpected death (where natural causes are not expected) and all deaths of detained patients must be referred to the coroner.

Defects and Failures – where incidents relate to a defect or failure involving engineering plants, infrastructure and/or non-medical devices a defect and failure report must also be submitted to the Department of Health

Health and Safety Executive (HSE) – serious incidents may need reporting under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). The trigger point for RIDDOR reporting is 7 days incapacitation.

Health Education England – are responsible for the education and training provided to medical, nursing, dental and Allied Health Professionals students and others. If involved in serious incidents, HEE have a responsibility to care for these students and as such they must be notified.

Information Governance, Caldicott and Data Protection – when reporting incidents data protection and information governance (IG) requirements must be adhered to. When incidents relate to information governance they should be reported within the IG toolkit.

Local Authorities – are responsible for commissioning specific public health services. Local authorities also have a particular role to play in relation to safeguarding.

Medicines and Healthcare products Regulatory Agency (MHRA) – suspected problems with a medicine or device should be reported to the MHRA using the Yellow Care Scheme.

Monitor – Foundation Trusts are required to notify monitor about relevant serious incidents requiring investigation.

NHS Protect – relates to security management incidents.

NHS Trust Development Authority (TDA) - NHS trusts should directly inform the TDA of all serious incidents.

Police – the police are likely to investigate incidents where there is evidence or suspicion that the actions leading to harm were reckless, grossly negligent or wilfully neglectful or if adverse consequences were intended.

Professional regulators and professional misconduct – if following a serious incident investigation it is identified that the incident may have occurred as a result of professional misconduct then relevant regulators may also need to be notified.

Public Health England – PHE screening and immunisation leads have a system leadership role for screening and immunisation programmes. They have a responsibility to support the oversight and management of incidents that occur within these programmes.

Serious Adverse Blood Reactions and Incidents (SABRE) – adverse incidents relating to blood and blood components should be reported to the MHRA, the UK Competent Authority for blood safety.

For further information relating to the Notification of Interested Bodies please refer to the full guidance contained within the NHS England Serious Incidents Framework (2015)

Appendix 8

Internal Incident Investigation Report – Example of Information Required from Providers & Suggested Report Content

The report of the internal investigation should be received by NHS Bolton CCG within 60 working days of the incident being identified. The following provides guidance on what NHS Bolton CCG's Serious Incident Review Group will be looking for within the completed reports;

Title

1. Post Incident Review – Serious Incident – StEIS reference number

Contents Page

2. If a report is in excess of 4 pages, a contents page should be included – especially if the report contains appendices. Page and paragraph numbering is required.

Background

3. A brief description of the matters and circumstances that have prompted the review, including the specific issues that need to be addressed within the report.
4. Care should be taken not to include here information that should be placed in the body of the report.
5. As this section is likely to set the tone of the document, particular care should be taken over use of language. In particular emotive language should be avoided.

Review Team and Terms of Reference

6. The Trust should appoint a review team at the earliest opportunity. The team should be led by a Chair of the Review Team, who ideally is experienced in incident investigation and trained in root cause analysis. The chair of the Review Team should also have sufficient authority (delegated or otherwise) within the Trust to be able to report recommendations to the Trust Board and partner organisations.
7. The other members of the review team should include appropriate clinicians, other health professionals, managers and others so that the review will be as balanced and as thorough as possible. The Trust should also consider including a lay person, patient or independent professional on the team, to provide an objective view of the circumstances.
8. The terms of reference should closely reflect the contents of paragraphs 3-5.
9. The terms of reference should be clear and free from ambiguity to permit focussed examination of the key issues.

10. If appropriate the terms of reference should be amended in the light of a significant fact/issue emerging from the ongoing review.
11. It may be that the new fact(s)/issue(s) would need to be addressed by a separate investigation. In this case this matter should be raised in the recommendations and/or in an appendix to the report.

Process (Methodology)

12. The report should clearly state the methodology and/or the process adopted to undertake the review. The report should contain information on the following:

(a) List of policies and documents examined by the reviewer(s);
(b) Whether patient records were examined and if so by whom, was an internal expert asked to comment on the records;
(c) List of persons who have provided written statements / interviewed with dates and times (including the length of individual interviews). It is recommended that the questions asked of the various interviewees should be included in an appendix and cross-referenced. It is also recommended that interview notes should also be included in the appendix;
(d) Any anomalies in the process e.g. key witnesses being unavailable should be mentioned here.

Facts Established

13. A history of the service user's treatment and care should be included. A chronological account of what is known to have happened – this should 'tell the story' of the unfolding of events relating to the matters under review. The report should carefully document the following:

(a) Whether the relevant and accurate diagnosis was /were made at the earliest available opportunity;
(b) Whether the diagnosis was made in the most efficient and efficacious manner;
(c) Whether the care given to the patient was effective and optimal;
(d) Whether there are any outstanding issues related to consent; and
(e) The consequence(s) of any defects/shortcomings in (b) and (c).

14. The report should make specific reference(s) (if appropriate) to any individual professional performance issues. If the performance of a professional is at issue, the report should make reference to any previous instances of poor performance and conduct. The report should also make reference to the steps taken by the Trust/PCT to address poor performance and/or conduct.
15. The above account should make explicit reference to any relevant existing policies (including clinical risk management and clinical governance policies), procedures and protocols. The report should also allude to the

extent of dissemination / staff knowledge of these policies, procedures and protocols.

16. The report should also make a reference to the extent to which the policies, procedures and protocols were adhered to in the management of the case under consideration (in relation to both the management of the care and treatment and the management of the incident).

Associated Relevant Factors

17. The report should include an examination of potential human error causal factors. Attention should be paid to:

- Staffing levels and skill mix at the time of the incident
- Pressure to achieve targets (e.g. A&E throughput, waiting list priorities)
- Fatigue or fitness of staff
- Communication difficulties between staff or with the patient
- Ability of staff to raise concerns (culture of organisation or team)
- Whether anyone raised a concern & if so how was it dealt with
- Whether minimum operating standards were complied with (e.g. equipment unavailable or faulty, mandatory training standards)
- Any confusion or misunderstandings about procedures or practices
- Clarity about each person's role in any procedure or practice
- Triangulation with incidents and complaints

NB: This list is not exhaustive

Points Causing Concern about the Evidence

18. This section should highlight any areas of conflict or ambiguity in the gathered evidence e.g. where people interviewed gave differing accounts about significant matters or where there are important gaps in the evidence.
19. The report should clearly state the criteria used to resolve conflict/inconsistencies in the evidence. The way in which the gap(s) in the evidence was /were handled should also be stated. The report should also give an indication as to how facts on which key conclusions are based / were established.

Analysis / Conclusions

20. There should be logical and sequential connections between the facts and evidence.
21. The report should analyse and comment on any mismatch between what is believed to have happened in practice and what should have happened

(given policy/procedures/protocols and/or professional judgement of review team or expert witnesses)

22. The authors should comment on the cause(s) of any such inconsistencies. The authors should support their views by the facts contained in the report and other evidence based on guidance and best practice.

Recommendations

The purpose of the recommendations is twofold: to minimise the impact of the present incident and to reduce the likelihood of the incident occurring again.

23. The recommendations should be precise and targeted at the appropriate level(s) of the organisation and should reflect the 'improvement' philosophy behind the review.
24. The recommendations should address any factor that is judged to have contributed to less than satisfactory service delivery (if latter is the case this should be made explicit). Such factors may be organisational, situational, procedural, resource related, or related to professional practice (personal style, communication, professional judgement, knowledge etc).
25. The recommendations made should be clearly listed in order of priority as deemed important by the review team. Please note if the Trust/CCG does not accept the recommendations, the GMAT must be informed of the reasons for rejection and any proposed alternatives.
26. The recommendations should be strengthened if they can be related to examples of good and effective practice elsewhere.
27. The action points contained in the recommendations should clearly state timescales for completion.

Actions

28. Each NHS organisation that reviews an incident should ensure that:

- The document is disseminated to relevant staff
- All relevant new staff are inducted in the resulting process changes
- Information is shared, where appropriate, across the health community
- There is evidence of how reports impact on future delivery of services and any changes made

Lessons Learned

29. The purpose of the lessons learned is twofold namely to highlight changes in the practices implemented since the incident and to ensure the information is readily accessible. Providers will be invited by Bolton PCT

to participate in a wider Post Incident Review so that lessons can be shared.

Authorship / Membership

30. The report should be addressed to the relevant officer of the Trust and signed and dated by the chair of the review. Full details of the members on the review team should be included in the report. Membership designation should be identified.

Appendices

31. SMART action plans should be included which clearly identify actions required, person responsible, timescales and progression towards completion.

Appendix 9

NHS England's – Levels of investigation

Information in this table provides an outline of the levels of systems-based investigations recognised in the NHS (currently referred to as RCA investigation). Within the NHS, most serious incidents are investigated internally using a comprehensive investigation approach. Resources to support systems-based investigation in the NHS are available online from: http://www.england.nhs.uk/ourwork/patientsafety/root-cause/

Level	Application	Product / Outcome	Owner	Timescale for completion
Level 1 **Concise internal investigation**	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact investigation report which includes the essentials of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld	**Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner** **All internal investigation should be supported by a clear investigation management plan**
Level 2 **Comprehensive internal investigation** (this includes those with an independent element or full independent investigations commissioned by the provider)	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity	
Level 3 **Independent investigation**	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved (see Appendix 1 and 3 for further details)	Comprehensive investigation report including all elements of a credible investigation	The investigator and **all** members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated.	**6 months from the date the investigation is commissioned**

NHS England Serious Incident Framework (2015) pp. 41

Appendix 10

Serious Incident Review Group – Terms of Reference

NHS
Bolton Clinical Commissioning Group

Serious Incident Review Group

Terms of Reference

Date of publication – October 2015

1. Introduction

This group will be known as NHS Bolton CCGs Serious Incident Review Group (SIRG).

2. Membership

The group will include the following members:-

Designation	Name (where possible)
Clinical Director	Dr. Colin Mercer
Chief Nurse	Mary Moore
Associate Director of Integrated Governance and Policy	Mike Robinson
Lead Nurse for Quality & Safety	Sue Mackie

The group membership may grow and change over time, in agreement with members of the group and additional members may be co-opted onto the group as necessary.

3. Attendance

Representation is desirable at each monthly meeting. All members unable to attend should send apologies.

4. Secretarial arrangements

- Information relating to serious incidents will be collated by the Lead Nurse for Quality & Safety and circulated to all group members prior to the next scheduled SIRG meeting.

- A record of discussions will be captured on the feedback template (Appendix 1), capturing all salient points which will then be shared with the provider following the meeting.

5. Quorum

The meeting will be quorate with a minimum of 2 members of the group.

6. Frequency of meetings

The Serious Incident Review Group will be held monthly

7. Remit and responsibilities of the group

Aim

- To review all serious incidents and to critically analyse the serious incidents reports, challenging where appropriate to provide assurance to the CCG with regards to the investigative process into serious incidents

- To work in partnership with Bolton FT and other healthcare providers.

Duties of the Group

- To ensure all serious incidents are reported and managed as per local and national policy.

- To be aware of all serious incidents that occur across the health economy involving Bolton residents.

- To review all incident reports, analyse the information and data, triangulate with previous incidents and to provide challenge and request additional information where appropriate.

- To identify any key themes or trends identified from the serious incidents and consider appropriate responses to these.

- To ensure any lessons learned are shared appropriately

8. Reporting Arrangements

A monthly report will be submitted to the Bolton CCG Quality & Safety Committee to provide ongoing assurance regarding the management of serious incidents and also to highlight any concerns in relation to the process.

9. Date Terms of Reference agreed: 30th September 2015

10. **Review Date:** every 12 months

SIRG – Appendix 1 – Feedback Template.

Serious Incident Review Group Minutes

Date:	
Present: Quorate – 2 members	Apologies:
Additional issues discussed:	
Incidents reviewed	
StEIS No: Concerns / issue to be feedback to the provider: **Outcome : Request more information from the provider / Close**	
StEIS No: Concerns / issue to be feedback to the provider: **Outcome : Request more information from the provider / Close**	
StEIS No: 2015/ Concerns / issue to be feedback to the provider: **Outcome : Request more information from the provider / Close**	

Appendix 11

Example of a StEIS Investigation Report Evaluation

NHS
Bolton Clinical Commissioning Group

StEIS Serious Investigation Assurance

StEIS Investigation Report Evaluation

Incident StEIS Number:	
Date Incident Reported:	
Date Report Due:	
Date Report Received:	
Date of SIRG Review:	
Date Feedback sent to Trust:	
Date Incident Closed by NHS Bolton CCG	

Action Required	Person Responsible	Date for Completion	Date Completed

Incident Investigation Report Evaluation

Criteria	Met	Partially	Unmet	Comments
1a) Incident Description. brief description of incident and outcome				
1b) Incident Description. Date of Incident included				
1c) Incident Description. Actual effect on the person / organisation harmed				
2) Appropriate terms of reference				
3) Details of an appropriate review team. The members of the review team should be appropriate to the incident in relation to knowledge, use of experts and use of external specialists. **See Appendix for definitions**				
Duty of Candour	**Met**	**Partially**	**Unmet**	**Comments**
4a) Evidence of appropriate communication with the person affected by the incident and / or their family. In line with the NPSA being Open Alert and Duty of Candour				
4b) Evidence of appropriate Involvement of the person affected by the incident and / or their family. In line with the NPSA Being Open Alert and Duty of Candour.				
4c) Evidence of appropriate support of the person affected by the incident and / or their family. In line with the NPSA Being Open Alert and Duty of Candour.				
5) Evidence that appropriate support provided to staff after the incident and during the investigation is sensitively handled.				
6) Summary of Investigations methods used. This may include statements, review of records, gaining reports, timelines etc.				
Root Cause Analysis	**Met**	**Partially**	**Unmet**	**Comments**
7) Clear fact based chronology of events leading up to and in advance of the incident. This should be comprehensive in order to create a picture of unfolding events.				
8a) Notable good practice reported when applicable.				
8b) Staff feedback reported when applicable.				
8c) NICE and/or appropriate guidance reported when				

applicable.				
9) Care and Service delivery problems identified. Areas of risk - What should have happened that didn't and what did happen that shouldn't				
10) Contributory Factors Identified. Things that have or may have contributed to the incident happening.				
11) Root causes identified. This should include identification of weak / unsafe systems within the organisation.				
12a) Clear links / threads between cause and effect (contributory factors). On reviewing report clear links between contributing factors can be seen. These are reflected in the conclusions made.				
12b) Clear links/threads between cause and effect (root causes). On reviewing report clear links between root causes can be seen. These are reflected in the conclusions made.				
Recommendations & Actions	**Met**	**Partially**	**Unmet**	**Comments**
13a) Recommendations. The recommendations address the root causes and contributing factors identified.				
13b) Action plan. The action plan is specific and measurable with clear timescales and completion dates, named action leads and monitoring arrangements are in place.				
14) Evidence of execution of action plan. Are local monitoring arrangements identified?				
15a) Has the report been circulated appropriately? Does the report indicate who the report has been shared with and where it is due to be reviewed?				
15b) Has the report been discussed within the reporting organisation?				
16) Have terms of reference which been adhered to? This should include a focus on systems and processes not just individuals.				
17) Has the StEIS web report been completed? Full completion of the StEIS record covering the above points e.g. date investigation completed, population of RCA/Lessons learned field. (To be checked by the CCG before closure).				