NHS Manchester Clinical Commissioning Group

Manchester Health & Care Commissioning

MANCHESTER CITY COUNCIL

Corporate Policy

Policy for the Performance Management of Serious Incidents and Never Events within Commissioned Services

Date Approved: September 2017

Contents

Document Control Sheet

Title of document:	Policy for the Performance Management of Serious Incidents and Never Events within Commissioned Services		
Supersedes:	Incident Reporting and Management Policy including Serious Incidents) V 1.1		
Placement in Organisation:	Manchester Health and Care Commissioning		
Consultation/Stakeholders	MHCC Leads Quality Team Corporate Services Team		
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Department/Team:	Quality and Performance Team		
Approved by:			
Approval date:		Review date:	August 2020
Implementation Date:			
Implementation Method:	MHCC Website Manchester Matters		

This document is to be read in conjunction with the following documents:

Serious Incident Framework, NHS England (2015)

Revised Never Events Policy and Framework, NHS England (2015)

1.0 Introduction	
1.1	This policy underpins Manchester Health and Care Commissioning (MHCC) risk management framework. It sets out the systems, processes and accountability within MHCC for the reporting; investigation; monitoring and management of MHCC serious incidents and provider serious incidents, including Never Events. The term 'provider' relates to any healthcare organisation that is commissioned by MHCC (NHS funded care) including acute NHS Trusts; small providers; mental health services; primary care organisations and nursing homes. By adopting this policy, MHCC aims to improve the organisation's ability to: • Commission high quality, safe and accountable health services, • Provide assurance there are appropriate systems and processes in place to mitigate future risk • Demonstrate a learning culture within the organisation • Minimise risk to patients and members of the public
1.2	The policy complies with NHS England's *'Serious Incident Framework: Supporting learning to prevent recurrence'* (2015). The Policy sets out locally agreed principles to ensure consistency in Serious Incident management. This reflects the recommendation in the Serious Incident Framework (2015) that commissioners must work collaboratively to agree how best to manage Serious Incidents that occur in commissioned services.
1.3	All Serious Incidents will follow the pathway set out in the Serious Incident Framework (2015) which is illustrated in Appendix A.
1.4	The priority of MHCC is to ensure that Serious Incident investigations achieve their fundamental purpose of ensuring that lessons are learnt and appropriate interventions and actions are implemented to prevent similar incidents from re-occurring.

1.5	The NHS England National Frameworks can be found at the following links: NHS England Serious Incident Framework: Supporting Learning to Prevent recurrence https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf • NHS England Serious Incident Framework 2015/2016 – Frequently asked questions https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2016/03/serious-incdnt-framwrk-faqs-mar16.pdf • NHS England Revised Never Events Policy and Framework https://www.england.nhs.uk/wp-content/uploads/2015/04/never-evnts-pol-framwrk-apr.pdf
1.6	The Serious Incident Framework (2015) replaces the following: • **'National Framework for Reporting and Learning from Serious Incidents Requiring Investigation'** issued by the National Patient Safety Agency (March, 2010). • NHS England's **'Serious Incident Framework'** (2013). • **'National Patient Safety Agency Independent investigation of serious patient safety incidents in mental health services, Good Practice Guide'** (2008). The Serious Incident Framework (2015) confirms the underlying principle of Serious Incident investigation which is to ensure that lessons are learned and that 'Fair Blame' is considered where necessary. The framework ensures that incidents are systematically analysed using a robust root cause analysis approach as a powerful mechanism for driving improvement

2.0 Purpose	
2.1	The purpose of this policy is to set out a consistent and explicit agreement as to how the principles of The Serious Incident Framework (2015) will be applied to the performance management of Serious Incidents that occur within the regions covered by MHCC.
2.2	The policy has been written to define the role of MHCC in managing their provider organisations to improve patient safety through the Serious Incident investigation process.
2.3	The NHS Standard contract advises that all providers must be complaint with NHS England's Serious Incident Framework. This policy is not intended to replace the policies of NHS funded care providers. All commissioned providers will be expected to incorporate the requirements of the NHS Serious Incident Framework (2015) within their organisational policies.
2.4	MHCC expects providers to remain cognisant of the interfaces with national guidance as listed below: Deaths in Custody- where health provision is delivered by the NHS Prisons and Probation Ombudsman (PPO): Clinical Reviews Part 1 – Commissioning bodies. September 2014 Serious Case Reviews Safeguarding Adult Reviews Working Together to Safeguard Children Domestic Homicide Reviews Domestic Violence, Crime and Victims Act 2004, Section 9 (3) NHS England. Serious Incident Framework: *Serious Incidents in National Screening Programmes* NHS England. Serious Incident Framework: • Homicide by patients in receipt of mental health care • Interim Guidance for Managing Screening Incidents (2015) MHCC expects all providers to remain updated of any changes to the above guidance and any other guidance updates around Serious Incidents without prompting by MHCC.

2.5	This policy does not replace the providers duties around informing necessary bodies such as the Care Quality Commission (CQC); Nursing and Midwifery Council (NMC)/ General Medical Council (GMC); Coroner etc. of incidents in accordance with The Serious Incident Framework (2015) as highlighted within Appendix B
2.6	MHCC will update this policy in line with changes to National guidance.

3.0 Operational Assurance Framework

3.1	The responsibilities for the management of Serious Incidents within MHCC lie within the Quality team. The ultimate responsibility sits with the Clinical Directors for MHCC. Please see the Terms of Reference and the Standard Operating Procedure in Appendices B&C.
3.2	**Provider Serious Incidents:** The management of Serious Incidents and the subsequent reports submitted to the MHCC are managed through a two level process. The first level is at Clinical Director (GP) level. The Clinical Director with responsibility for quality independently reviews the Serious Incident report. Their comments are forwarded to the Serious Incident Officers, to be disseminated to the Serious Incident Operational Panel (SIOP) members- to be considered during the SIOP meeting. The second level is a multi-disciplinary SIOP. This panel consists of a Clinical Director; nurse/midwife; safeguarding nurse/midwife; medicines management and a Serious Incident Officer (administration). There is an expectation that all members will have read each report and therefore in a position to offer comment during the SIOP. A number of Serious Incident Reports are reviewed at this panel and feedback to the provider is created, in line with the 20 day timeframe stated in the Serious Incident Framework (2015). A collective decision is made to determine if the panel are assured that future risk has been mitigated on completion of the action plan. A report may not be assured at local level if more detailed information is required from the provider. If the provider does not offer adequate assurance then this will be

	escalated to the Clinical Director to seek assurance from a similar level director within the trust. A closure checklist, amended from the Serious incident Framework (2015), is completed and the decision to close the incident on the Strategic Executive Information System (StEIS) is agreed.
3.3	**MHCC Serious Incidents:** For incidents that occur within MHCC itself the process is effectively the same, in that the incident is investigated by an appropriately trained lead investigator and panel at MHCC. The Serious Incident Team will support investigators through the whole process. The subsequent report is reviewed by the Serious Incident panel at Greater Manchester Health & Social Care Partnership (GMHSCP) where a collective decision is made to determine if the panel are assured that future risk has been mitigated on completion of the action plan. A closure checklist is completed and the decision to close the incident on StEIS is agreed. A report may not be assured at this level if more detailed information is required from MHCC, when further information has been received and agreed the incident is closed on StEIS.
3.4	**Safeguarding:** For Serious Incidents involving a child, the MHCC must ensure that its responsibilities are carried out in accordance with the NHSE Serious Incidents Framework (2015). Providers and commissioners must liaise regularly with the Local Authority. To ensure a coherent multi-agency approach to the investigation and response to safeguarding concerns. All child deaths are reviewed by a Child Death Overview Panel (CDOP). If a child death is also a Serious Incident then the MHCC Serious Incident Team will review the report as part of the normal process and forward the report and the SIOP comments/feedback to the CDOP for their consideration. Where there are safeguarding concerns which require further enquiry these will be reviewed under the Local Children's Safeguarding Board Structures (LSCBs). Where the Serious Incident does not lead to the death of a child these will be reviewed as per this policy for all Serious Incidents. Any Serious Incident involving safeguarding adults may be reviewed as part

	of the Safeguarding Adults Review processes. The results of these investigations will form part of the overall report. MHCC must be complaint with NHSE Serious Incident Framework (2015) and the Care Act (2014). Where a safeguarding concern is raised as part of the review process these will be shared with the safeguarding teams of MHCC, this will then be taken into consideration within the local panel and also SIOP. Domestic Homicide reviews will follow the process outlined within the NHSE Serious Incident Framework (2015). MHCC must provide a panel member and work with the Community Safety Partnership, in accordance with the Domestic Violence, Crime and Victims Act (2004), to ensure that all action plans are implemented locality ensuring lessons learned are shared across providers. Deaths in Custody must be managed as per NHSE Serious Incident Framework (2015). If the patient has been detained under the Mental Health Act (2005) the provider is responsible for reporting this to the CQC without delay. MHCC will be informed by the provider where the cause of death is unknown or where there is reason to believe that the death may have been avoidable or unexpected including suicide and self-inflicted death. MHCC can then expect the incident to be investigated as per the Serious Incident Framework (2015) with consideration to commissioning an independent review.
3.5	**Terms of reference for reviews:** Terms of reference have been developed for the Clinical Director and SIOP reviews, which can be found in Appendix B.
3.6	**Aims and Objectives of the Clinical Director review and SIOP** The aims and objectives of the panels are as follows: i) To review and monitor all Serious Incidents occurring within services commissioned by MHCC, in line with the National guidance and the Serious Incident Management Policy.

ii) To receive Serious Incident investigations completed by other commissioning organisations when they concern patients who are registered with MHCC GPs

iii) To determine if Serious Incidents have been adequately investigated and if the root causes and contributory factors have been appropriately identified

iv) To determine if the recommendations and action plan adequately address the root causes and contributory factors identified

v) To agree that sufficient action has been taken to eliminate or reduce risk of recurrence to an acceptable level and that action plans are completed in a timely manner

vi) To use thematic analysis to identify themes and trends reporting appropriately into boards and committees. This work should also include the work streams between MHCC and the providers to implement agreed improvement plans

vii) To agree to closure of an incident once panels are satisfied that lessons learned have been identified and practicable risk mitigated

viii) Receive reports from the Director of Public Health in relation to serious incidents reports for Health Care Associated Infections

Escalate any concerns identified to quality and performance meetings and/ or clinical lead.

4.0 Responsibilities

4.1 **RASCI Matrix**

A generic RASCI Matrix is illustrated in Appendix D as a guide to roles and responsibilities of the Serious Incident process within MHCC, detailed responsibilities are described below.

4.2	**Accountable Officer** The Accountable Officer has overarching accountability for managing providers responses to Serious Incidents and where appropriate for commissioning and co-ordinating SI investigations.
4.3	**MHCC Board** MHCC must assure itself of the quality of services commissioned and hold providers to account for their management of Serious Incidents. MHCC Board receives quality and performance reports regarding all provider Serious Incidents; root causes; trends; and lessons learned which demonstrates organisational learning and actions to prevent recurrence. It receives a summary of noteworthy investigations, including all Never Event investigations, with recommendations and actions in the confidential section of its meeting.
4.4	**MHCC Committee with Responsibility for Quality** Serious Incidents are reported into the Quality and Performance Committee monthly. These reports are generated by the Serious Incident officers and signed off by the Clinical Quality Manager; they detail themes and trends of each provider organisation. The Committee receives assurance from the provider that the actions taken to investigate Serious Incidents and to mitigate the risk of future occurrences are appropriate, robust and in line with national guidance.
4.5	**MHCC Clinical Director with Responsibility for Quality** Overall responsibility for the management of Serious Incidents rests with the MHCC Clinical Directors who are accountable to the Chief Accountable Officer. The Clinical Leads are responsible for ensuring that MHCC has appropriate systems and processes embedded to support effective management and evaluation of Serious Incidents. These arrangements must include a

	Standard Operating Procedure for the process; ability to assess the quality of the Root Cause Analysis report; national standards to support closure of the incident on StEIS and robust processes for monitoring thematic and bespoke action plans that arise from Serious Incidents.
4.6	**Quality Team** The Quality Team has responsibility for participating in the MHCC process to ensure all commissioned providers are reporting; investigating; learning appropriate lessons from Serious Incidents and implementing actions to mitigate risk in line with this policy. Individual responsibility is detailed below.
4.7	**Quality Lead** The Quality Lead has responsibility for the strategic management of the process and is a source of advice relating to all matters arising from Serious Incidents. • Presentation of Serious Incident themes, clusters and trends to Quality and Performance Committees.
4.8	**Clinical Quality Manager** Clinical Quality Manager has responsibility for the tactical management of the process and is a source of advice relating to all matters arising from Serious Incidents. • Escalating SIOP issues to the within MHCC (see Appendix F for escalation criteria) Quality Improvement Committee or NHS England when indicated. • Supporting providers where timeliness or quality concerns have been identified in the Serious Incident process. • Attendance at relevant meetings with providers, neighbouring CCGs and NHS England to review trends and best practice concerning Serious Incidents. • Presentation of Serious Incident status and trends; themes and clusters at Provider Analysis Meeting and FQP (as necessary).

- Review further assurances forwarded by the provider, as necessary, ahead of closing incidents.

4.9 **Serious Incident Manager**

- Operational Management of the Serious Incident process, including overseeing the organisation of SIOP and ensuring that time frames for reporting and feedback are adhered to.
- Reviewing and approving any extension requests that may be received from providers. See Appendix E for extension criteria.
- Reviewing and approving downgrade requests, which includes any incident that providers are either unsure is a Serious Incident or feel no longer meet the threshold, taking advice from the Clinical Directors as necessary. See Appendix E for extension criteria.
- Closing incidents on StEIS following SIOP.
- Support the Clinical Quality Manager in the review and update relevant guidance to reflect changing policy and practice as and when required.
- Ensure StEIS is always up to date.

4.10 **Serious Incident Officers**

The Serious Incident officers have responsibility for:

- Reviewing and uploading all StEIS alerts received into Datix within two working days of receipt.
- Maintaining and updating the data about each Serious Incident on Datix; the internal database and StEIS.
- Monitoring Serious Incident deadlines and liaising with providers to ensure a timely response, escalating any delays or extension

requests to the Serious Incident Manager or the Clinical Quality Manager for consideration.

- Coordinates and sends out Serious Incident reports to GPs for comments, ahead of SIOP
- Administration responsibility for twice monthly SIOPs, which includes:
    - Organising dates and booking rooms for SIOPs
    - Collating a file for all Serious incidents to be reviewed
    - Preparing the Serious Incident reports
    - Gathering comments provided by health professionals unable to participate in the SIOP
- Attends SIOP to complete the closure checklist at SIOP, noting MHCC feedback
- Forwards MHCC feedback to providers
- Files the closure checklist and outcome of SIOP in Datix and internal database
- Compiling and circulating and managing actions following each panel
- Supports the Serious Incident Manager, Quality Lead and Clinical Quality Manager in undertaking the required actions identified at each panel
- Requests any additional information required by panels for assurance from providers
- Liaising with other MHCCs in multi-commissioner Serious Incidents

4.11 **Duties of commissioned organisations**

Serious Incident management is a critical component of corporate and

	clinical governance, the burden of responsibility rests with the provider of care where the incident occurred. The provider is accountable to MHCC as the lead commissioner for their healthcare services. The provider has a responsibility to have a policy in place for the management of Serious Incidents and robust systems to support this process. Healthcare providers have an obligation to identify; correctly categorise incidents; report incidents, including internal reporting incident systems and external bodies, such as StEIS; investigate incidents using Root Cause Analysis methodology; learn lessons and put improvements in place to avoid recurrence, in line with the Serious Incident Framework (2015).
5.0 Definitions of Terms Used	
5.1	For a full list of the terminology please refer to the NHS England Framework 2015 which can be downloaded from: https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/serious-incidnt-framwrk-upd2.pdf
5.2	For a full list of the terminology used for Never Event definitions please refer to the NHS England Revised Never Events Policy and Framework which can be downloaded from: https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/never-evnts-pol-framwrk-apr2.pdf
5.3	A list and narrative around reporting to external bodies can be found in Appendix G.
6.0 Process for Approval & Ratification	
6.1	This policy will require approval from the Quality and Performance Committee. Once ratified this policy will supersede all previous incident reporting policies and procedures.
7.0 Dissemination, Training & Advice	
7.1	In order that this policy is disseminated and implemented correctly the following will occur after ratification:

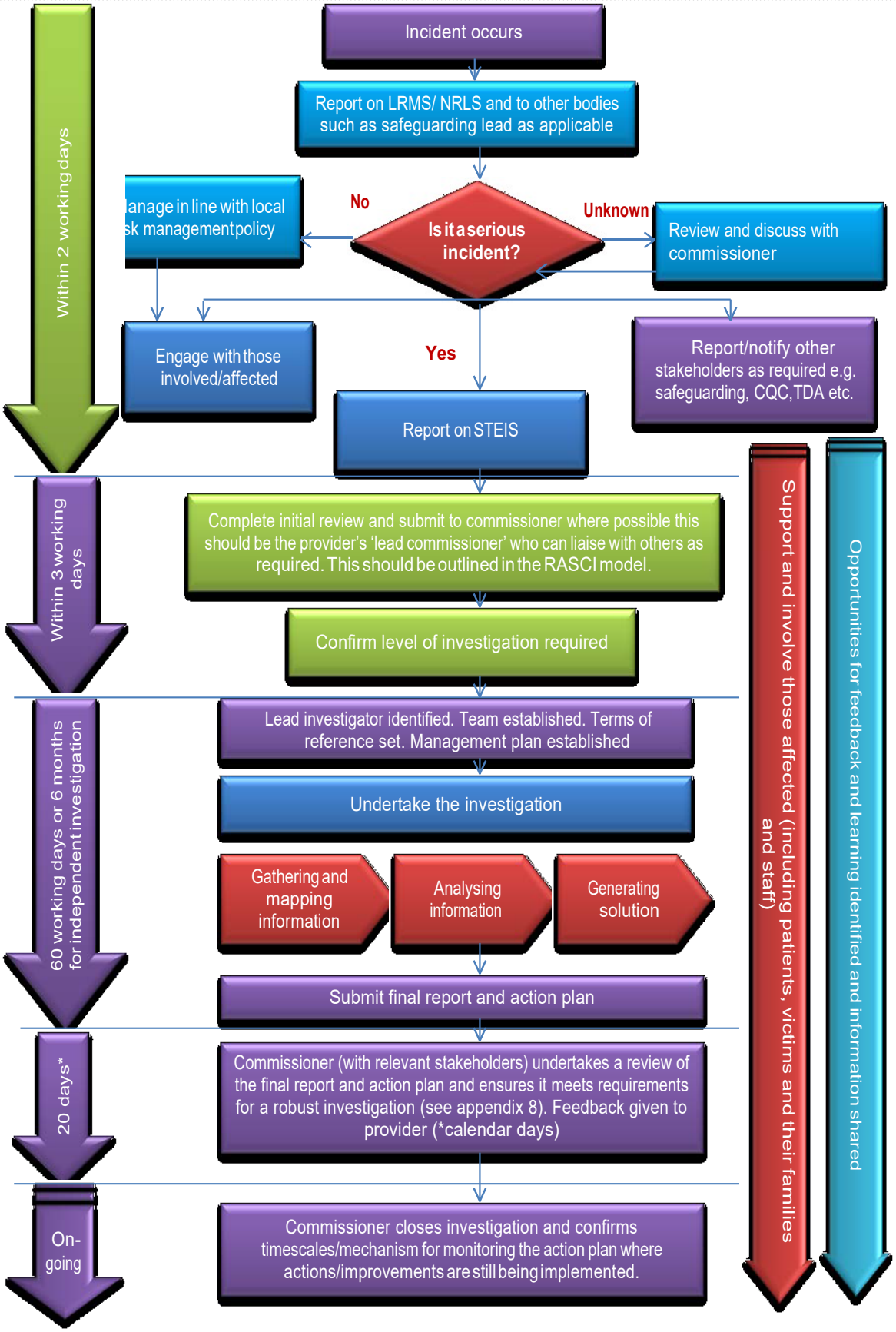
	• The policy will be published on the MHCC website and relevant links sent out via the communications and engagement department. • Senior managers will make their staff aware of the policy. Training and advice regarding Serious Incidents within the MHCC can be sought through the Serious Incident Team.
8.0 Review, Monitoring and Compliance	
8.1	This policy will require review every three years. Should national guidance change before the review date or if local practices change, then earlier review will be necessary.
9.0 Legislation and Guidance	
9.2	This policy is underpinned by the following legislation, NHS guidance and policies: • NHSE- Serious Incident Framework (2015) • NHS England Revised Never Events Policy and Framework • Domestic Violence, Crime and Victims Act 2004, Section 9 (3) • Prisons and Probation Ombudsman (PPO): Clinical Reviews Part 1 – Commissioning bodies. September 2014
10.0 References	
10.1	NHS England Framework 2015 which can be downloaded from: https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/serious-incidnt-framwrk-upd2.pdf
10.2	NHS England Revised Never Events Policy and Framework which can be downloaded from: https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/never-evnts-pol-framwrk-apr2.pdf

11.0 Version Control

V1	31/08/2017	*Original Policy*

PLEASE NOTE: the most recent version of this document is available on the MHCC website. Printed copies (or saved electronic copies) must be checked to ensure they match the most recent version.

Appendix A: Serious Incident Pathway



Appendix B: ToR and Structure for Clinical Director Reviews & SIOP

Serious Incident GP review and Serious Incident Operational Panel

Terms of Reference

1. Structure

When a Serious Incident (SI) occurs in a Healthcare organisation a Root Cause Analysis investigation is undertaken by the provider and a report is submitted to MHCC. A SI means that a patient, visitor or member of staff has suffered moderate to severe harm or there is significant learning from an incident which warrants reporting.

The reports are initially reviewed by a GP from MHCC, with responsibility for leading on quality for Manchester.

A Serious Incident Operational Panel (SIOP) meets to discuss a collection of SI reports with the purpose to provide feedback to the provider and close the incident on StEIS (Strategic Executive Information System). The reports are scrutinised to ensure the correct root cause and contributing factors have been identified and the action plan addresses these, in order to mitigate the risk of recurrence. The panel also has responsibility for gaining assurance from providers regarding lessons learned, appropriate dissemination of learning together with reviewing evidence that supports changing practices, reinforced by policy amendments as applicable.

The SIOP reports into the Quality and Performance (Q&P) Committees of both MHCC and Trafford CCG- highlighting numbers of SIs from the different Providers; numbers of SIs that remain active and closed on StEIS; themes and trends and actions in progress (thematic).

2. Membership

2.1. *The GP review:*

2.2. This review is undertaken by a GP with responsibility for leading Clinical Quality.

2.3. The opinion of the GP should include any clinical challenge to the findings in the report; commendable practices; identification of the correct root cause and

contributing factors; appropriate action to mitigate future risk and any objection to the incident being assured and subsequently closed on StEIS.

2.4. Their comments are forwarded to the SIOP members for consideration at the SIOP.

2.5. *The SIOP:*

2.6. In order for the SIOP meetings to be effective, it is essential that there is representation from various clinical and non-clinical backgrounds including medical; nursing; safeguarding; medicines management and patient representation to ensure meaningful discussion and to inform the feedback.

2.7. The SIOP will be chaired by a GP Quality Lead on a rotational basis.

2.8. The deputy chair will be one of the MHCC Quality team.

2.9. The Group may nominate other expert representatives as appropriate.

2.10. Deputies should be nominated to attend in the absence of quoracy member or as a minimum their comment forwarded to the SIOP members.

Specialist Area	Representation
Medical	GP (Clinical Quality Lead)
Nursing	Quality Lead; Clinical Quality Manager
Safeguarding	Designated Safeguarding Nurse
Medicines Management	Medicines Optimisation Advisor
Patient Representation	Quality Officer
Administration	Serious Incident Officer

MHCC	
GP Clinical Director GP Clinical Lead	Dr Manisha Kumar manisha.kumar1@nhs.net David Adams-Strump david.adams-strump@nhs.net
Senior Clinical Quality Manager (RN & RM)	Bev Hunt Beverley.hunt@nhs.net

Serious Incident Manager	TBC
Quality administration	Catherine Whiteley catherine.whiteley@nhs.net
Safeguarding Adults Nurse	Anne Kubiak Anne.kubiak@nhs.net Louise Honour Louise.honour@nhs.net
Safeguarding Children Nurse	Anna Berry (CW) anna.berry@nhs.net
Medicines Management	Mary Crabb m.crabb@nhs.net

3. Quoracy

3.1. It is preferable that representatives attend SIOP from each of the membership groups stated in the table, above. As a minimum a SIOP can only proceed with the attendance of the following or their deputies:

- Clinical Quality Lead (GP);
- Clinical Quality Manager or Quality Lead (nurse);
- SI Manager or SI Officer or Quality Officer.

3.2. The meeting can proceed without the attendance of safeguarding representatives or medicines management providing they have submitted relevant feedback, in writing, relating to their specialism.

4. Timeline for reviews and SIOP

4.1. On receipt of an SI report by the SI Team, the SI Report will be forwarded to the GP Quality Leads on a weekly basis (typically Wednesday or Thursday)

4.2. The GP feedback will be expected to be returned to the SI inbox within 5 working days

4.3. SIOPs will be held twice monthly or weekly- as necessary

4.4. New reports received by the SI officers (in the SI inbox) will go through the following process:

a) The incident will be reviewed by a GP Clinical Lead
b) The incident will be added to the next SIOP
c) GP's feedback disseminated to SIOP panellists
d) The reports for the SIOP will be disseminated to the panellists for them to read, at least 5 working days ahead of the SIOP
e) The SIOP is held and the incident is discussed and feedback formed
f) The panel feedback is forwarded to the provider (assured or assurances sought) within 20 calendar days (Serious Incident Framework, 2015)
g) Further assurances received (as appropriate)
h) The incident is closed on StEIS (not time limited)

4.5. Where relevant the non-attendees will provide panellists with their comments at least 3 working days prior to the SIOP.

4.6. Reports that are part of a notable backlog will be managed by the Clinical Quality Manager, in terms of a timetable will be agreed with the SI Officers to execute. This will be subject to which element of the process the reports have failed to be reviewed.

5. Purpose

5.1. The purposes of both the GP review and the SIOP are to:

- Comprehensively review all SI reports that are submitted by the provider to MHCC from a multi-disciplinary perspective.
- Ensure critical analysis of all reports, in that they include a root cause; contributing factors; no individuals were inappropriately blamed; the action plan addresses the issues raised; there is clear learning identified and Duty of Candour standards have been met.
- Review additional assurances when they have been submitted by the provider- as requested by the SIOP/expert panellists.
- Make the decision at the SIOP for final closure once the panellists are satisfied that the incident was investigated by the provider with demonstrable integrity.
- Production of themes and trends reports into MHCC Q&P Committees together with an annual report for the overarching locality to report to the Boards.
- Clarifying duties within the teams which will then form part of the action log

- Where required, and as a result of thematic trends, contract variation discussions may need to take place with the provider. The decision to raise an action will be taken by members of the SIOP.
- Regular review of MHCC *'Policy for the Performance Management of Serious Incidents and Never Events within commissioned providers.'*

5.2. The SIOP will consider all issues identified in relation to the above and report them in an action log for appropriate actions, escalating where necessary to the Q&P committees for MHCC and Trafford CCG.

6. Scope & Duties

6.1. The SIOP will critically review the reports submitted by the providers, seeking further assurance where required.

6.2. The Quality Team senior representative will have a clinical background.

6.3. All members of the SIOP must be satisfied that the report meets the closure guidance, set out in the *'Serious Incident Framework' (2015),* before it is recommended for closure on StEIS.

6.4. This group will monitor and review the themes and trends of incidents and quality for all serious incidents for all commissioned services for the patients of MHCC.

6.5. SIOP will be responsible for the final decision to close on StEIS. Inherent in this is the acknowledgement that MHCC devolve this responsibility to whichever clinical director is chairing that meeting.

7. Responsibilities

7.1. Administrative support for the SI process is provided by the SI Officers within MHCC Quality Team. All correspondence and subsequent actions will be documented and followed up by them, using the Datix system and the MHCCSI Database. The SI Officers are responsible for monitoring and auditing SIs for MHCC and producing reports to be fed into MHCC Q&P Committee by the Serious Incident Manager/Clinical Quality Manager/Quality Lead.

7.2. The Quality Officers have responsibility for offering comments to the SIOP from a patient experience angle, as necessary.

7.3. The Safeguarding nurses have responsibility for providing feedback relating to all aspects of safeguarding, including legislation such as Deprivation of Liberty Safeguards within the Mental Capacity Act (2005).

7.4. The Medicines Management representative has responsibility for providing feedback regarding the prescribing, dispensing and administration of all medications including pharmaceutical, non-pharmaceutical and intra venous fluids.

7.5. The Serious Incident Manager will be responsible for the operational management of the whole process, ensuring the providers and MHCC Quality Team meet the national guidance for SIs.

7.6. The Clinical Quality Manager will have responsibility for the tactical management of the SI process from a nursing and midwifery perspective, including professional adherence to the NMC Code of Professional conduct. The Clinical Quality Manager will be responsible for reporting and presenting PowerPoint Presentations to MHCC Q&P Committee.

7.7. The Quality Lead has responsibility for overseeing the SI process from a strategic perspective and escalating any issues as necessary to the Director of Quality and Performance.

7.8. The GP Clinical Quality Lead has responsibility for chairing the SIOP meetings and managing the SI process from a medical, including professional adherence to the GMC Code of Practice (2013). The Clinical Quality Lead has responsibility for tactical management of the SI process from a medical viewpoint.

7.9. The Clinical Director has strategic responsibility for the SI process.

7.10. Overall, the panel has responsibility for gaining assurance from the provider that all necessary steps have been taken to mitigate the risk of recurrence. The panel must be assured that the provider demonstrates a ‘learning culture’ and can evidence dissemination of learning across the service and organisation.

8. Reporting & Authority

8.1. If significant issues arise, such as a notable backlog of SI reports that have not been appropriately reviewed, an action log will be created and submitted to the Q&P Committee for MHCC. The Clinical Quality Manager will take ownership of the actions and provide regular updates to the Q&P Committee until such time the issues have been resolved.

8.2. Where required, the action log will be escalated to Board as deemed appropriate by the Quality Lead or Clinical Quality Director.

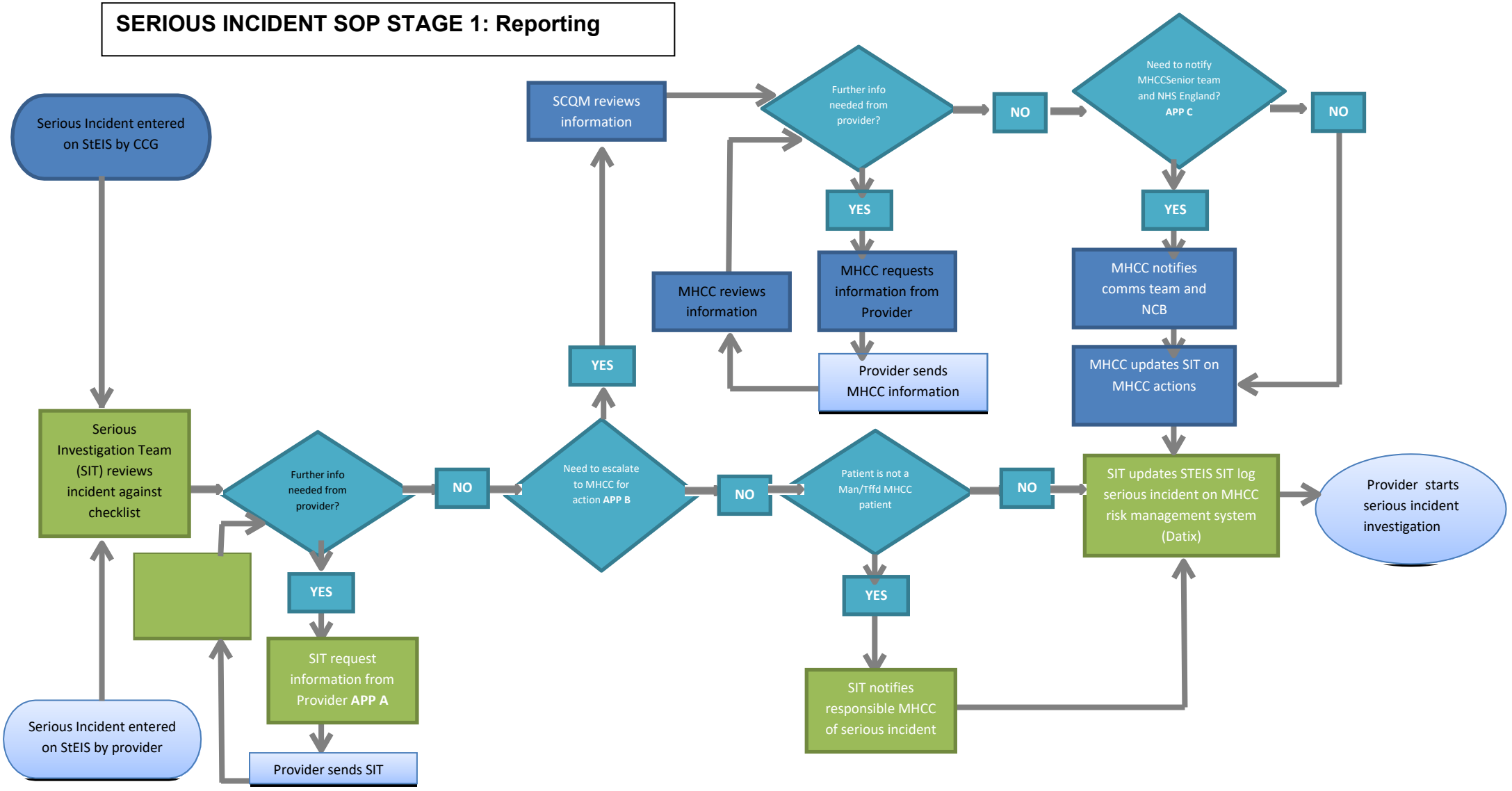
9. Review of Terms of Reference

9.1. The Terms of Reference for the GP review and SIOP will be reviewed as necessary, guided by the publication of amended, new and contemporary national guidance from NHS England, but as a minimum every 3 years.

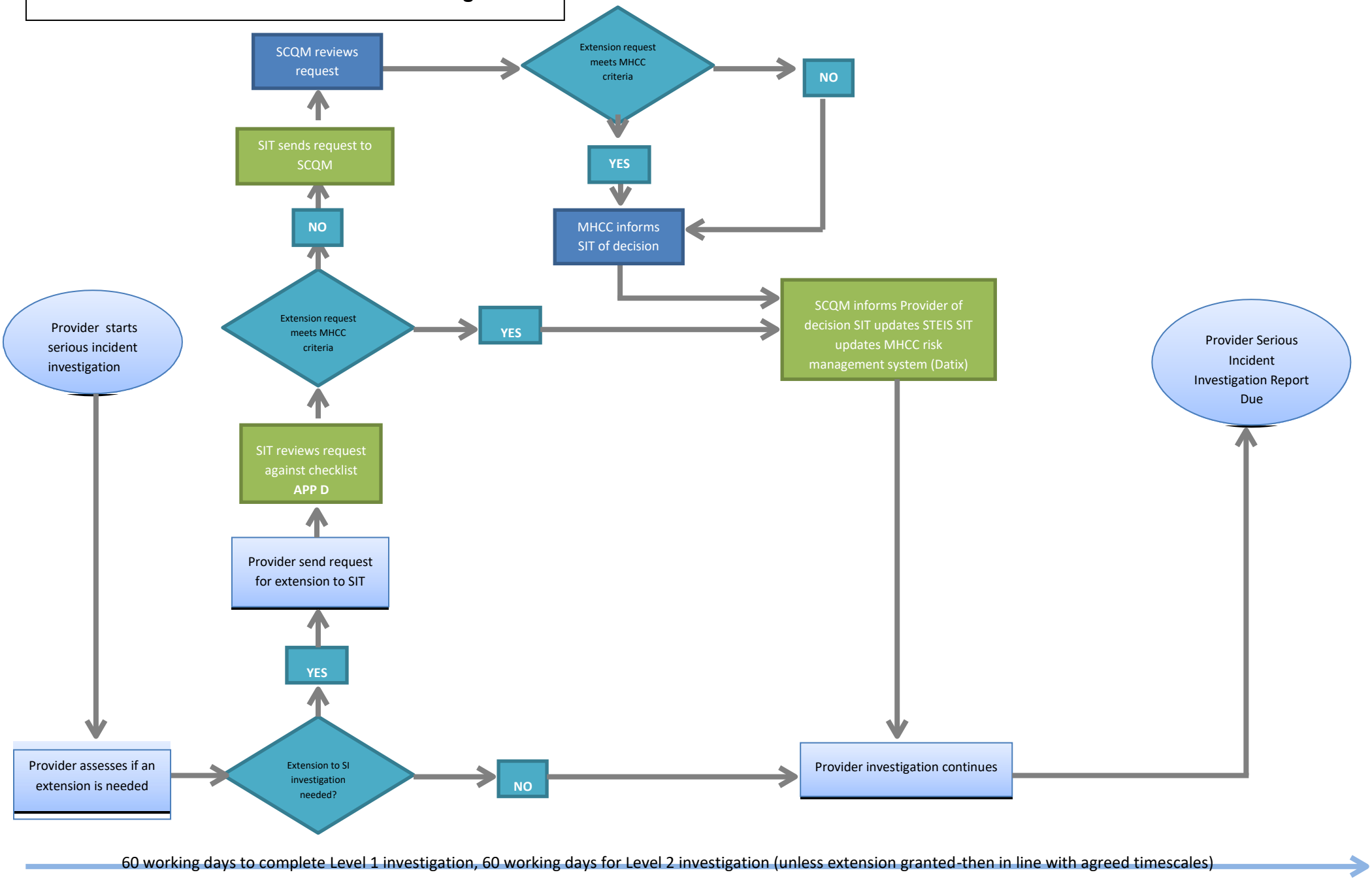
Date Terms of Reference Agreed – August 2017
Date of Next Review – August 2020

Appendix C: Detailed Standard Operating Procedure

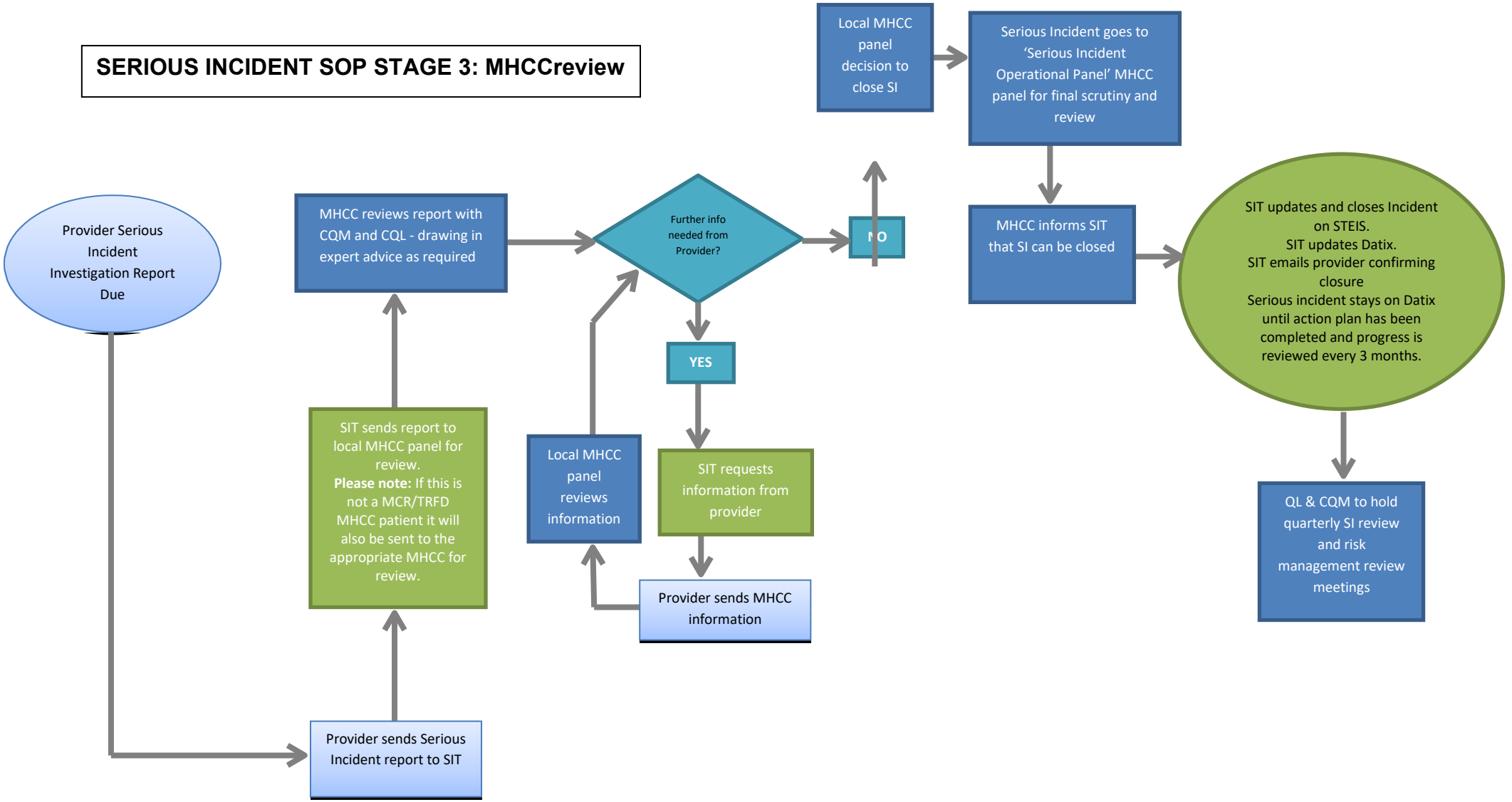
SERIOUS INCIDENT SOP STAGE 1: Reporting



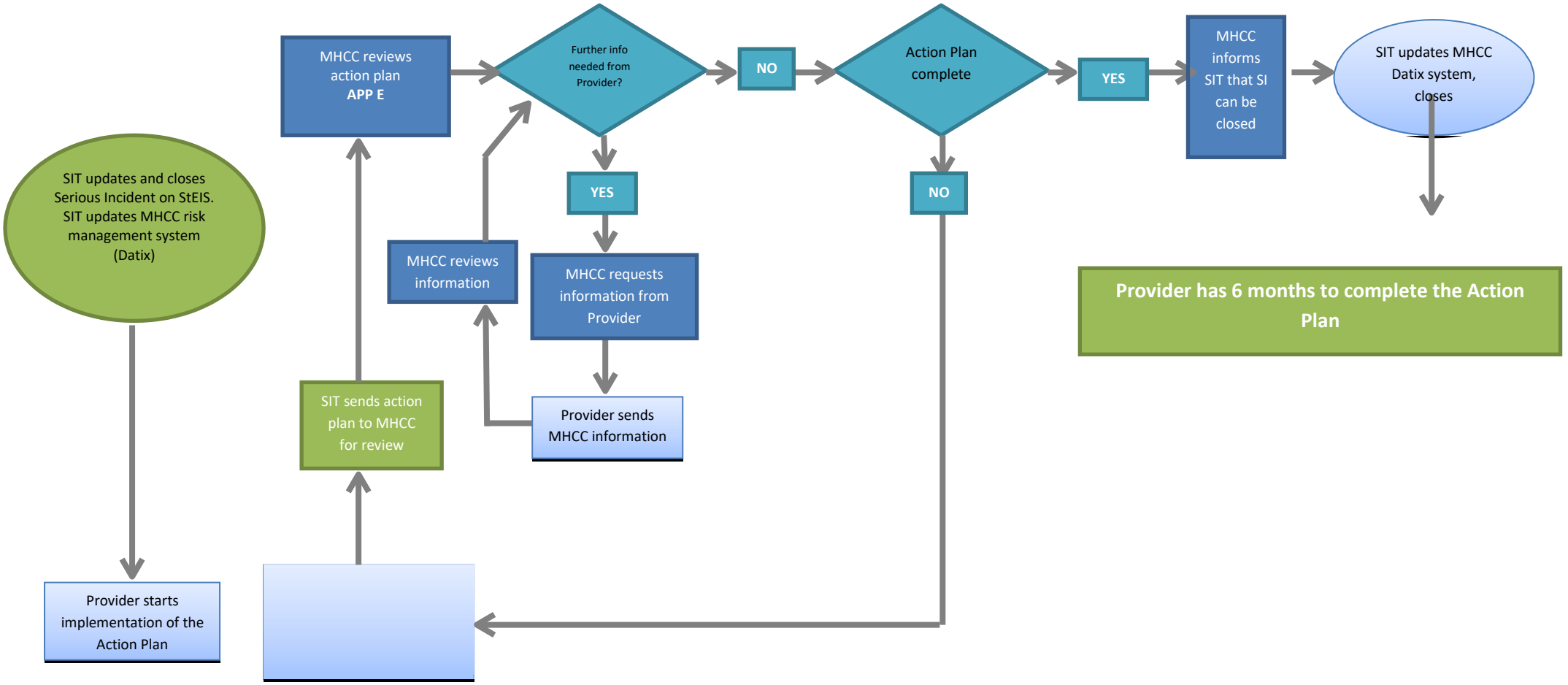
SERIOUS INCIDENT SOP STAGE 2: Investigation



SERIOUS INCIDENT SOP STAGE 3: MHCCreview



SERIOUS INCIDENT SOP STAGE 4: Closure



Appendix D: RASCI Management Matrix

Responsible	Accountable	Supports	Consulted	Informed

Action	Accountable officer	MHCC Board	MHCC Committee	Clinical Director	Quality Lead	Clinical Quality Manager	Serious Incident Manager	Serious Incident Officer
The management of Serious Incidents (process)	A	I	I	R	C	R	R	S
Ensuring that MHCC has appropriate systems and processes embedded to support effective management and evaluation of Serious Incidents.	I	I	I	A	R	R	C	S
Ensuring that providers adhere to the national guidance and local policies for reporting Serious Incidents	I	I	I	A	A	R	R	S
Escalating non-adherence to national guidance and local policy, communicating and supporting providers to rectify issues within the process	I	I	I	R	A	R	I	S
Organising SIOPs and disseminating reports ensuring MHCC process is robust	I	I	I	C	C	A	R	R
Monitoring the management of all providers' Serious Incidents on internal systems	I	I	I	C	C	A	R	R
Reviewing Serious Incident reports	I	I	I	A	I	A	R	S
Provide feedback to providers following SIOP panel with a view to being assured and close on StEIS	I	I	I	A	C	A	R	S
Reviewing and approving extension and downgrade requests.	I	I	I	A	C	A	R	S
Escalating queries to NHS England as necessary	I	I	I	C	A	R	R	S
Presentation of Serious Incident themes, clusters and trends at Quality and Performance Committees	I	I	I	C	A	C	R	C
Presentation of Serious Incident status at Provider Analysis Meetings	I	I	I	C	C	A	R	C

Appendix E: Extension and Downgrade Criteria

EXTENSION CRITERIA

An extension from a provider will be granted if it meets the following criteria:

- The police are involved
- The HSE are involved
- The Coroner is involved
- It requires an independent review
- The post mortem is not done and the Trust are awaiting cause of death
- Reallocated investigation because of unplanned/unforeseen event
- SI involving multiple agencies
- If further investigation is warranted due to key quality issues raised/emerging during the investigation

DOWNGRADE CRITERIA

A downgrade request from a provider will be granted if it meets the following criteria:

- Following the 72 hour review the provider investigation panel has determined that the level of harm sustained was low or none and therefore does not meet the criteria for a Serious Incident investigation.
- Following the 72 hour review the provider investigation panel has determined that all appropriate care was given and there is no further learning to be gained from a Serious Incident investigation.
- Reported as a Serious Incident in error (doesn’t meet the criteria for a Serious Incident)

Appendix F: Escalation criteria

ESCALATION CRITERIA

The following types of serious incidents should be escalated immediately for MHCC attention:

- Inpatient suicides (including following absconding)
- Maternal deaths
- Child protection incidents
- Never events (Contract Lead to be informed)
- Accusation of physical misconduct of harm
- Data loss of information security (DH Criteria level 3-5)
- A major system failure with multiple stakeholders
- Any serious incident where media interest is indicated
- Any SI categorised as 'other'
- Breach of Duty of Candour (Contract Lead to be informed)

NOTIFICATION CONTACTS

- Within working hours MHCC CAO and Director on call should be called, and then an email should be sent out as specified in the table below.
- If a serious incident occurs out of hours and it is media worthy the provider will contact the Director on call directly to notify them of this.

MHCC	
MHCC Chief Accountable Officer	Ian Williamson ian.williamson3@nhs.net
MHCC GP Clinical Lead	Dr Manisha Kumar manisha.kumar1@nhs.net
Director	Michelle Irvine michelle.irvine2@nhs.net
Quality Lead	Kate Provan kate.provan@nhs.net
Head of Corporate Services	Nick Gomm n.gomm@nhs.net
Executive Nurse	Craig Harris craig.harris2@nhs.net
Contract Lead	Peter Ball peter.ball3@nhs.net
MHCC Communications	Penny Shannon penny.shannon@nhs.net

Appendix G: External Reporting Bodies

The following is referenced from The Serious Incident Framework, NHS England 2015 national 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

HSCA notification must be made by all services registered under the Health and Social Care Act (HSCA). This includes all NHS Trusts, independent healthcare, adult social care, primary dental care and independent ambulance providers.

The way in which notifications are made will depend on their nature and the type of service. The process differs slightly for NHS Trusts than for other providers

For NHS Trusts, the requirement to report incidents is typically met by reporting incidents to the National Reporting and Learning System. Please refer to the CQC's notification guidance which outlines how each type of notification needs to be made: http://www.cqc.org.uk/content/notifications

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 suspected) and all deaths of detained patients must be reported to the Coroner by the treating clinician. This should be done immediately. It is recognised that, following an unexpected death, a serious incident may not be identified until the issuing of the coroner's report.

Coroners make two sorts of referral to the police:

- For an investigation under the Coroner's Act where the Coroner expects a police officer to investigate the death and prepare a file for the inquest by obtaining witness statements and other evidence.
- For a criminal investigation where the Coroner is concerned that the circumstances of the death may involve criminal liability.

Investigating police officers should be clear with the NHS and other organisations when they are acting on behalf of the Coroner to establish the cause of death, rather than investigating a crime. If the matter becomes a criminal investigation, the investigating officer should make it clear to the NHS organisation and others that the status of the investigation and their role in it has changed.

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 should also be submitted by the organisation to the Department of Health via the defect and failure reporting portal http://efm.hscic.gov.uk/

Health and Safety Executive (HSE)

The HSE is responsible for the enforcement of the Health and Safety at Work Act 1974 (HSWA) and ensuring that "risks to people's health and safety from work activities are properly controlled". Serious incidents may need to be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). The trigger point for RIDDOR reporting is over 7days' incapacitation (not counting the day on which the accident happened). Further information on reporting is available at http://www.hse.gov.uk/riddor/report.htm

Incidents involving work-related deaths (or cases where the victim suffers injuries in such an incident that are so serious that there is a clear indication, according to medical opinion, of a strong likelihood of death) should be reported under RIDDOR and managed in accordance with the Work-Related Deaths Protocol. In the first instance the incident should be reported within the organisation in the normal way and to the commissioning organisation.

Health Education England

Directors of Education and Quality (DEQ) in Health Education England (HEE) and its Local Education and Training Boards are responsible for the quality of the education and training provided to medical, nursing, dental and Allied Health Professionals (AHP) students and others, and training grade doctors. These students may be involved in serious incidents and HEE have a duty of care to them. Also they are an excellent source of feedback on the standard of patient care experienced in their placement.

HEE DEQs should therefore be informed about serious incidents where trainees are involved. The provider should ensure that the responsible DEQ is made aware of the incident as soon as possible. This does not, however, alter the serious incident management process which should be undertaken in line with national serious incident Framework.

Care must be taken to ensure all parties understand that notification of serious incidents involving trainees is focussed on supporting those trainees and ensuring the standard of training is appropriate. It is very rare that serious incidents are the result of individual failings and notifications sent to DEQs are not intended as a comment or judgement on the capability of trainees.

Information governance serious incidents, Caldicott and data protection

When reporting serious incidents, providers must comply with Caldicott, data protection and information governance requirements. Where incidents relate to information governance (IG) issues they should be reported within the IG toolkit, in line with the Health and Social Care Information Centre guidance HSCIC Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation and subsequent guidance.

The severity of the incident must be assessed using the scale and severity factors outlined within the HSCIC guidance. All incidents which reach the threshold for a level 2 IG related serious incidents are reported publicly via the IG toolkit and should be reported and investigated as serious incidents under this Framework. Serious incidents relating to information governance have to be reported on the NHS serious incident management system, STEIS or its successor, as well as the IG toolkit.

Organisations must be registered to access the HSCIC IG toolkit. Login details will

be provided when the organisation undertakes the initial IG assessment which is a dual functionality of the toolkit and provides NHS organisations with a means of self-assessing performance against key aspects of information governance. For further information relating to the assessment and reporting process please refer to the HSCIC guidance or contact your regional information governance lead.

Organisations must be aware that the information reported to the IG toolkit will be published within the public domain. Consequently, the transfer of STEIS reports to the IG toolkit is not recommended unless the content has been approved for publication and a separate report is typically required. It is acknowledged that reporting to both the IG toolkit and STEIS represents duplication of reporting, however the IG toolkit does not currently provide a mechanism for informing relevant commissioners of IG serious incidents and so STEIS reporting is required to ensure that information is shared.

Local Authorities

Local authorities are responsible for commissioning specific public health services including health protection, health improvement and population healthcare. Responsibility for the quality of care being provided is recognised by the governance arrangements within the local authority. Local Authority commissioners must use their interactions with health care providers and commissioners to identify any actual or potential quality problems.

As part of the local Quality Surveillance Groups, Local Authorities will share information and intelligence and learning in relation to serious incidents. Health and Wellbeing Boards also provide a link to the Local Authorities' quality agenda where intelligence should be shared to inform local leadership for quality improvement.

Local Authorities also have a particular role to play in safeguarding adults and children and young people in vulnerable circumstances. Providers and commissioners must ensure that information about abuse or potential abuse is shared with Local Authority safeguarding teams.

The interface between the serious incident process and local safeguarding procedures must therefore be articulated in the local multi-agency safeguarding protocol and policies. Providers and commissioners must liaise regularly with the

local authority safeguarding lead to ensure that there is a coherent multi-agency approach to investigating safeguarding concerns, which is agreed by relevant partners.

Medicines and Healthcare products Regulatory Agency (MHRA)

Organisations should report suspected problems ('adverse incidents') with a medicine or medical device to the MHRA using the Yellow Card Scheme as soon as possible if:

- A medicine causes side effects
- Someone's injured by a medical device, either because its labelling or instructions aren't clear, it's broken or has been misused
- A patient's treatment is interrupted because of a faulty device
- Someone receives the wrong diagnosis because of a medical device
- A medicine doesn't work properly
- A medicine is of a poor quality
- You think a medicine or medical device is fake or counterfeit

Further details are available at:
http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

NHS Improvement

NHS Foundation Trusts are required to inform NHS Improvement about relevant serious incidents (i.e. any incidents which may reasonably be regarded as raising potential concerns over compliance with their licence) requiring investigation.

NHS Protect

NHS Protect, through their contractual standards, stipulate that appropriate security management arrangements must be in place. This includes the provider employing or contracting a qualified person to undertake and/or oversee the delivery of the full range of security management work. The qualified person (the Local Security Management Specialist (LSMS)) works with the Area Security Management

Specialist (ASMS) to ensure robust arrangements are in place.

The Security Incident Reporting System (SIRS) is an electronic tool which allows NHS health bodies to report security incidents occurring on their premises to NHS Protect, enabling the creation of a national picture of such incidents across the NHS in England, for use in detecting and preventing crime in a national, regional and sector specific context.

Where a serious incident occurs to a member of staff resulting from a physical or non-physical assault, there is a requirement to report this to NHS Protect via the Security Incident Reporting System (SIRS). The same reporting requirement relates to incidents involving loss or damage to property and assets of NHS organisations, staff and patients.

Users can access an online web portal for incidents to be added or edited, and SIRS can also integrate with local NHS risk management systems to allow a single or bulk upload of records.

More information can be found here http://www.nhsbsa.nhs.uk/4247.aspx

NHS Trust Development Authority

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 (including acts of omission) were reckless, grossly negligent or wilfully neglectful;
- evidence or suspicion that harm/adverse consequences were intended

In the first instance the incident should be reported within the organisation in the normal way and to the commissioning body. Referral to the police should be undertaken by a senior member of staff in the reporting organisation.

Professional regulators and professional misconduct

The vast majority of serious incidents are caused by the failure of systems and not

the actions of individuals and this must be recognised by the team handling the investigation. Serious incident management process should be followed and progressed in line with the national Serious Incident Framework even if grounds arise to suggest that a serious incident may have occurred as a result of 'professional misconduct'. If grounds for professional misconduct are suggested it is important that the appropriate lead (e.g. the Responsible Officer/Medical or Nursing Director) within the provider organisation is alerted (within 2 days) to ensure that appropriate action is taken as and when required. Appropriate action includes the investigation and/or HR team taking time to carefully assess or refer on to experts the actions or omissions in question, within the context of the incident, to identify whether these are considered reckless or malicious, as opposed to slips, lapses, or a situation where there are others routinely taking the same route or in need of similar levels of support, supervision or training. Systems failures are most likely to be at the core of the problem and, the most effective place to target improvements/solution to prevent recurrence.

The Incident Decision Tree should be used to determine if action is required in relation to individuals

Information relating to all Statutory Regulators and the process for managing professional misconduct can be found in the statutory regulators directory http://www.professionalstandards.org.uk/regulators/statutory-regulators-directory

Public Health England

Public Health England (PHE) Screening and Immunisation Leads, based within NHS England Sub-regions, have a system leadership role for screening and immunisation programmes. They have a responsibility to support the oversight and management of incidents which occur within these programmes and will liaise with other PHE experts to ensure that the investigation and response to an incident is managed appropriately. PHE's Screening Quality Assurance team also has a key role in the investigation and management of serious incidents within screening programmes. Screening and Immunisation Leads within NHS England must ensure the Screening Quality Assurance team is notified when incidents occur within screening programmes.

PHE also has a broader role in supporting the management of serious incidents that occur within other NHS services, where there is a potential for the incident to have

adversely affected the health of a wider population. Such incidents may include decontamination failures; inadvertent contact on NHS premises of patients and staff with someone with a transmissible infectious disease such as measles or TB; outbreaks of health care associated infections; the finding of a Health Care Worker infected with a blood borne virus; failure of microbiological laboratory practice; release/widespread exposure to harmful chemicals or a source of radiation.

Where the potential exists for the health of a wider group of people to be adversely affected by an incident in the NHS, the responsible NHS provider must contact the relevant Public Health England Centre through their Health Protection Team and involve PHE as part of the local incident control team. Commissioners must work with the providers of services which they directly commission to ensure this is the case. Public Health England will provide expert input to the assessment of population risk and advice on the management of public health aspects of the incident. The local team will draw on regional and national expertise within PHE as necessary.

Serious Adverse Blood Reactions and Incidents (SABRE)

The UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive require that serious adverse incidents and serious adverse reactions related to blood and blood components are reported to the MHRA, the UK Competent Authority for blood safety. This information is vital to the work that the Serious Hazards of Transfusion (SHOT) uses to compile its reports.
Further details on reporting can be found at:
http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Blood/index.htm