

The future of patient safety investigation- Consultation response

1. NHS England Patient Safety Domain (now NHS Improvement) (2015) Serious Incident Framework: Supporting learning to prevent recurrence. Available online at: <https://improvement.nhs.uk/resources/serious-incident-framework/>

1. Please state how you are responding to this survey

I am responding on behalf of an organisation

2. Which group do you represent

Royal College

3. If you are responding as a group/team/department or organisation and are happy to state the name of your group/team/department and/or organisation, please do so:

Royal College of Anaesthetists

4. How could the Serious Incident Framework be revised to reduce defensiveness and increase openness so that patients, families, carers and staff are more effectively involved and supported? Please let us know your ideas

The Royal College of Anaesthetists (RCoA) strongly believes that improving the safety and quality of care being provided to patients must be at the heart of all decisions relating to investigation of clinical errors. For many years we have called for steps to facilitate a 'no-blame' learning environment where staff and healthcare organisations can learn from mistakes when they occur. We welcome this review of the serious incident framework as an opportunity to improve the quality of inquiry and the learning from investigations that are undertaken under its auspices.

- **The RCoA would like to see newer approaches to safety science incorporated into the framework, including highlighting positive as well as negative aspects of the cases investigated.**
- **There should be robust protection from prosecution afforded to staff submitting evidence to an investigation. The inquiry should either be classified as 'legal' in which case all staff have an absolute right to silence if advised by their legal team, or 'investigative' where staff evidence is not available to police or other legal bodies for use in criminal proceedings. NHS staff, including our fellows and members,**

must feel able to reflect openly and truthfully on their practice without fear that this will be used against them, or learning will not take place.

- **The patient or their family members should be involved at different stages of the investigation process, ensuring that they remain up to date with developments. This requires careful and sympathetic management of expectations, ensuring that the extent of their involvement is clear from the outset.**

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

Providing patients/families/carers with clear standardised information explaining how they can expect to be involved. This will mean they can more easily judge if an organisation is meeting these requirements and if it is not, raise this with the organisation (with support from their key point of contact that organisations are required to provide)	Somewhat effective
Requiring organisations to establish a process for gathering timely feedback from patients/families/carers about the investigation process. Concerns can then be more easily addressed and reliance on the formal complaints process as a means of addressing potential problems reduced	Somewhat effective
Asking patients/families/carers to complete a standard feedback survey on receipt of the final draft investigation report that asks whether their expectations were met. This could help those responsible for overseeing investigations determine if a report can be signed off as complete	Completely ineffective

6. How effective you you think each of the following approaches would be in promoting an open and supportive involvement of staff

Requiring organisations to have dedicated and trained support staff who listen to and advise staff on their worries and concerns following incidents	Very effective
Requiring a formal assessment to be completed to determine whether an individual intended harm or neglect, acted with unmitigated recklessness or has performance, conduct or health issues before the employer takes any action against a staff member	Not very effective. However, this is a step that could be determined early to guide the route the next steps would take; ie, either 'legal' or 'investigative'. Doing this later would be very ineffective.
Requiring those making judgements about the need for individual action to demonstrate up to date training and understanding of just accountability	Somewhat effective

7. Please add any further comments or ideas below
8. How could the Serious Incident Framework best support more effective use of investigation resources. Please tell us your ideas
- **The RCoA would like to see fewer, more effective investigations, and wider sharing of the results. Prolonged and multiple investigations have a detrimental effect not only on staff directly involved in serious incidents, but also on their colleagues and on patients and their relatives.**
 - **Delays in investigation have been shown to increase the costs involved for the NHS. As part of its inquiry into the costs of clinical negligence, the Commons' Public Accounts Committee received evidence in 2017 from a number of law firms. The Committee noted that time delays in the investigation process- due in large part to the delay in reporting an incident- had a direct inflationary impact on a claims financial value. It also noted that failure by trusts to conduct an early investigation is the main cause for claimant lawyers to initiate their own investigation (Source: Public Accounts Committee, Oral evidence: Managing the costs of clinical negligence in trusts, HC 397. Monday 16 October 2017).**
 - **The use of dedicated, independent teams within hospitals to conduct investigations would improve their quality and timeliness.**

However, we strongly believe that specialist clinical knowledge needs to be married with that of other non-medical experts in order to effectively analyse and interpret findings and carry out fair and impartial investigations.

- **The involvement by clinical specialists would require release of these staff from other duties. Experience to date suggests that trusts do not routinely release clinical staff to participate in investigations, despite being encouraged to do so by Professor Sir Bruce Keogh, in his report 'Review into the quality of care and treatment provided by 14 hospital trusts in England', who stated: 'Providers should actively release staff to support improvement across the wider NHS, including future hospital inspections, peer review and education and training activities, including those of the Royal Colleges. Leading hospitals recognise the benefits this will bring to improving quality in their own organisations...' (Ambition 5, pg 11: <https://www.nhs.uk/nhsengland/bruce-keogh-review/documents/outcomes/keogh-review-final-report.pdf>)**
- **HSIB, or another suitably qualified body may have a role in training teams within organisations to conduct investigations to ensure consistency and quality.**

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

Continuing to discourage the use of prescriptive serious incident lists as a tool for reporting	Very effective
Setting minimum resource requirements for an investigation team	Somewhat effective
Setting a nationally agreed minimum number of investigations for each organisation (based on the size of the organisation) so that each organisation can plan how it achieves this number with the appropriate resources to deliver good quality outputs	Completely ineffective
Requiring organisations annually to develop an investigation strategy that identifies and describes which incidents will be investigated and how their investigation will be resourced	Somewhat effective
Stating that incidents do not always have to be investigated if an ongoing improvement programme is delivering measurable improvement/reduction of risk	Very effective

Providing decision aids and record-keeping templates that help determine which incidents should be fully investigated	Somewhat effective
Providing information on other processes for managing incidents that may be appropriate for certain types of concerns/issues raised	Very effective

10. Please add any further comments or ideas below

11. What changes could be made to the assurance processes to better foster an environment for learning and improvement? Please tell us your ideas

The establishment of methods for ensuring that lessons are learnt from investigations that take place, and that these are disseminated across and between NHS organisations.

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

Providing clearer descriptions of roles and responsibilities at each level of the system	Somewhat effective
Requiring a designated trained person in provider and commissioning organisations to oversee processes associated with Serious Incident Management	Very effective
Setting minimum training requirements for board members and commissioners signing off investigation reports (covering behaviours as well as process to support learning and improvement)	Very effective
Introducing a standardised quality assurance tool to support investigation sign off and closure	Somewhat effective
Requiring increased involvement of patient and family representatives in the sign off process	Somewhat effective

13. Please add any further ideas or comments below

Improvements could also be made by:

- **Provision of training, mentoring and guidance to those taking part in investigations on behalf of NHS organisations, and standardisation of the methods by which these investigations are conducted and reported.**

- **As mentioned above, improved practice by NHS trusts in relation to releasing clinical staff to take part in investigations**

14. What changes could be made to the framework to identify and facilitate cross-system investigations? Please tell us your ideas

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

Requiring a cross-system investigation to be considered each time an investigation is initiated and, if it is not considered appropriate the recording of why	Somewhat effective
Having a designated trained lead in all sustainability and transformation partnerships who can work with all relevant organisations when a cross-system investigation is necessary	Somewhat effective
Continuing to discourage the use of Serious Incident data for performance management	Very effective
Mandating through contracts/future regulation the need to contribute to cross-system investigations as required	Somewhat effective
Rewarding those who initiate and/or engage in cross-system investigation	Somewhat effective. Note that by 'reward' we understand the 'recognition of their time' eg by paid release from main clinical duties – this is absolutely essential to any process (but Trusts may not comply). However if by 'reward' is meant some additional incentives to take part, we are not yet convinced that this is necessary.

16. Please add any further comments or ideas below

17. How could the Serious Incident framework best ensure that the necessary time and expertise are devoted to investigation? Please tell us your ideas

This framework should require NHS organisations to employ dedicated, trained staff to conduct investigations, and ensure that clinical staff are released to participate. As mentioned above, experience to date

suggests that not all trusts routinely release clinical staff to participate in investigations.

18. How effective do you think the following approaches would be in ensuring the necessary expertise is devoted to investigation?

Requiring each provider to have a flexible, trained team of investigators comprising staff employed by the organisation who combine investigation and management or clinical roles, but have dedicated and protected time for investigation duties. Additional clinical or managerial expertise should be sought as required on a case by case basis	Very effective
Requiring 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	Very effective
Requiring each provider to base the number of investigators it employs on its size and the number of investigations it expects to conduct each year, eg four whole time equivalent (WTE) lead investigators to conduct 20 investigations a year	Somewhat effective
Requiring each provider to have a trained head of investigation who selects, supports and oversees patient safety investigation management processes	Very effective
Requiring a trained head of investigation oversight for commissioning organisations	Somewhat effective

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

Removing the 60 working day timeframe and instead allowing the	Very effective
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investigation team to set the timeframe for each investigation in consultation with the patient/family/carer (as is often the case in the complaints process)	
Keeping the set timeframe at 60 working days but reducing the number of investigations undertaken	
Keeping the set timeframe at 60 working days but requiring organisations to rationalise their internal approval processes to allow more time for investigation before external submission	Somewhat effective
Recommending a 60 working day timeframe but allowing providers some leeway on meeting it and not managing performance against it	Somewhat effective

20. Please add any further ideas or comments below

The RCoA supports an approach that moves away from a fixed timescale for investigations to be completed, while taking into consideration the wishes and needs of patients and/or their family members.

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

22. 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?

A checklist may be developed after several investigations are completed, in consultation with clinical staff involved and patients or their families, but the RCoA does not advocate developing this in advance of the framework being adopted.

Please add further comments and ideas below

Root cause analysis rarely finds a single root cause.

23. A revised set of principles has been proposed below for your consideration

Strategic

- *Boards focus on quality of output, not quantity*
- *Resources are invested to support quality outputs*
- *Boards recognise the importance of findings*
- *There is a culture of learning and continuous improvement*

Preventative

- *Investigations identify and act on deep-seated causal factors to prevent or measurably and sustainably reduce recurrence*

- They do not seek to determine preventability, predictability, liability, blame or cause of death

People focused

- Patients families, carers and staff are active and supported participants

Expertly led

Investigations must be led by trained investigators with the support of an appropriately resourced investigation team to ensure they are:

- Open, honest and transparent
- Objective
- Planned
- Timely and responsive
- Systematic and systems-based
- Trustworthy, fair and just

Collaborative

- Supports system-wide investigation (cross-pathway/boundary issues)
- Enables information sharing and action across systems
- Facilitates collaboration during multiple investigations

Do you think these principles could support the implementation of good practice

Yes

Please explain your answer

The new principles are fewer in number, more specific and more sensible and humane.

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

Yes

25. Is there anything you would like to change in the drafted principles?

Please give us your ideas

26. 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?

Don't know/undecided

27. If you have any further comments or ideas, please share these with us below

The RCoA welcomes this review of the serious incident framework, and the opportunity to facilitate a 'no blame' environment and culture within the NHS of learning from mistakes. In summary, the issues that require addressing in the current framework are as follows:

- **The RCoA believes that highlighting positive as well as negative aspects of the cases investigated will improve engagement of staff in the investigation process and allow for additional learning to take place.**
- **Many serious incidents arise from a combination of individual and systemic failures or genuine error, often as a result of challenging working conditions and lack of adequate resources. Doctors must**

feel able to reflect openly and truthfully to investigating teams without fear that this will be used against them, or learning will not take place.

- **Investigation teams require dedicated, independent, trained personnel and expert clinical input. They need to be skilled in making judgements about the incident and also in supporting staff during a very difficult time. This in turn requires NHS organisations to provide funding and to release clinical staff to provide input to investigations.**
- **The framework should give guidance to NHS organisations about which incidents should be investigated, focusing on those where learning can take place, and ensuring that any learning is disseminated widely across the organisation and other organisations. Prolonged, multiple investigations of similar incidents are inefficient financially, and if managed inappropriately, can cause further distress for families and the clinical staff involved.**