Performance Management of Serious Incidents and Never Events

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Involving everybody in improving the health and wellbeing of the people of Halton
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1. **Introduction**

The responsibility for the performance management of Serious Incidents, (SIs), and Never Events was transferred post 2008 from Strategic Health Authorities to commissioning PCTs. This role was confirmed in The National Framework for Reporting and Learning from Serious Incidents Requiring Investigation issued by the National Patient Agency in March 2010. NHS Halton Clinical Commissioning Group took over the responsibility for the performance management of SUI/Never Events from 1 April 2013.

In February 2009 the National Patient Safety Agency, (NPSA), published a framework for the reporting and investigation of eight serious and largely preventable patient safety incidents, (Never Events) which should not occur if the available preventative measures have been executed by provider organisations. This list has subsequently been expanded to 14 Never Events. Never events reported to NHS Halton Clinical Commissioning Group will be treated as a SI.

The role of NHS Halton Clinical Commissioning Group is to ensure that SIs and Never Events are reported, investigated and acted upon by provider organisations from whom, they commission/contract services to ensure that patient and staff safety is maintained and improved. This policy outlines the responsibilities of NHS Halton Clinical Commissioning Group in relation to performance management of Serious Incidents/Never Events.

**Please note**: this policy does not replace the systems and processes associated with a Serious Case Review in the event of a death of a child or young person below the age of 18 or the need to complete a management review/safeguarding investigation in the relation to the care of a vulnerable adult.

2. **Purpose**

The purpose of this policy is to outline the NHS Halton Clinical Commissioning Group’s governance arrangements for the performance management of Serious Incidents/Never Events and therefore will serve to address the concerns of patients and promote public confidence. The execution of this policy will assist NHS Halton Clinical Commissioning Group in ensuring that its commissioned services are of a high quality and provide assurance that appropriate risk management systems are in embedded within commissioned services to ensure patient/staff safety.

The policy describes the requirements for Serious Incident/Never Event reporting and management within NHS Halton CCG and is in line with:

- Previous NHS North West: Serious Untoward Incident Reporting Protocol March 2008

- NPSA: The National Framework for Reporting and Learning from Serious Incidents Requiring Investigations issued in March 2010

- Department of Health: The Never Events List 2012/13, Policy Framework for use in the NHS


The systems improvement approach to patient safety acknowledges that the causes of actions cannot simply be linked to the actions of an individual. This policy will therefore adopt the systems approach advocated by the NPSA. The policy will also support openness, trust and continuous learning resulting in service improvements.

NHS Halton Clinical Commissioning Group is expected to use patient safety intelligence, provider performance knowledge and lessons learned to inform a commissioning process that actively reduces the risk of harm to patients.

The role of the NHS England (Merseyside) Local Area Team and the CCG is to ensure incidents/never events are investigated properly, that appropriate action is taken to improve clinical quality and that lessons are learnt in order to minimise the risk of similar incidents occurring in the future.

A further requirement of this process is that all Foundation Trusts and other commissioned services providing NHS Funded care report SIs/Never Events to the Commissioning organisation for the purpose of performance management.

NHS Halton Clinical Commissioning Group will make explicit within their contracts with all providers, their expectations regarding incident/never events reporting and management. The policy will cover the following types of commissioned services:

- NHS Trusts
- Foundation Trusts
- Primary Care Providers Trusts
- Independent healthcare provider organisations
- Independent practitioners, General Practitioners
- Integrated Services and Care Trusts
- 3rd sector organisations/registered charities

3. Definition of a Serious Incident/Never Events

3.1 Serious Untoward Incidents:

The principal definition of a serious incident (SI) is any incident on an NHS site, or elsewhere, whilst in NHS-funded or NHS regulated care involving:

- Patients, relatives/carers or visitors
- Staff
- Contractors working for the NHS, equipment, building or property

And which may or has;

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 healthcare within the recent past;

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

o 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.

3.1.1 A Never Event

All Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death (See Appendix 1 for a list of defined Never Events).

3.1.2 An Incident

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 (Appendix 2)
- 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.

Adverse outcomes reasonably associated with routine NHS activity such as major surgical procedures, trauma interventions etc are excluded from the above list.
3.2 Definition of Never Events

The Department of Health have defined a Never Event as a serious and wholly preventable patient safety incident, which should not occur if the available preventative measures have been implemented.

An incident which is a Never Event will fulfil the following criteria:

1. They are wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers.
2. Each Never Event type has the potential to cause serious patient harm or death. However serious harm or death is not required to have happened for the incident to be categorised as a never event.
3. There is evidence that the category of never Event has occurred in the past, for example through reports to the National reporting and learning system (NRLS) and a risk of recurrence remains.
4. Occurrence of the Never Event is easily recognised and clearly defined- to help minimise disputes around classification and ensures the focus is on learning

In March 2015 the Department of Health issued a revised list of never events. This list can be reviewed in Appendix 1 of this policy.

3.3 Incidents Relating to National Screening Programmes

Examples of incidents which are reportable can be found in Appendix 2 of this policy, incidents relating to national screening programmes will be managed through Public Health England screening leads.

3.4 Reporting managers will need to exercise a degree of judgement in deciding a threshold for reporting an incident. Where it is not clear whether or not an incident fulfils the definition of a serious incident, providers will engage in open and honest discussion to agree appropriate and proportionate responses, this process includes near misses where there is a significant risk of system failure and serious harm and when an initial investigations suggest that there are no acts of omissions in care which are caused or contributed to the outcome. Organisations are advised to contact the Chief Nurse at NHS Halton Clinical Commissioning Group if in doubt (please see page 11 of this policy for contact details).

3.5 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 (2006) 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.

3.6 For serious incidents involving children and young persons under the age of 18, refer to the appropriate Local Safeguarding Children Board Procedures, and the statutory guidance ‘Working Together to Safeguard Children’ (2013) - See Appendix 3. For Safeguarding Adult Boards Procedures refer to appropriate Local Authority and national guidance ‘No Secrets'
4. Procedures that all Commissioned Organisations providing NHS funded care must have in place

- All organisations providing NHS funded care are responsible for identifying serious incidents and taking effective action in each instance. It is expected that clear local procedures are in place at each organisation for identifying, reporting and investigating SIs/Never Events. A copy of current local procedures will be held by the Chief Nurse at NHS Halton Clinical Commissioning Group within the contract for each provider.

- All organisations must have a number of staff trained in undertaking SI/Never Events investigations using root cause analysis techniques. Each SI/Never Event investigation team must have an assigned staff member who is trained in Root Cause Analysis.

- Each organisation should have an authorised named person who is responsible for deciding when an incident should trigger the serious untoward incident procedure. Chief Executives/Managing Directors/ Senior Partners must ensure that local procedures are in place so that all staff are fully aware 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 Chief Nurse at NHS Halton Clinical Commissioning Group will maintain a register of the named person and their contact details for all provider organisations.

- The named person should involve their Communications lead in the assessment of incidents for potential media impact. The organisation or NHS Halton Clinical Commissioning Group should prepare a press release to respond to media enquiries where media interest is anticipated. It is essential that clear agreements are made regarding who the lead organisation for communications will be in relation to any incident, in which there may be shared responsibility or for which an organisation such as the NHSE local team or another commissioning body will take responsibility for managing the performance of an incident. NHSE Area Team Communications Team is available for advice and will offer support in media handling for high profile incidents.

- Mental Health Trusts should have due consideration to the guidance contained within HSG (94) 27 (revised June 2005) relating to the discharge of patients and care in the community: [http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publication sandstatistics/Lettersandcirculatirs/Healthserviceguidelines/DH_4104914](http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publication sandstatistics/Lettersandcirculatirs/Healthserviceguidelines/DH_4104914)

- When a vulnerable adult, 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 vulnerable adult/child protection procedures must be followed and the appropriate Designated Nurse for Vulnerable Adults/ Local Safeguarding Children Team must be informed immediately the incident is identified.

When cases fall under the authority of the local Safeguarding Children’s Board, a joint media strategy will be agreed.

Halton Clinical Commissioning Group

- Involvement of multiple providers – where there are numerous providers involved in a serious incident, the organisation that identifies the serious incident is responsible for recognising and alerting other providers and commissioners where relevant. The expectation across Cheshire and Merseyside is that all providers will follow the local multi agency guidance in order to deliver one single investigation.

5 Reporting Serious Incidents

All organisations providing NHS funded care must report any Serious Incident/NEver Events to NHS Halton Clinical Commissioning Group within 48 hours (Maximum of 2 working days) of the incident occurring or being recognised following notification. Large NHS organisation will notify NHS Halton Clinical Commissioning Group of a SUI/NEver Event using the StEIS database. All other organisations will notify the Chief Nurse for NHS Halton Clinical Commissioning Group via telephone/or email, the Chief Nurse will then report the incident onto StEIS on the reporting organisations behalf. Please see Appendix 4 for a Flow Chart of Reporting Serious Incidents.

In the absence of the Chief Nurse please contact remaining personnel as outlined in section 7.2 of this policy. NHS Halton Clinical Commissioning Group expect that incidents which may lead to media interest or cause a declaration of a major incident to be reported to the Director on call via the internal Director on Call systems out of normal office hours.

5.1 Grading of Serious Incidents and Reporting on StEIS

The NPSA Framework for Reporting and Learning from Serious Incidents Requiring Investigation introduced a grading tool with the purpose of grading serious incidents to indicate the level of investigation required. The table below outlines the guidance for grading along with the suggested investigation timescales and monitoring requirements.

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<thead>
<tr>
<th>STEIS SI Level</th>
<th>Application</th>
<th>Product/ Outcome</th>
<th>Owner</th>
<th>Timescale for Completion</th>
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<tr>
<td>Level 1</td>
<td>Concise internal investigation</td>
<td>Suited to less complex incidents which can be managed by individuals or a small group at a local level</td>
<td>Concise/compact investigation report which includes the essentials of a credible investigation</td>
<td>Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld</td>
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<tr>
<td>Level 2</td>
<td>Comprehensive internal investigation (this includes those with an independent element or full independent investigations commissioned by the provider)</td>
<td>Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable</td>
<td>Comprehensive investigation report including all elements of a credible investigation</td>
<td>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</td>
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On rare occasions, extensions to the above timescales can be agreed. Extensions must be agreed with the Lead Commissioner. The reason for the extension must be included in the ‘further information’ section of the Strategic Executive Information System (STEIS) incident form.

For Organisations reporting incidents via the STEIS database, care should be taken to ensure that all sections of the reporting form 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 STEIS reporting system being unavailable, contact with the Chief Nurse at NHS Halton Clinical Commissioning Group should be made via telephone, and the incident entered onto STEIS once the system is back online (Please see paragraph 7.2 for details).

If relevant, the following information should also be provided in the 'Further Information' field on the STEIS electronic report form:

- Number of patients affected
- Impact on patient(s)
- Designation of staff involved
- Confirmation of which, if any, medical devices or equipment were involved
- Confirmation of which, if any, medicines were involved
- The impact of the incident on staff
- Whether the patient’s family has been informed and if not, state if there are plans to do so; if a decision not to inform the family has been taken, has this been properly recorded – was the patient involved in this decision
- If the family has been contacted- how is contact with the family being maintained, is there a named person for this purpose
- Any other information deemed relevant by the reporting organisation
- To support the process of reporting to associate CCGs the provider will be asked to identify which CCG is responsible for the patient/s.

5.2 Having completed the initial STEIS report form, the reporting organisation must then take appropriate measures to investigate the SI using Root Cause Analysis Techniques. The onus of responsibility lies with the reporting organisation to inform NHS Halton Clinical Commissioning Group of any problems or delays in the investigation process. NHS Halton Clinical Commissioning Group will endeavour to ensure the investigative process is not
hampered by unnecessary contact. There will be a number of reported incidents that meet
the escalation criteria issued by NHS England, in these cases NHS England locally or
regionally will continue to perform management the incident.

5.3 Where the authorised named individual in a Trust believes that the incident has significant
implications for the NHS in terms of clinical, managerial or media issues, and warrants the
immediate involvement of NHS England Area Team out of hours, the NHS England Area
Team on-call Executive Director can be contacted when the situation requires escalation. If
so, they will agree any action that needs to be taken with the relevant NHS organisation.

Please refer to the flowchart in Appendix 4 for the recommended process, and Appendix 5
for Reporting Serious Incidents Involving Data.

6 Initial Assessment

In all cases a RASCI (Responsible, Accountable, Supporting, Consulted, and Informed) model will be
agreed across commissioning within Cheshire and Merseyside. This provides clear guidance about
which commissioner is responsible for having oversight of the investigation, and where accountability
ultimately resides. This model supports the identification of a single ‘lead commissioner’ with
responsibility for managing oversight of serious incidents within a particular provider. This ensures
that a provider reports and engages with one single commissioning organisation who can then liaise
with other commissioners as required. This process removes ambiguity and therefore reduces the
risk of serious incidents being overlooked.

On reporting a SI/Never Event, NHS Halton Clinical Commissioning Group (as responsible
commissioner) will discuss, if required, the performance management process with the provider and
will expect the provider to have commenced its internal investigation immediately.

As the responsible commissioner NHS Halton Clinical Commissioning Group will acknowledge receipt
of the initial report via email within 3 working days and will identify and inform any collaborative CCG
involvement as appropriate within 48 hours of the collaborative CCG being identified.

The following options will be considered;

6.1 Criteria for SI Management

- The incident does not meet the StEIS reporting criteria or has been reported for
  notification only and no further action is needed. The incident may be closed on StEIS
  following discussion with the reporting organisation

- NHS Halton Clinical Commissioning Group will undertake performance management of
  the incident and advise NHS England Merseyside as appropriate. If NHSE Area Team
  considers it necessary, NHSE Area Team may retain the performance management of
  the incident and liaise with NHS Halton Clinical Commissioning Group, but in either case the
  reporting organisation will be requested to proceed with its internal investigation processes
  and provide NHS Halton Clinical Commissioning Group and/or NHSE Area Team an
  internal investigation report within 60 working days or agreed extension from the date the
  incident was reported onto StEIS

- The incident may meet NHSE Sub Regional Team escalation criteria and will then be
  managed by NHSE Sub Regional Team in collaboration with NHS Halton Clinical
  Commissioning Group.
In the event of escalation of an incident, NHSE Area Team will brief the NHS England national office if/as appropriate and agree the level of involvement with the Trust. Depending on the severity of the incident this could include;

- Agree terms of reference and investigation/review panel
- Submission of internal investigation report within 60 working days
- NHS England may commission an independent investigation

7. **NHS Halton Clinical Commissioning Group Role and Responsibilities**

7.1 **Commissioning Responsibilities**

NHS Halton Clinical Commissioning Group will as commissioner manage Serious Untoward Incidents/Never Events for NHS Halton patients in the following Trusts;

- The Royal Liverpool and Broadgreen Hospitals NHS Trust
- Liverpool Women’s NHS Foundation Trust
- Alder Hey Children’s NHS Foundation Trust
- Liverpool Heart and Chest Hospital NHS Trust
- Mersey Care NHS Trust
- Liverpool Community Health
- Boroughs Partnership
- The Walton Centre NHS Foundation Trust
- St Helens and Knowsley NHS Trust
- Aintree University Hospital NHS Foundation Trust
- Southport and Ormskirk Hospitals NHS Trust & Integrated Care Organisation
- Bridgewater Community Healthcare NHS Trust – St Helens & Halton Division
- Warrington and Halton Hospitals Foundation Trust

7.2 **Executive & Non Executive Responsibilities**

The Chief Officer has overarching accountability and responsibility for the performance management of SUIs/Never Events however has delegated the responsibility to the Chief Nurse. The Chief Nurse as lead for Quality Improvement & Patient Safety has responsibility for the performance management of the system and the incidents reported.

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

- **Jan Snoddon**  
  Chief Nurse  
  01928 593575

- **Jennifer Owen**  
  Deputy Chief Nurse  
  01928 593469
For SI's involving children and young persons under the age of 18 which may fall under local Safeguarding Board Procedures or vulnerable adults, contact the Designated Nurses for NHS Halton Clinical Commissioning Group;

Helen Smith, Designated Nurse for Safeguarding Adults  
0151 495 5469  
Anne Dunne, Designated Nurse for Safeguarding Children  
0151 495 5295

In order to ensure NHS Halton Clinical Commissioning Group meets its obligations as previously delegated for the performance management of Serious Incidents, it must have the following in place:

**Governance**
- Contracts with local healthcare provider organisations which clearly set out the organisation’s obligations to meet the requirements of this policy
- Procedures and relevant skills and resources to receive and appropriately manage, monitor and follow up and, where appropriate, escalate serious incidents in accordance with this policy
- Arrangements providing assurance to NHS England Cheshire and Merseyside that the requirements of the policy are being met
- Local procedures agreed with the Local Safeguarding Adults/Children Boards that set out the arrangements for the notification and management of serious care reviews, including action planning and learning from incidents.

**Reporting**
- Arrangements to assure that serious incidents are reported by provider organisations to the CQC and other bodies as appropriate
- A process to report serious incidents, including never events to the Quality Committee of NHS Halton Clinical Commissioning Group, and plans for recording Never Events in annual reporting requirements.

**Investigations and Action Planning**
- Monitoring arrangements to ensure that serious incidents are managed and investigated by providers according to best practice
- Arrangements for receiving assurance from provider organisations that action plans have been implemented following a serious incident and advising provider organisations when incidents are closed formally
- Arrangements for agreeing commissioning of independent investigations with provider organisations and NHSE Area Team if there is a requirement to do so
- Support or leadership for independent contractors in undertaking an investigation
- Co-ordination of complex multi-agency investigations/RCA.

**Learning and Follow Up**
- Arrangements for the dissemination of learning from serious incidents and recommendations from independent investigations are implemented across NHS Halton Clinical Commissioning Group and where appropriate across the wider NHS through other mechanisms.
- Arrangements for sharing national information on serious incidents and risks across NHS Halton Clinical Commissioning Group and to providers of services, (including Independent contractors)
• Arrangements to carry out thematic reviews of serious incidents to identify trends and patterns across NHS Halton CCG and ensure the wider implications and key learning points are disseminated across NHS providers within Merseyside and the wider NHS
• Arrangements are in place annually for public reporting of Never Events in their providers: the numbers, type and actions taken.

7.3 Committee Reporting

Reports detailing for each provider the number of incidents open/closed, themes and progress to date on investigations will be delivered to the following committees;

- NHS Halton Clinical Commissioning Group Quality Committee

7.4 NHS Halton Clinical Commissioning Group SUI /Complaint Review Group

NHS Halton Clinical Commissioning Group has established a SUI/Compliant Review Group (see Appendix 6 for Terms of Reference. Core members will include the following;

- Chief Nurse – Nurse Advisor
- Deputy Chief Nurse
- Quality Programme Manager
- Specialist Advisor for Mental Health
- Head of Complex Care

Clinical representation and specialist advisors will be called upon to support the process as and when required

- Additional specialist Clinical/ Nurse Advisor (as and when required)
- Medical Advisor (as and when required)
- Head of Medicines Management
- Designated Nurse for Safeguarding Adults and Children
- Integrated Safeguarding Team – Local Authority
- Contract Lead/Lead Commissioner of service (as and when required)
- Any other such member that reflects the degree of expertise required and as warranted by the nature of the incident

Additional expertise, knowledge and experience will be utilised depending upon the type of service reporting the incident/event and the type of event reported. NHS Halton Clinical Commissioning Group will ensure that the team has sufficient knowledge and experience of the subject matter to enable an objective assessment of the adequacy of the scope of the review and subsequent review report, together with any recommendations made. The group will also facilitate incident closure on receipt of assurances that recommendations have been implemented. If it is appropriate to do so, a member of the provider investigation team may be invited to the performance management group.

8 Quality Standards for the Review Process

8.1 Notification & Initial Review

Following notification of a SI the Chief Nurse at NHS Halton Clinical Commissioning Group will:
- Identify additional members if necessary with appropriate expertise to support the core members of the SI/Complaint Review Group

- Will inform the SI/Complaint Review Group of the incident being reported

- Will liaise with the reporting organisation to confirm the appropriate level of investigation

- Will expect the investigation report to be received within 60 working days from the date the incident was reported onto STeIS system

- If the reporting organisation faces unavoidable delays in its investigation of an incident e.g. police investigation, the Chief Nurse should be notified of the reason for the delay and the anticipated delay period and a new reporting timescale will be negotiated on a case by case basis as required

- Will contact cross county commissioning organisations including Clinical Commissioning Group leads depending on which county the patient resides in

- Will offer to review the draft report on a voluntary basis before the 60 day limit and offer initial feedback to the provider, the purpose of this review is to attempt to identify inadequate investigations at an early stage. Providers will need to be aware that it is the responsibility of NHS Halton Clinical Commissioning Group SI/Complaints Review Group to make the final decision to close an incident, this decision will be taken following a review of the report and confirmed completion of the action plan.

8.2 Notification & Involvement of Cross Boundary Commissioning Organisations including Clinical Commissioning Groups

Commissioning organisations will be notified within 48 hours of NHS Halton Clinical Commissioning Group being notified of the SI/Never Event or as soon as the information is received confirming the need to inform.

The collaborative CCG will also be provided with a copy of the final report into the SUI/Never Event by NHS Halton Clinical Commissioning Group once depending on the circumstances of the SI in question, there may be early implications for a collaborative CCG which may warrant their participation in the performance management process but this will be determined on a case by case basis.

8.3 Criteria for Assessing the 60 Working Day Internal Investigation Reports

The following criteria will be used when appraising the 60 working day Internal Investigation reports;

- Has the report been written reflecting appropriate methodology, NHS Halton Clinical Commissioning Group will expect all reports to be presented using the NPSA guidance on investigation methodology (RCA)

- 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 Trust. Has the report assessed whether these systems are fit for purpose
• 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 considered local or national guidance in relation to the areas/subject being investigated

• Has the investigation utilised Root cause Analysis Techniques and is the investigation of sufficient depth

• Has the report adequately addressed all of the investigation terms of reference

• Have the affected party/parties of the incident been informed of the incident in line with “Being Open”

• 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 reports’ recommendations

• Do the recommendations address the root causes of the incident

Any further action will be agreed with the Provider on a case by case basis as required. Once completed the incident may be recommended for closure by NHS Halton Clinical Commissioning Group SI/Complaints Review Group.

An evaluation template will be utilised by NHS Halton Clinical Commissioning Group to provide feedback to the Provider organisation. The evaluation template can be found in Appendix 7.

8.4 Criteria for Incident Closure

Closure of incidents reported on StEIS may be considered after submission of the internal investigation report and action plan which demonstrates execution of actions. NHS Halton Clinical Commissioning Group will confirm in writing the closure of an SUI with the provider organisation. In general, NHS Halton Clinical Commissioning Group will look to ensure;

• The report is robust and has fulfilled the terms of reference

• An action plan has been agreed between the relevant organisations, which addresses the recommendations and has been ratified by the relevant Trust committee

• Evidence has been submitted that significant recommendations have been implemented

9. Data Collection & Analysis

The CSU Services manager will have responsibility for updating the StEIS database with the actions taken by NHS Halton Clinical Commissioning Group in relation to SI/Never Events.
10. **Learning from Experience**

NHS Halton Clinical Commissioning Group is committed to 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.

NHS Halton Clinical Commissioning Group will make explicit reference within contracts as to its expectation regarding 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 an SI.
# NHS England Never Event List 2015/16

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<th>Description</th>
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<td>1</td>
<td>Wrong Site Surgery</td>
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<td>• All patients receiving NHS funded care</td>
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<tr>
<td>2</td>
<td>Wrong Implants/Prosthesis</td>
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<td></td>
<td>• All patients receiving NHS funded care</td>
</tr>
<tr>
<td>3</td>
<td>Retained Foreign Object Post-Procedure</td>
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<td>• All patients receiving NHS funded care</td>
</tr>
<tr>
<td>4</td>
<td>Mis-selection of a Strong Potassium Containing Solution</td>
</tr>
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<td></td>
<td>• All patients receiving NHS funded care</td>
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<tr>
<td>5</td>
<td>Wrong Route Administration of Medication</td>
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<td></td>
<td>• All patients receiving NHS funded care</td>
</tr>
<tr>
<td>6</td>
<td>Overdose of Insulin due to Abbreviations or Incorrect Device</td>
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<td></td>
<td>• All patients receiving NHS funded care</td>
</tr>
<tr>
<td>7</td>
<td>Overdose of Methotrexate for Non-Cancer Treatment</td>
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<td></td>
<td>• All patients receiving NHS funded care</td>
</tr>
<tr>
<td>8</td>
<td>Mis-selection of High Strength Midazolam during Conscious Sedation</td>
</tr>
<tr>
<td></td>
<td>• All Healthcare Premises</td>
</tr>
<tr>
<td>9</td>
<td>Failure to Install Functional Collapsible Shower or Curtain Rails</td>
</tr>
<tr>
<td></td>
<td>• All Mental Health Inpatient Premises</td>
</tr>
<tr>
<td>10</td>
<td>Falls from Poorly Restricted Windows</td>
</tr>
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<td></td>
<td>• All patients receiving NHS funded care</td>
</tr>
<tr>
<td>11</td>
<td>Chest or Neck Entrapment in Bedrails</td>
</tr>
<tr>
<td></td>
<td>• All settings providing NHS funded healthcare, including NHS funded patients in Care Home settings, and equipment provided by the NHS for use in patient’s own homes.</td>
</tr>
<tr>
<td>12</td>
<td>Transfusion or Transplantation of ABO-incompatible Blood Components or Organs</td>
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<td></td>
<td>• All patients receiving NHS funded care</td>
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<tr>
<td>13</td>
<td>Misplaced Naso- or Oro-gastric Tubes</td>
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<tr>
<td></td>
<td>• All patients receiving NHS funded care</td>
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<tr>
<td>14</td>
<td>Scalding of Patients</td>
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<tr>
<td></td>
<td>• All patients receiving NHS funded care</td>
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</table>

For the full NHS England document detailing Never Events please follow the following links, which covers rationales for changes and case discussions:

- [2015-2016 Never Events Policy Framework](#)
- [2015-2016 Never Event Frequently Asked Questions](#)
- [2015-2016 Never Events List](#)
<table>
<thead>
<tr>
<th>Theme</th>
<th>Categories of Serious Incidents</th>
</tr>
</thead>
</table>
| Identify Population | • Failure to identify the eligible population  
• Failure to run fails safe systems to invite those who have moved house and/or General practitioner. |
| Inform | • Consent not sought for screening |
| Invite | • Failure to offer screening to the eligible population including substantial inappropriate exclusions  
• Sending an appointment to a deceased baby or a deceased person |
| Uptake | • Failure to administer test in those for have accepted screening. |
| Test: To maximise performance of the screening test. | • Test failure/laboratory error  
• Failure to report abnormal result/refer person/baby  
• Affected person/baby not identified through screening programme.  
• Failure to follow correct screening policy/procedure  
• Recording incorrect screening test results or outcomes  
• Misinterpretation of images/test results. |
| Minimising harm | • Persons/parents of baby who has died contacted for repeat test.  
• Process and contingency/back up failure that interrupts screening  
• Report not sent to GP or clinician |
| To maximise performance of diagnostic test. | • Affected person/baby not confirmed through diagnostic test. |
| Referral | • Referral from screening not made |
| Diagnosis/assessment | • Failure to offer assessment/diagnosis to screen positive people/babies  
• Failure to record pregnancy outcomes following prenatal diagnosis  
• Error in prenatal diagnostic analysis, (e.g. errors in sampling or analysis such as contamination). |
| Intervention or treatment | • Delays in treatment/intervention leading to known serious harm in a single patients or potential harm to several patients.  
• Reporting lead times too long for appropriate clinical actions to be taken. |
| To optimise population and individual health outcomes in the target population | • Adverse outcome in a diagnosed person/baby with treatment/management |
To ensure that the whole screening programme is provided by trained and competent workforce

- Deliberate contamination of the sample
- Untrained screening/grading staff participating in screening programmes.

Equipment failure

- Equipment not services or maintained
- Images/results lost or delayed.

Info and IT

- IT failure – leading to rescreening
- Loss of patient date/images
- Breaches in confidentiality

To ensure effective commissioning and governance of national screening programmes

- Programmes approaching or crossing an unsafe threshold for performance standards
- Programme delays/backlogs leading to delayed screening.

Incident Examples Relating to the Mental Health Incidents

<table>
<thead>
<tr>
<th>Theme</th>
<th>Categories of Serious Incidents</th>
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</thead>
<tbody>
<tr>
<td>Death = Grade 2</td>
<td>Any Death</td>
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</table>
| Severe = Grade 1-2 | Any incident that appears to have resulted in permanent harm to one or more person and/or has had a severe outcome. Examples include:  
- Attempted suicide  
- A serious sexual assault  
- A serious physical assault  
- A serious accident or injury  
- Actual or attempted escape from a secure setting  
- Mayor fire  
- Serious self-harm  
- Significant outbreak of health care associated infection |
| Moderate = Grade 1 | Any incident that resulted in a moderate increase in treatment and/or which caused significant but not permanent harm, to one or more persons. Examples include:  
- Physical /verbal assault  
- Moderate/minor self- harm  
- Sexual assault  
- Fire  
- Accident injury  
- Medication errors  
- Absconision from a ‘non secure’ setting |
| Low or no harm= Grade 0 | Any incident that required extra observation or minor treatment and/or caused minimal harm, to one or more persons. This category includes prevented incidents, near misses and no harm incidents. e.g. fell and grazed arm, dressing applied |
Local Safeguarding Children Board (LSCB) responsibilities for the child death review processes – Chapter 7 Working Together (2006).

From 1st April 2008, a sub-committee of Liverpool LSCB is responsible for reviewing information on all child deaths and deaths of young persons’ up to the age of 18 years (excluding those babies who are stillborn) in Sefton and is accountable to the LSCB Chair. The disclosure of information about a deceased child is to enable the LSCB to carry out its statutory duties relating to child deaths.

There are two inter-related processes for reviewing child deaths (either of which can trigger a Serious Case Review):

1. A rapid response by a group of key professionals who come together for the purpose of enquiring into and evaluating each unexpected death of a child
2. An overview of all child deaths (under 18 years) in the LSCB area undertaken by a panel

Definition of an unexpected death

An unexpected death is defined as the death of a child which was not anticipated as a significant possibility 24 hours before the death or where there was a similarly unexpected collapse leading to or precipitating the events which led to the death (Fleming et al 2000; Royal College of Pathologists and Royal College of Paediatrics and Child Health). The designated paediatrician responsible for unexpected deaths in childhood should be consulted where professionals are uncertain about whether the death is unexpected.

Serious Case Reviews – Chapter 8 Working Together

When a child dies, and abuse or neglect are known or suspected to be a factor in the death, organisations must consider immediately whether there are other children at risk of harm who require safeguarding (for example siblings, other children in an institution where abuse is alleged). Thereafter, organisations should consider whether there are any lessons to be learned about the ways in which they work together to safeguard and promote the welfare of children. Consequently when a child dies in such circumstances, the LSCB should always conduct a serious case review into the involvement with the child and family of organisations and professionals. The CCG should always inform its NHSE Sub Regional Team of every case that becomes the subject of a serious case review. Additionally LSCBs should always consider whether a serious case review should be conducted:

- Where a child sustains a potentially life-threatening injury or serious and permanent impairment of health and development through abuse or neglect, or
- A child has been subjected to particularly serious sexual abuse, or
- Their parent has been murdered and a homicide review is being initiated, or
- The child has been killed by a parent with a mental illness, or
- The case gives rise to concerns about inter agency working to protect children from harm

Allegations of Abuse Made Against a Person Who Works with Children – Chapter 6 Working Together (2013).
The guidance in Appendix 5 of Working Together should be followed in respect of any allegation that a person who works with children has;

- Behaved in a way that has harmed a child, or may have harmed a child, or
- Possibly committed a criminal offence against or related to a child, or
- Behaved towards a child or children in a way that indicates s/he is unsuitable to work with children, in connection with the person’s employment or voluntary activity

If concerns arise about the 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.
Flow Chart for Reporting Serious Incidents to NHS Halton Clinical Commissioning Group

DURING OFFICE HOURS
Call 01928 593479 and ask for the Chief Nurse or if unavailable contact one of the other initial contacts for SI reporting.

If SI is considered to be urgent or in event of StEIS system failure:

In all cases provider completes StEIS Report Form within 48 hours of incident & further details entered within 3 days.

NHS Halton Clinical Commissioning Group receive initial StEIS report – acknowledge receipt within 3 working days.

The Customer Services Manager (CSU) at NHS Halton Clinical Commissioning Group notifies the appropriate members of the SI Review Group.

Customer Services Manager acknowledges either investigation process has begun to provider; actions required if external investigation is to occur; agrees submission date of report; agrees actions to be taken by NHS Organisation.

NHS Halton Clinical Commissioning Group contact with NHS organisation requesting further information/actions if necessary.

NHS Organisation to complete and send any incident report to NHS Halton Clinical Commissioning Group within 60 working days.

Close Case Provider notified Post Incident Review format agreed with provider

Review to be assessed by SI Review Group

Agree any further level of investigation and monitoring of procedures by NHS Organisation through SI Review Group and report to Quality Committee.

OUT OF HOURS
If Immediate Involvement necessary call NHSNW Health Control Desk on 0860 833 5287 and ask for Mid Mersey On Call, for NHS Halton Clinical Commissioning Group immediately.
Overview of Responsibilities & Relationship, NHS Providers, NHSE SRT & NHS Halton CCG and other CCGs

PROCESS BEGINS
NHS Trust Provider – reports on STEIS

CCG Initial Assessment and reviews report against guidance.

Liaison by NHS Halton Clinical Commissioning Group with NHS Provider Lead Officer in line with policy.

NHS Halton Clinical Commissioning Group will performance manage and report to commissioning CCG.

NHSE may performance manage the SI in certain cases.

NHS Provider receives confirmation. Liaison between NHS Halton Clinical Commissioning Group & NHS Provider Lead Officer re: outline of report, Terms of Reference of Review/ Timescales via CSU.

NHS Halton Clinical Commissioning Group SI Review Group will monitor provider’s performance against 60 day deadline and will review the final investigation report.

NHS Halton Clinical Commissioning Group will provide written feedback to the provider on the adequacy of the investigation report and recommendations.

NHS Provider to proceed with review and provide initial or full management.

Where recommendations NOT agreed between NHS Halton Clinical Commissioning Group & Provider, NHSE AT to arbitrate on remedial.

NHS Halton Clinical Commissioning Group and Provider will agree monitoring arrangements against actions recommendations.

NHS Provider to provide assurances of implementation of recommendations and action plans as agreed with NHS Halton Clinical Commissioning Group.

NHS Providers provide assurances that actions

NHS Halton Clinical Commissioning Group feedback loop on outcome of cases.

NHS Halton Clinical Commissioning Group SI review Group provide Trust with confirmation of closure when satisfied that recommendations have been executed.

NHS Halton Clinical Commissioning Group feedback loop on outcome of cases.

NHS Halton Clinical Commissioning Group SI review Group share lessons learned with other CCGs and NHS North of England, NPSA & parties with vested interest.
Reporting Serious Untoward Incidents Involving Data

Checklist for Reporting, managing and Investigating Information Governance Serious Untoward Incidents

Reporting of Personal data Related Incidents

Incidents classified at a severity rating of 1-5 as highlighted in the table below are those that should be captured as Serious Untoward Incidents and should be reported via StEIS. Incident graded level 3 or above should be reported to the Information Commissioner.

Incidents classified at a severity rating of 1-2 should be treated as “for notification only “.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>No significant reflection on any individual or body. Media interest very unlikely</td>
<td>Damage to an individual's reputation. Possible media interest e.g. celebrity involved.</td>
<td>Damage to a team’s reputation. Some local media interest that may not go public.</td>
<td>Damage to a services reputation/ Low key local media coverage</td>
<td>Damage to an organisation’ s reputation / Local media coverage</td>
<td>Damage to NHS reputation/ National media coverage</td>
</tr>
<tr>
<td>Minor breach of confidentiality. Only a single individual affected</td>
<td>Potentially serious breach. Less than 5 people affected or risk assessed as low e.g. files were encrypted</td>
<td>Serious potential breach &amp; risk assessed high e.g. unencrypted clinical records lost. Up to 20 people affected</td>
<td>Serious breach of confidentialit y e.g. up to 100 people affected</td>
<td>Serious breach with either particular sensitivity e.g. sexual health details, or up to 1000 people affected</td>
<td>Serious breach with potential for ID theft or over 1000 people affected</td>
</tr>
</tbody>
</table>
Serious Untoward Incident /Complaint Review Group
Terms of Reference

Membership

Membership of the SUI/compliant Review Group will be determined in the context of the facts of the SUI but will be drawn from:

- Chief Nurse – Nurse Advisor
- Head of Mental Health/Deputy Chief Nurse
- Clinical representation and specialist advisors will be called upon to support the process as and when required
  - Additional specialist Clinical/ Nurse Advisor (as and when required)
  - Medical Advisor (as and when required)
  - Contract Lead/Lead Commissioner of service (as and when required)
  - Any other such member that reflects the degree of expertise required and as warranted by the nature of the incident

Purpose of Group

The purpose of the SUI /Complaint Review Group is to:

(a) Receive notification of all SUIs/Never Events in services commissioned by the NHS Halton Clinical Commissioning Group

(b) Receive trend analysis reports for complaints received about commissioned providers

(c) Ensure that learning from SUI/Never Event and Complaint investigations is used in the commissioning process and that lessons learnt are appropriately disseminated.

For SUI/Never Events

- Review initial information provided
- Identify and engage additional expertise as required
- Cross reference detail of initial serious untoward report with provider’s terms of reference for review
- Identify potential gaps and make recommendations to be included or excluded from review
- Confirm lead for communications with provider
- Review draft report against terms of reference
- Accept / reject initial management report and review draft action plan
- Agree actions in terms of performance / standards / governance contract review
- Accept / reject action plan
- Confirm update frequency on action plan
- Monitor progress of action plan
- Make recommendations to providers in order to improve quality/safety of the services provided
- Agree assurances and agree closure of incident
- Provide Performance Reports to Commissioning Groups (CQPGs)
- Manage poor performance issues with provider
The group will meet fortnightly, reviewing all new incidents and any reports or action plan updates received.

**Reporting Arrangements**

The SUI Performance Management Group Management Group will report via NHS Halton Clinical Commissioning Group’s Quality Committee according to the corporate calendar.
## SI /Complaints Review Group

### SI Investigation Report Evaluation Template

<table>
<thead>
<tr>
<th>Incident Ref Number</th>
<th>Date Incident Reported</th>
<th>Date Report Due</th>
<th>Date Report Received</th>
<th>Date of SI Performance Management Review</th>
<th>Date feedback sent to Trust</th>
<th>Date Incident Closed by NHS Halton Clinical Commissioning Group</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Action required</th>
<th>Person responsible</th>
<th>Date for completion</th>
<th>Date completed.</th>
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<table>
<thead>
<tr>
<th>Essential Criteria</th>
<th>Met</th>
<th>Not Met</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1) Incident Description:</strong> Brief description of incident and outcome. This should include date of incident and actual effect on the person/organisation harmed as a result of the incident</td>
<td></td>
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<tr>
<td><strong>2) Appropriate terms of reference which have been adhered to.</strong> This should include a focus on systems and processes not just individuals.</td>
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<tr>
<td><strong>3) Details of an appropriate review Team.</strong> The members of the review team should be appropriate to the incident in relation to knowledge, use of experts and use of external specialists.</td>
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<td>4) Evidence of appropriate communication, involvement and support of the person affected by the incident or their family. In line with the NPSA Being Open Alert</td>
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<td>5) Evidence of appropriate support provided to staff after the incident and during the investigation.</td>
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<tr>
<td>6) Summary of investigations methods used. This may include statements, review of records, gaining reports, timelines etc.</td>
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<td>7) Clear fact based chronology of events leading up to the incident. This should be comprehensive in order to create a picture of unfolding events.</td>
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<td>8) Notable practice sensitively reported when applicable.</td>
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<tr>
<td>9) Care and Service delivery Problems identified. Areas of risk, what should have happened that did not and what did happen that should not.</td>
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<tr>
<td>10) Contributory Factors identified. Things that have or may have contributed to the incident happening.</td>
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<tr>
<td>11) Root causes identified. Causes identified backed up with evidence. This should include identification of weak /unsafe systems within the organisation.</td>
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<tr>
<td>12) Clear links /threads between cause and effect. On reviewing report clear links between root causes and contributing factors can be seen. These are reflected in the conclusions made.</td>
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<tr>
<td>13) Recommendations and action plans. The recommendations address the root causes and contributing factors identified. The action plan is specific and measurable with clear completion dates and monitoring arrangements are in place.</td>
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<tr>
<td>14) Evidence of execution of action plan. Is there evidence that actions have been started / completed</td>
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<td>15) Has the report been circulated appropriately Does the report indicate where it has been or will be discussed within the reporting organisation</td>
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Lessons for Commissioners

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