



NATIONAL QUALITY BOARD

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Paper for:

Decision	Discussion	Information
X	X	X

THE FUTURE OF NHS PATIENT SAFETY INVESTIGATIONS

SUMMARY

The NHS conducts patient safety investigations after things go wrong in patient care to learn from these events and to inform changes to prevent them happening again. The current Serious Incident framework published in 2015 sets expectations for when and how the NHS should conduct a safety investigation.

Compelling evidence from patients, families, carers and staff has however revealed weaknesses in the way NHS organisations investigate, communicate and learn when things go wrong. This evidence forms the cornerstone of many recent national reports and reviews on the issue.

From 20th March 2018 the NHS Improvement national patient safety team is leading a 12 week engagement programme to gather views on how and when the NHS should investigate Serious Incidents. Responses will be used to shape a new Serious Incident Framework document.

We are asking people to get involved by completing our questionnaire, but a range of other interactive events are also planned. Details, together with the discussion











document that provides context to the questions, are available at:
<https://improvement.nhs.uk/resources/future-of-patient-safety-investigation/>

PURPOSE

The NQB is asked to:

- 1) **Note** the engagement that will inform the review of the Serious Incident Framework;
- 2) **Confirm** areas of the consultation that NQB wish to bring back for discussion as proposals for the new Serious Incident Framework are further developed; and
- 3) **Provide views** in relation to the key issues upon which engagement is centred and how NQB can take a global view on this alongside:
 - the work of CQC on the never events thematic; and
 - the cross-system work led by the MHRA on safety messaging.

ALB Involvement in development and sign-off of paper:

			
X	X	X	
			
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THE FUTURE OF NHS PATIENT SAFETY INVESTIGATIONS

1. BACKGROUND

- 1.1 The current [Serious Incident Framework](#) published in 2015 sets expectations for when and how the NHS should conduct a safety investigation.
- 1.2 However, recent reports (*by the Public Administration Select Committee in March 2015, the government's response in July 2015, the Parliamentary and Health Service Ombudsman's report in December 2015 and the Care Quality Commission's (CQC) Learning, candour and accountability in December 2016*) have identified shortcomings in adherence to this guidance and problems with existing investigation practice across the NHS in England.
- 1.3 In April 2017 the Healthcare Safety Investigation Branch (HSIB) was established to demonstrate and support 'gold standard' investigation practice in the NHS. While HSIB will undertake a number of independent exemplar investigations (exploring issues that exist across the whole system), HSIB cannot lead all investigations that are required across the NHS.
- 1.4 NHS organisations will therefore continue to play a crucial role in identifying why incidents have occurred and what can be done to reduce the risk of them happening again. The Serious Incident Framework therefore continues to be a key document, setting expectations around investigations.

2. Key issues

- 2.1 While the Serious Incident Framework sets clear expectations on provider organisations, we now know that providers are not all able to reliably and routinely meet those expectations. Similarly, while the Serious Incident Framework makes organisations accountable to their commissioners for carrying out good quality investigations, and CQC considers the process of investigation in its inspections, these accountability systems are not ensuring good quality investigations take place.



2.2 Our work and the work of others (particularly the CQC) has identified several key areas of concern in relation to current NHS investigation practices, together with key questions to generate discussion and feedback. The key issues are summarised below, and the survey questions associated with each of these issues are summarised at the end of this document;

- a) **Failure to ensure proper patient, family and carer support and engagement in investigation processes..**
- b) **Lack of staff support and engagement during investigations.**
- c) **NHS organisations are completing high volumes of investigations and the quality of investigations is generally low.**
- d) **Misaligned oversight and assurance processes**
- e) **Staff in provider organisations report having insufficient time, expertise and resources to conduct good quality investigation.**
- f) **A focus on meeting the 60 day deadline is often prioritised over the delivery of good quality investigations in a timely manner.**
- g) **Lack of uptake of the standard investigation approach and investigation report templates.**
- h) **Lack of clarity around patient safety investigation principles and purpose.**
- i) **The Serious Incident investigation process, language and terminology is perceived as punitive and inhibits improvement.**

3. **Engagement approach**

3.1 Each of the above issues will be explored through a programme of engagement led by the NHS Improvement national patient safety team. The programme will run for 12 weeks, from 20th March to 12th June 2018, and we will gather views on how and when the NHS should investigate Serious Incidents.



3.2 We are asking people to take part by completing our questionnaire, but we are also planning a range of other activities including face to face events, videos, twitter chats etc, to make the 12 week engagement period as interactive as possible. Details are available on our website, along with the discussion document that provides context to the questions.

<https://improvement.nhs.uk/resources/future-of-patient-safety-investigation/>

3.3 Responses will be used to shape a new Serious Incident Framework document providing national guidance on the systems, processes and behaviours that providers, commissioners and oversight bodies are expected to adopt to ensure we respond appropriately when things go wrong.

4. Timeline and next steps

4.1 Pre-engagement activity was conducted with some key stakeholders including NHS England, CQC, HSIB, the Department of Health, and our own patient and public representatives ahead of this launch. We also hosted two days of mini-seminars with NHS staff and other delegates at the Patient First conference on 21 and 22 November 2017. These discussions informed further planning.

4.2 Formal engagement was launched on 21st March 2018 and will close on 12th June 2018.

4.3 We anticipate that the resultant revised version of the Serious Incident Framework will be published end by end of 2018.

4.4 As well as informing review of the Serious Incident Framework and subsequent publication of revised expectations for how NHS organisations should undertake and oversee investigations, we anticipate this work will also inform a longer term programme of implementation and support.



APPENDIX: Survey questions associated with the key areas of concern in 2.2 above

- a) **Failure to ensure proper patient, family and carer support and engagement in investigation processes.** Too often, families and patients are not informed of investigations that are taking place, are not involved in setting terms of reference, are not kept updated on progress, are not asked to provide information to the investigation and are not treated with respect and compassion.

Q. How effective do you think each of the following approaches would be in promoting open and supportive involvement of patients, families and carers?

- Clear standardised information explaining how patients/families can expect to be involved and a key point of contact
- A process for gathering timely feedback from patients/families /carers about the investigation process.
- Standard patient/families/carers feedback survey on whether their investigation needs were met.

- b) **Lack of staff support and engagement during investigations.** Often staff involved in incidents are let down by the investigation process. Many are inappropriately suspended, required to undertake periods of 'self-reflection', left to fend for themselves without support and/or not kept properly informed about the progress of an investigation.

Q. How effective do you think each of the following approaches would be in improving staff supportive and involvement?

- Dedicated and trained support for staff
- A formal assessment to determine culpability or fitness to practice before the employer takes any action
- Those making assessments to be trained in just accountability

- c) **NHS organisations are completing high volumes of investigations and the quality of investigations is generally low.** Investigation of repeat incidents generate little, if any, additional learning. There is therefore an argument for supporting organisations to rationalise incidents for investigation, without compromising their duty to ensure patients and families receive timely and clear information.



Q. How effective do you think the following approaches would be in promoting better use of existing investigative resources?

- Discourage use of prescriptive Serious Incident lists
- Set minimum resource requirements for an investigation team
- Set nationally agreed minimum number of investigations for each organisation (based on the size of the organisation)
- Annual local investigation strategies to declare incidents to be investigated and appropriate resourcing
- Stating that incidents do not always have to be investigated if an ongoing improvement programme is delivering measurable improvement/reduction of risk.
- Decision aids and record-keeping templates that help determine which incidents should be fully investigated.
- Information on other processes for managing incidents that may be appropriate for certain types of concerns/issues raised.

d) **Misaligned oversight and assurance processes**

While processes seek to maintain and improve the quality of Serious Incident management, evidence suggests that a more considered approach to oversight and assurance may be needed. Performance metrics are applied to serious incident investigations and are relatively simple and process focused, providing little information on the quality of investigation. Focusing on these metrics can drive unintended consequences (e.g. where incidents are attributed to an organisation there is little encouragement to work across organisational boundaries; and patients, families and key staff members not always may not be involved because these activities take time and could cause a 'breach' of the 60-day deadline.)

Current oversight and assurance processes can therefore, paradoxically, have a detrimental effect on the quality of investigations.

Q. How effective do you think each of the following approaches would be in developing an environment for learning and improvement?

- Clearer descriptions of roles and responsibilities at each level of the system.
- A designated trained person in provider and commissioning organisations to oversee Serious Incident management.
- Setting minimum training requirements for board members and commissioners signing off investigation reports



- A standardised quality assurance tool to support investigation sign off and closure.
- Increased involvement of patient and family representatives in the sign off process.

Q. How effective do you think each of the following approaches would be in helping organisations to identify and conduct cross-system investigations?

- A cross-system investigation to be considered each time an investigation is initiated and, if not appropriate recording why.
- A designated trained lead in all STPs to work with all relevant organisations when a cross-system investigation is necessary.
- Discouraging the use of Serious Incident data for performance management.
- Mandating the need to contribute to cross-system investigations
- Rewarding those who initiate/engage in cross-system investigation

e) **Staff in provider organisations report having insufficient time, expertise and resources to conduct good quality investigation.** Often staff are expected to investigate in addition to their full-time day job. Some people are also asked to investigate infrequently or without sufficient training or supervision. Similar issues, in relation to insufficient time and investigation expertise, also exist at a commissioner level which impacts a commissioner's ability to support an effective investigation oversight process.

Q. How effective do you think each of the following would be?

- Each provider to have a flexible, trained team of investigators who combine investigation and management or clinical roles, but have dedicated and protected time for investigation duties (with additional clinical or managerial expertise should be sought as required on a case-by-case basis.)
- Each provider to have a dedicated team of trained lead investigators with no duties in that organisation other than investigation (Additional clinical or managerial expertise should be sought as required on a case-by-case basis.)
- Each provider to base the number of investigators it employs on its size and the number of investigations per year
- Each provider to have a trained head of investigation who selects, supports and oversees patient safety investigation management processes.
- A trained head of investigation oversight for commissioning organisations.



- f) **A focus on meeting the 60 day deadline is often prioritised over the delivery of good quality investigations in a timely manner.** This may relate to timeliness of completion being easier to measure than other aspects of investigation quality.

Q. How effective do you think each of the following approaches would be in ensuring the necessary time is devoted to investigation?

- Removing the 60 working day timeframe, allowing the investigation team to set the timeframe for each investigation in consultation with the patient/family/carer
- Set the timeframe at 60 working days but reduce the number of investigations undertaken.
- Set timeframe at 60 working days but require organisations to rationalise their internal approval processes to allow more time for investigation before external submission.
- Set a 60 working day timeframe but allow providers some leeway on meeting it and not managing performance against it.

- g) **There is a lack of uptake of the standard investigation approach and investigation reports.** Local organisations adopt their own processes and reporting templates which miss out key aspects of an effective investigation.

Q. How could the Serious Incident framework support uptake of evidence-based investigation approaches? Please tell us your ideas.

Q. How strongly do you agree that a mandated investigation report template and assurance checklist could help to standardise and improve evidence-based practice across the NHS?

- h) **Lack of clarity around patient safety investigation principles and purpose.** (In relation to the importance of systems-thinking, risk management principles and the recognition that the vast majority of incidents relate to weaknesses in systems and processes rather than being the result of wilful negligence, malice or dangerously reckless behaviour)

Q. Do you think the revised principles could support the implementation of good practice?

Q. Do you think these principles are clear and comprehensive?

Q. Is there anything you would add or change in the drafted principles?



i) **The Serious Incident investigation process, language and terminology is perceived as punitive.** This inhibits a culture of learning and improvement.

Q. Do you think the name of the Serious Incident framework should be changed to reflect the step change in process and behaviour that may be required in some areas to embed good practice?

Q. If yes, can you suggest a name?