

The future of NHS patient safety investigation: engagement feedback

November 2018

We support providers to give patients safe, high quality, compassionate care within local health systems that are financially sustainable.

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Introduction

On 20 March 2018 NHS Improvement launched an engagement programme to seek views from a wide range of stakeholders about how and when patient safety incidents should be investigated. This followed our work and that of others identifying that organisations are struggling routinely to meet the expectations of the current [Serious Incident framework](#). Often those affected by incidents are not appropriately supported or involved in the investigation process; the quality of investigation reports is generally poor; and improvements to prevent the recurrence of harm are not effectively implemented. Early exploration of these issues (as described in the [engagement document](#)) identified that problems are driven by: (1) defensive cultures and lack of trust; (2) inappropriate use of the Serious Incident investigation process; (3) misaligned oversight and assurance processes; (4) lack of time and expertise; and (5) lack of uptake of an evidence-based approach.

To obtain views on the problems with the current approach to the investigation of Serious Incidents, the issues driving these problems, and how such issues might be resolved, we ran an online survey, national workshops and a live twitter chat, and held discussions with many individuals including patients, families, NHS staff, regulators and others. This document summarises the feedback received.

Acknowledgement

We received over 400 comprehensive responses to the engagement survey from a wide group of stakeholders. Both individual and collective responses were received (see Appendix 1 for further details). Separate responses were also received from stakeholders who could not participate via the online survey – their comments are included in the summaries of free text responses for each engagement topic. We are extremely grateful to everyone who responded.

We also thank all those who attended one of the national workshops, and the individual patients, families and staff who have been in touch with the patient safety team to share insight and experience. This engagement has provided vital intelligence about the issues we need to address.

High level reflections

Many of the suggestions in the engagement survey received a positive response. However, requests to focus on enabling culture change through supporting and investing in people (rather than process) to achieve the right outcomes were common. The need to work holistically to support systemic and systematic improvement was also emphasised because “doing one thing in isolation will not work”.

“The desired improvements will not take place without support from organisations and teams who can work with providers and commissioners to deliver the changes required. This isn't a one-off exercise but needs to be part of an ongoing national programme of improvement and support. Trusts need more support, training and guidance including learning from the areas of the NHS where there is good practice and a better understanding of how to link in with regional and national bodies that can support them in making improvements.”

Many responses recognised the efforts already made to develop processes to support Serious Incident investigation across the NHS, as well as calling for attention to be drawn to and learning taken from the positive work being done in some areas. But alongside this feedback were numerous comments highlighting the under-developed safety cultures at different levels of the NHS (including provider, commissioning and regulatory organisations), and that such cultures are often reinforced rather than resolved by the current Serious Incident management process. Some respondents believe this has become a “political and punitive process” that “impedes learning”.

Many stakeholders suggested that a wider programme of work will be needed to achieve the changes required, with work tailored to the diverse challenges relating to structure, skills, culture and capacity. Several respondents said that some of the suggestions in the survey focused on developing the system embedded in secondary care without appropriately considering the issues and potential solutions in primary care, for example.

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The difficulties of delivering improvement in a system that is facing significant operational and financial challenges were also highlighted. Although investment is needed to enable improvements in patient safety investigation, respondents recommended that this is considered alongside other organisational challenges and that the cost, implications and benefits of any future national requirements are carefully considered before implementation.

Table 1 is a summary of the suggestions for each engagement topic that received the most positive and negative responses. The corresponding sections in the document and Appendix 2 give further information, including a summary of workshop discussions.

Table 1: High level summary of responses to multiple choice survey questions

Engagement topic	Suggestion receiving the most positive response	Suggestion receiving the most negative response
1. Defensive cultures and lack of trust		
(a) Supporting and involving patients, families and carers	Providing patients/families/carers with clear standardised information explaining how they can expect to be involved so 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 who organisations are currently required to provide).	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.
(b) Supporting and involving staff	Requiring organisations to have dedicated and trained support staff.	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.
2. Inappropriate use of the Serious Incident investigation process	Providing information on other processes for managing incidents that may be appropriate for certain types of concerns/issues raised.	Setting a nationally agreed minimum number of investigations for each organisation (based on the size of the organisation) so that each

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Engagement topic	Suggestion receiving the most positive response	Suggestion receiving the most negative response
		organisation can plan how it achieves this number with the appropriate resources to deliver good quality outputs.
3. Misaligned oversight and assurance process		
(a) Support an environment for learning and improvement	Setting minimum training standards for boards and those signing off reports.	Increased involvement of families at the sign off stage.
(b) Supporting cross-system investigation	Continuing to discourage the use of Serious Incident data for performance management.	Rewarding those who initiate and/or engage in cross-system investigation.
4. Lack of time and expertise		
(a) How to ensure sufficient time is devoted to investigation	<p>Removing the 60 working day timeframe and instead allowing the 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).</p> <p>and</p> <p>Recommending a 60 working day timeframe but allowing providers some leeway on meeting it and not managing performance against it.</p>	Keeping the set timeframe at 60 working days but reducing the number of investigations undertaken.
(b) How to ensure sufficient expertise is devoted to investigation	Requiring each provider to have a trained head of investigation who selects, supports and oversees patient safety investigation management processes.	<p>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.</p> <p>and</p>

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Engagement topic	Suggestion receiving the most positive response	Suggestion receiving the most negative response
		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.

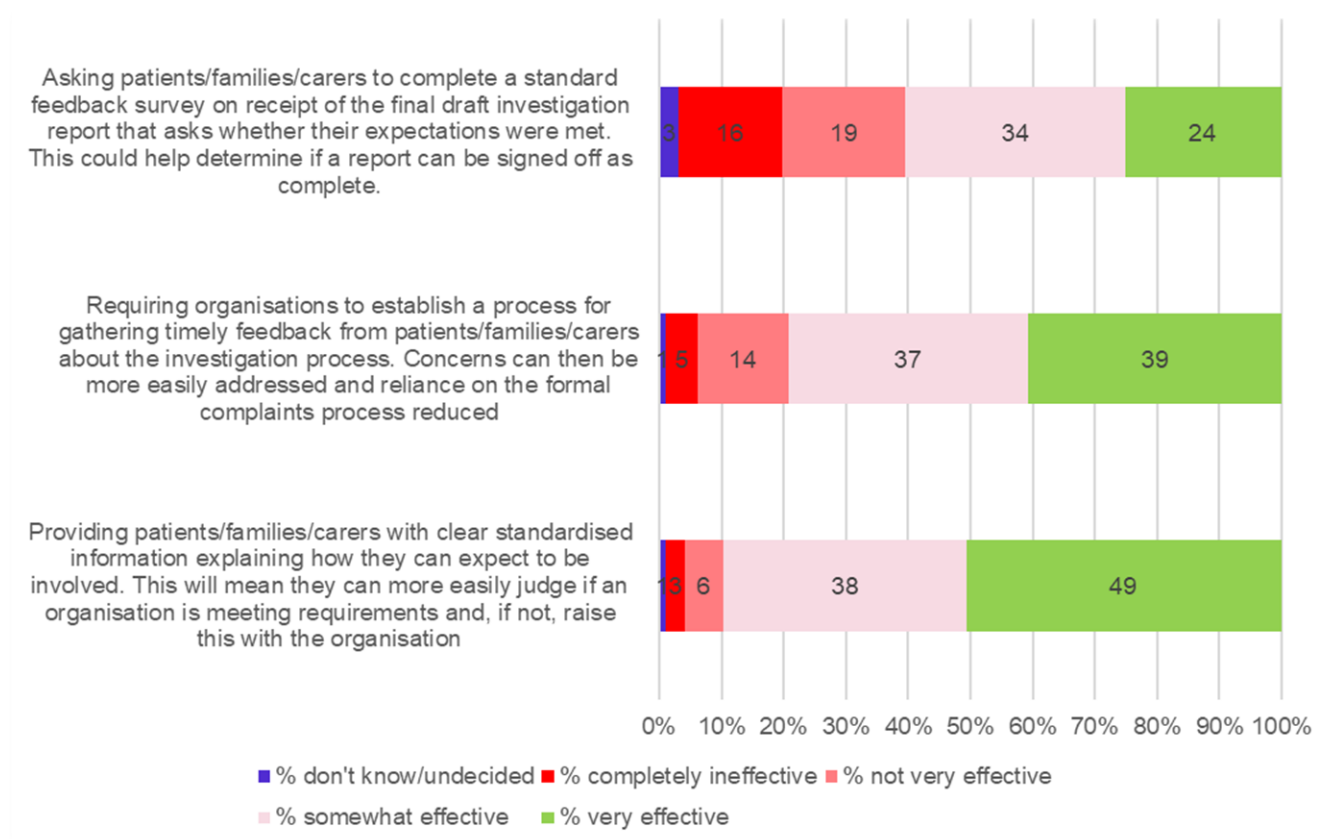
In relation to the fifth topic surveyed – lack of uptake of evidence-based approaches:

- 66% of respondents either strongly agreed or agreed (31% and 35% respectively) that mandated investigation templates and assurance checklists could potentially help support the uptake of an evidence-based approach.
- Most (81% and 87% respectively) thought the suggested principles (see section 8) (i) could support implementation of good practice and ii) were clear and comprehensive.
- 48% thought the name of the Serious Incident framework should be changed; 27% thought the name should not be changed; and 25% stated that they did not know/were undecided.

1. Supporting and involving patients, families and carers

1.1. Survey question (MCQ)

We asked respondents to indicate how effective the following suggestions could be in supporting and involving patients, families and carers in investigations.



1.2. Summarised free text comments

- 1.2.1. Providing patients, families and carers with clear standardised information relating to the investigation process was rated the most potentially effective suggestion. Feedback via the survey suggests many patients and families are 'in the dark' about what to expect.

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- 1.2.2. We learnt that some patients feared the process: “What did they mean by Serious Incident? How ‘serious’ was it? I thought there was something they were not telling me about the damage that had been done. I also thought it might be a problem I caused; maybe they were investigating me?”
- 1.2.3. Other patients and families have welcomed and/or fought for incidents to be investigated as ‘Serious Incidents’ in the hope that this process will answer their questions and help prevent the same thing from happening to someone else. However, lack of information, support and opportunity to contribute to the investigation were reported to prevent this from happening: “Families are often ‘managed’ rather than treated as central to the process, despite holding key evidence and information.”
- 1.2.4. Respondents stressed the need for dedicated staff (with the right skills, seniority and resources) to support a two-way conversation that runs from the start of an investigation process to its end. Stated good practice requirements included: “allowing patients and families to ask their questions at the outset; continuing to receive questions during the investigation process; making sure that views are recorded in the report – even if the trust disagrees with it – patients and families need to know that their views have been heard and considered”.
- 1.2.5. Several respondents endorsed a more independent approach as: “without this families will continue to report concerns of bias and a conflict of interest that drives the post incident or death investigation process”. The need for greater independence in response to incidents that trigger Article 2 (the right to life) was highlighted. Parity for the recognition and investigation of incidents that involve people with learning disabilities was also emphasised.
- 1.2.6. Concerns were raised (by those affected) about the current processes for dealing with disagreements about the Serious Incident reports (to StEIS) and/or investigation processes experienced. These are often referred to the complaints process, which can mean they take a long time to be addressed. Of course, there was consensus that efforts should be made to prevent the occurrence of disagreements in the first place through meaningful involvement of those affected. However, respondents suggested that if a disagreement does arise, it should be dealt with as part of the Serious Incident investigation process wherever possible, rather than

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being referred on as a complaint. For example, if a patient or family states that information is incorrect or missing in a report, then this should be considered by those managing the investigation as an intrinsic part of the process so that appropriate action can be undertaken. Several respondents suggested that those who raise concerns should be viewed as partners who can enrich the investigation or direct more concise inquiry, and not as “complainants” or “vexatious”.

1.2.7. Patient, families, carers and their representatives stressed that they can feel there is nowhere to take their concerns and that each part of the system can act in a way that makes their situation worse – that is, the system feels increasingly closed, defensive and ineffective.

1.2.8. The suggestion: ‘Patients/families/carers should be asked to complete a standard feedback survey on receipt of the final draft investigation report that asks whether their expectations were met (which could help those responsible for overseeing investigations determine if a report can be signed off as complete)’ received the least positive response. Patients, families and staff highlighted potential issues and concerns with this suggestion which included:

- potential pressure on patients and families if this became something organisations were performance managed on
- it should not be something that patients and families feel forced to do
- the level of responsibility some patients or families may feel and an assumption that patients and families would want this
- potentially too much focus at the end of the process rather than at the start and during.

1.3. Feedback from national workshops

1.3.1. Many participants expressed an interest in adapting the patient and family liaison approach used by the police to give patients and families a single contact for guidance and support throughout the investigation process.

1.3.2. Participants (in agreement with survey feedback) stated that to undertake this role effectively, contacts would need appropriate training and support, and have sufficient seniority and exposure to managing investigations.

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Exposure to the impact of Serious Incidents on others and the implications of not responding appropriately was considered vital for shaping the right behaviour when supporting patients, families and carers.

- 1.3.3. Participants (in agreement with the survey respondents) stressed the need for clearer information (written and verbal) about the investigation process and its purpose.
- 1.3.4. Discussions with patients and families highlighted the weakness of links between patient safety-related complaints and the Serious Incident investigation processes, together with confusion about the scope and purpose of these two processes. Patients and families can believe that the complaints process is the only route open to them to initiate concerns about clinical incidents. Patient reports of clinical incidents are therefore often investigated through the complaints process rather than a patient safety investigation. The complaints process and patient safety investigations are separate and differ in purpose: complaint investigations aim, primarily, to respond to the substance of the issue being complained about and, safety investigations are undertaken to identify opportunities for system learning more generally. This means that if the patient/family/complainant does not realise this, or know quite what to expect or request at the start, the complaint investigation may not provide the system learning they want to see. Feedback suggests this difference between the two processes is not clearly understood and expectations (for both processes) are often set and measured against the Serious Incident framework. Patients and families stressed that both processes have issues that need to be resolved (and some such as involvement and openness may be common), but that the relationship between them and the scope and purpose of each needs to be better described and understood.
- 1.3.5. Patient and family representatives continue to highlight the need for more independent investigations. Problems with achieving independence in a system as connected as the NHS were discussed. Participants acknowledged that the Healthcare System Investigation Branch (HSIB) can only do a small number of investigations a year, and the NHS (via providers or commissioners) has to commission external companies to undertake 'independent investigations' on its behalf. Concerns were raised about cost, capacity, consistency (in terms of when the need for independence is

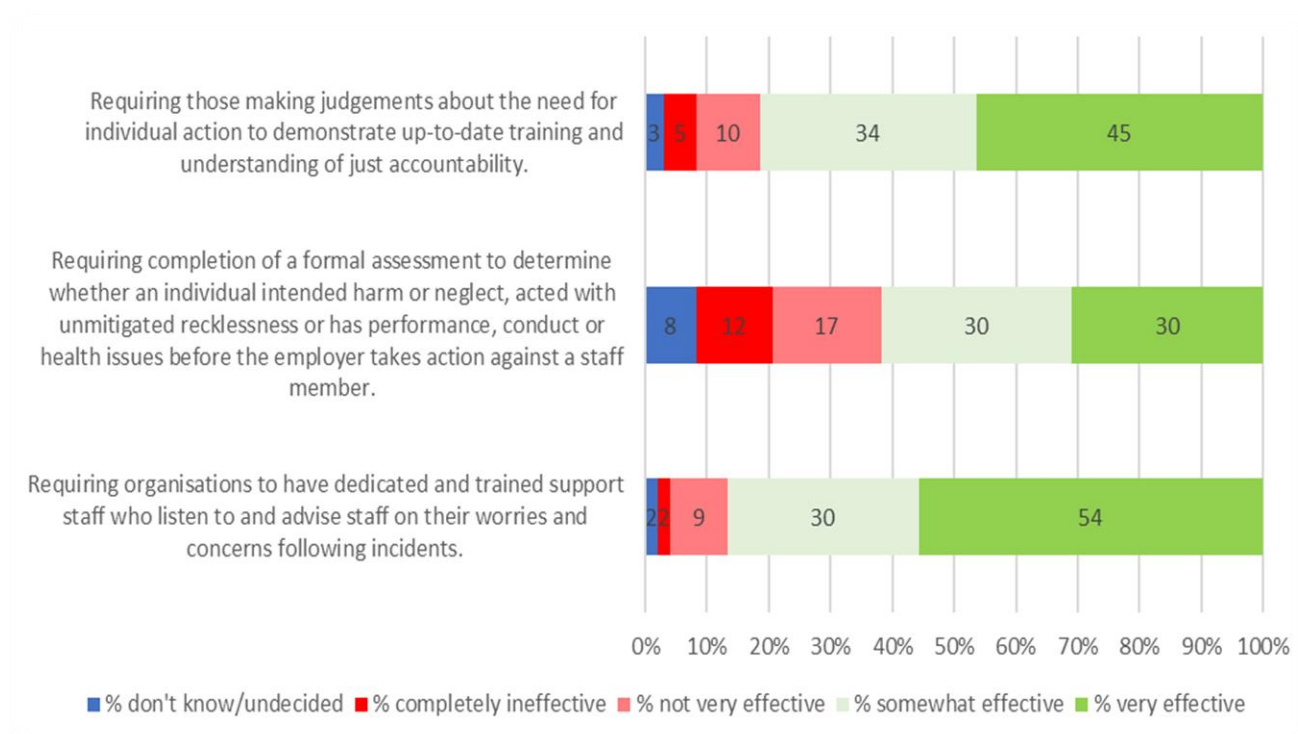
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considered) and different beliefs about what constitutes independence. Interest was expressed in developing an approach similar to the Independent Office of Police Conduct.

2. Supporting and involving staff

2.1. Survey question (MCQ)

We asked respondents to indicate how effective the following suggestions could be in supporting and involving staff in investigations.



2.2. Summarised free text comments

- 2.2.1. Many respondents indicated that requiring organisations to have dedicated and trained staff to support staff members going through the investigation process could be an effective way to improve staff support and involvement. Respondents also suggested that the new framework recognises the importance of line managers and peers as well as separate, dedicated support where this is needed.
- 2.2.2. Many respondents raised concerns that the suggestions relating to the formal assessment and training of those making judgements about

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individual action (see above) do not effectively recognise the separation needed between HR/fitness to practice investigations and safety investigations. Comments highlighted the general agreement that suspension should not be the default action and that those making judgements about individual action need appropriate training (and should apply appropriate guidance such as [A just culture guide](#)).

- 2.2.3. Several respondents suggested that patient safety and HR teams need to better understand the relationship between their investigations but that the terms of reference of these must not be conflated.
- 2.2.4. Concerns relating to equality, diversity and inclusion were also raised; there was a sense that some professional groups were treated differently and that certain groups within different professions were disproportionately represented in investigations. For example: “historically doctors with protected characteristics are disproportionately represented in fitness to practice processes... there are a higher number of referrals from employers about particular cohorts of doctors. We believe it is essential to underpin the principles with a commitment to equality, diversity and inclusion ...”.
- 2.2.5. Feedback on investigation findings was described as a significant issue; staff are often “kept in the dark”. Weeks, months and even years pass without staff receiving information about the investigation findings, what the outcome is likely to be and whether they will be blamed for mistakes made or the harm caused.
- 2.2.6. Concerns were also raised about involvement in Serious Incident investigations being mentioned in medical revalidation. Any involvement in a Serious Incident investigation can be seen as a direct indication of ‘wrong doing’.

2.3. Feedback from national workshops

- 2.3.1. Participants suggested that staff also need to be supported by a liaison/key point of contact who can facilitate their involvement throughout the investigation process. Some organisations have developed support networks and systems of peer support for those involved in an investigation and their staff report that such initiatives have been a positive step.

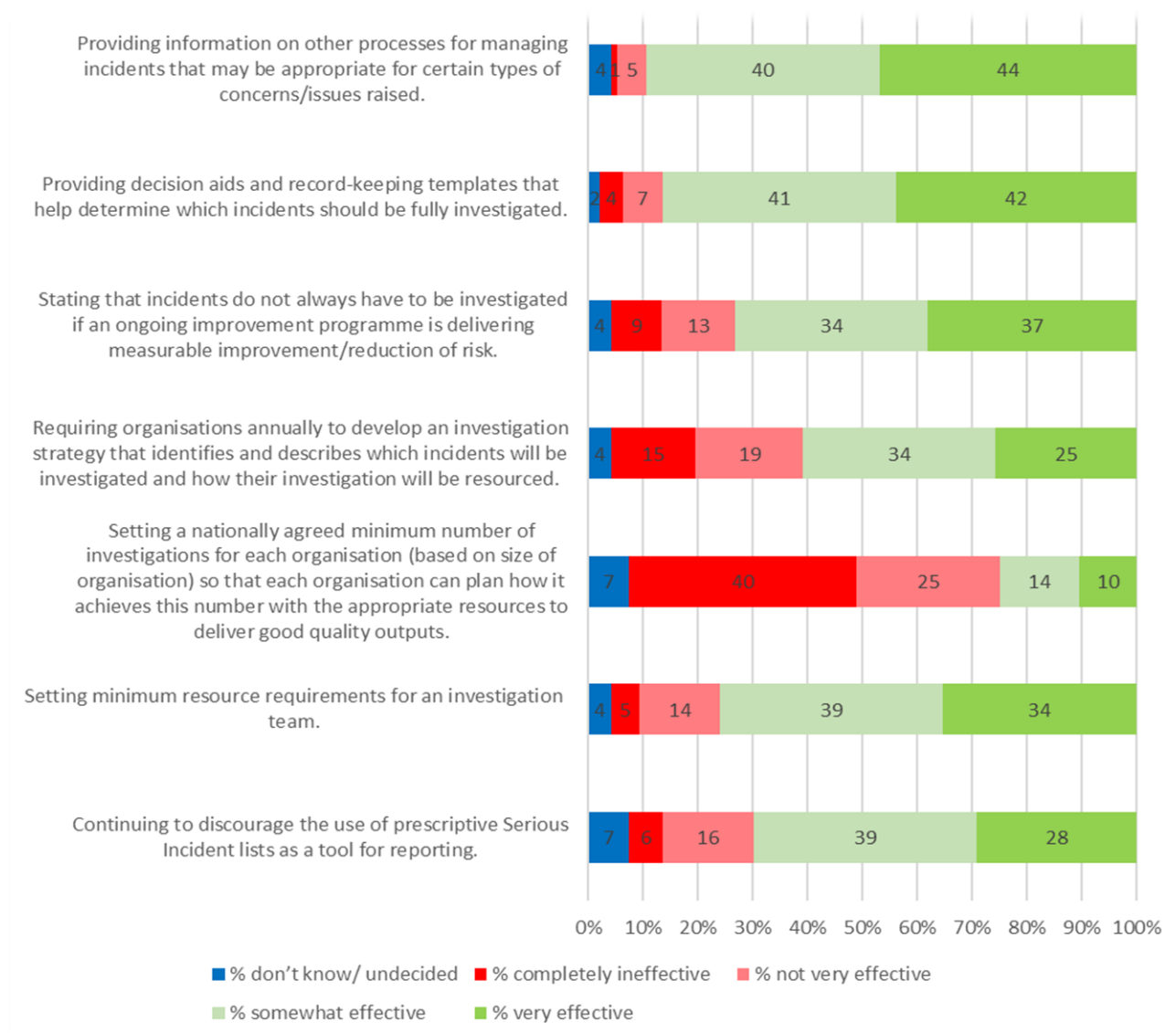
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- 2.3.2. Several participants stressed the importance of informing staff about investigations in an appropriate and sensitive way. Formal letters or emails are often sent to staff by corporate teams, and the recipients may not even know that an incident has occurred. Staff are left feeling fearful and isolated. Participants said staff need to be told about their involvement in an investigation 'in the right way' – that is, in person (although written information should follow) by someone who is personable. Support then needs to be made available.
- 2.3.3. We were repeatedly told that staff are uncertain whether suspension is still considered a 'neutral act'. Questions were also raised about the specific incident types where staff may need to be suspended until an investigation has concluded, eg where abuse or sexual assault has been alleged. Participants felt further clarity was needed.
- 2.3.4. Participants also raised concerns about organisational policies that prevent staff from working once an investigation in which they are involved has been declared. Such policies can particularly affect contracted (third party) staff who can in effect be suspended without pay until the investigation concludes. Participants said penalising staff in this way had implications for the wider organisational safety culture (as individuals fear being blamed) as well as staffing pressures (as it reduces an already stretched workforce).

3. Inappropriate use of the Serious Incident investigation

3.1. Survey question (MCQ)

Respondents were asked how effective the following suggestions could be in supporting more effective use of Serious Incident investigations.



3.2. Summarised free text comments

- 3.2.1. The suggestion 'Setting a nationally agreed minimum number of investigations for each organisation (based on size of organisation) so that each organisation can plan how it achieves this number with the appropriate resources to deliver good quality outputs' received the least positive response. Respondents expressed concerns about having nationally agreed numbers that the system will use as targets: "this will cause the focus to remain on the numbers".
- 3.2.2. There was interest in exploring a safety investigation strategy but questions about how this would be delivered and whether cross-system strategies could be agreed to ensure cross-system investigation/collaborative working. "The investigation strategy is a great idea but will need to be reviewed if arrangements differ throughout the year. The strategy should include reference to the audit arrangements following each investigation."
- 3.2.3. The suggestions 'Providing information on other processes for managing incidents that may be appropriate for certain types of concerns/issues raised' and 'Providing decision aids and record-keeping templates that help determine which incidents should be fully investigated' received the most positive response.
- 3.2.4. Respondents acknowledged that Serious Incident investigation is 'overused' and further exploration of guidance to articulate when/how other approaches can be used was thought worthwhile. "There must be a distinction made between alerting commissioners and regulators to a Serious Incident and the need for a proportionate investigation."
- 3.2.5. Concern was raised that the 'emotional response' to incident reporting, from commissioning, oversight and regulatory bodies, leads to additional workload that detracts from the investigation process because multiple briefings and updates are required to provide 'reassurance'.
- 3.2.6. External reporting requirements can also inhibit an organisation's ability to prioritise which incidents are investigated. Respondents stressed that investigations need to focus on learning and improvement, not the fulfilment of external reporting requirements.

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- 3.2.7. Several respondents expressed their support for a stepwise approach whereby, before making a decision about investigation, incidents/cases are assessed or reviewed first to establish what happened, and to compare findings with what should have happened. The work involved in this (for example, a structured judgement review, timeline/chronology, 'after action review') should be shared with the family to uphold/support compliance with Duty of Candour. It was suggested that the information from the initial assessment/review would also help make the terms of reference for an investigation more specific and appropriate.
- 3.2.8. Respondents suggested that clear information about the different investigation types would help clarify their various purposes and potentially avoid duplication. Some types of incidents will be subject to more than one investigation: safeguarding; mental health-related homicide; information governance incidents; potentially HSIB maternity investigations. Rationalising the number of investigations and/or reviews where possible (that is, only where their terms of reference are aligned) could support better use of resources. Some respondents recommended using a memorandum of understanding to support joint work and others suggested that clarifying issues with investigation hierarchy would help reduce confusion/disagreement.
- 3.2.9. Where different types of investigations are required, the reasons for this should be clearly communicated: "a clear document should be made available for patients, families, carers and healthcare professionals alike which outlines the purpose and aim of different types of investigations (eg coroner's investigation, patient safety investigation, fitness to practice investigation)".
- 3.2.10. Respondents recognised the challenge of responding to incidents that have recurred because large-scale multifactorial processes/projects (eg recruitment or service redesign) have still to be completed. In such cases: "it may not be beneficial to conduct a full Serious Incident investigation given the amount of resource a robust investigation requires and instead, it could be better to focus on implementation and monitoring of ongoing actions". Respondents recognised that not investigating an incident might not be acceptable to families and patients and, in circumstances where a full investigation was not deemed beneficial, sufficient information would

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need to be provided to respond to the patient or families queries and/or concerns.

- 3.2.11. Respondents highlighted their concern that incidents might not be investigated on the basis that “the same themes are expected to emerge”. A respondent suggested that recurrence should serve as an “alert that the root causes are not being identified”. Fewer but more indepth investigation of common incidents (such as pressure ulcers and falls) might be needed.
- 3.2.12. Feedback also suggested a risk management approach should be considered – “identifying high risk incidents/near misses and investigating in a proactive way with a focus on improving practice using examples of where it has gone well”. It was suggested that such an approach could identify “overall magnitude of the risk and potential for making safety gains”. Thematic reviews were suggested as another approach.
- 3.2.13. Currently some organisations are required to complete numerous report templates to provide information about the incident and to update different organisations (namely commissioning and oversight boards) about the investigation process. Respondents suggested better use of IT to simplify and standardise reporting, potentially saving time and effort.
- 3.2.14. Respondents also suggested more appropriate allocation of tasks and sufficient administrative support would allow investigators to use their time more effectively. Those leading an investigation often need to set up meetings and organise information and their time would be better spent identifying and analysing evidence.
- 3.2.15. Respondents recognised that there may need to be fewer investigations if these are to be done to a high standard and meaningful action is to result from them. However, respondents were concerned about how a patient or family member would feel if an incident that affected them was not deemed to warrant an investigation. Patients and families may want an investigation, even if the type of incident is the subject of an improvement programme.
- 3.2.16. Respondents also recognised investigators need time, training and support if they are to improve the quality of investigation. National training and sharing of good practice were recommended.

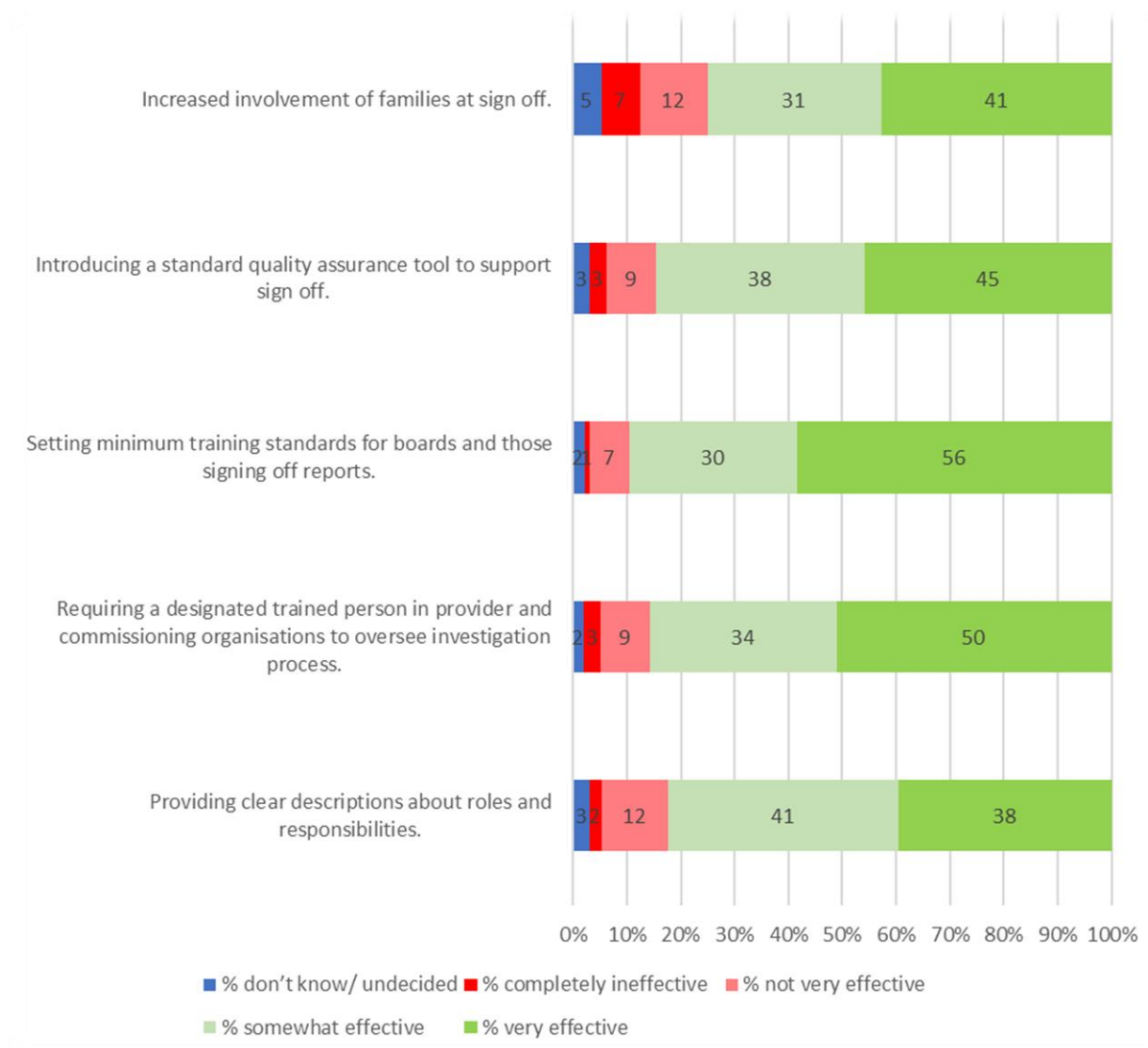
3.3. Feedback from workshops

- 3.3.1. Some stakeholders expressed a sense of feeling lost: “the terms of reference are unclear”, and suggested that firm standards (and standardised terms of reference) would help as “everyone is trying to influence what the investigation is trying to find”.
- 3.3.2. Discussions focused on the need to move away from prescriptive reporting lists and to clarify the purpose of the Serious Incident investigation process.
- 3.3.3. The importance of appropriate time and expertise to enable investigators to deliver good quality outputs that can generate change and improvement was highlighted; producing poor quality reports over and over again was deemed a “waste of NHS resource”.

4. Oversight and assurance

4.1. Survey question (MCQ)

Respondents were asked to indicate how effective the following suggestions could be in developing an environment for learning and improvement.



4.2. Summarised free text comments

4.2.1. The suggestion to provide minimum training standards for those quality assuring investigations and to have a designated trained lead in both

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commissioning and provider organisations received the most positive response.

- 4.2.2. Respondents suggested sign off should be a one-step process, not multiple steps going back and forth between different committees in provider and then commissioning organisations – everyone should be in the room together to come to this agreement.
- 4.2.3. Many respondents expressed an interest in increasing the level of ‘ownership’ and understanding at board level. Some suggested that board members might not be “best placed to sign off/approve” investigations but that they do need to understand and support the processes in their organisations to ensure systems support good quality outputs and improvement.
- 4.2.4. Respondents stressed the need to break the “them and us mentality” between providers and clinical commissioning groups (CCGs) and for a new focus on how “we” can get it right
- 4.2.5. The general sense was that the current ‘checking’ process does not add value: “work is sent off for marking” and “feedback is not provided in a supportive learning way”. Some respondents suggested that commissioners should: “not be the judge with ability to penalise, but participants in discussion about how to improve”.
- 4.2.6. Many comments reflected the need to be much more open with information generated from the investigation process; the lack of access to this information makes the process feel closed and defensive. Respondents suggested information needs to be published and work done to support communication between organisations – more national support to do this was requested.
- 4.2.7. Respondents also emphasised the need to clarify the roles of all organisations, including the Care Quality Commission (CQC) and NHS Improvement, not just providers and commissioners. Respondents suggested that regulators should be holding organisations to account for delivering the improvement following an investigation and that CQC could inspect against clearer guidance/regulations/standards around this (so

expectations are clear). Currently there is too much focus on individual incidents and this needs to shift to system improvement and culture.

- 4.2.8. Some respondents, particularly patients and families, feel there is no accountability for the quality of an investigation, with commissioners, NHS England, NHS Improvement and CQC appearing to condone poor practice because none of them provides clear advice on how patients and families can raise concerns about the quality of an investigation. There is a sense of being “passed around” and/or ignored and this allows poor practice to continue. Concerns about compliance with Duty of Candour were also raised; some respondents suggested there were no implications for organisations that were not open and honest.

4.3. Feedback from workshops

- 4.3.1. Discussion centred on the disproportionate focus on meaningless targets – that is, numbers of incidents reported and compliance with the 60 working day timeframe.
- 4.3.2. Participants questioned the value of commissioners checking every investigation at the end of the process. They suggested focusing on the infrastructure to support investigation and how to ensure report recommendations feed into future commissioning decisions to support safe services.
- 4.3.3. Participants highlighted the need for those ‘signing off’ or ‘approving’ investigation reports to understand what a good investigation looks like. They expressed concern that reports become more and more “watered down” as they proceed through the organisational tiers of approval, describing this process as “clevering” – that is, while the final report may read well, its intended meaning may have been lost.
- 4.3.4. Participants highlighted the need to consider the board roles and responsibilities. Some felt that assigning specific roles and responsibilities to a member of the board would help ensure high quality, provided the board member was given relevant training/development. Participants felt that ownership/responsibility for the sign off of investigation reports should rest with the provider board (rather than commissioning organisation) because it is the provider organisation (rather than the commissioning

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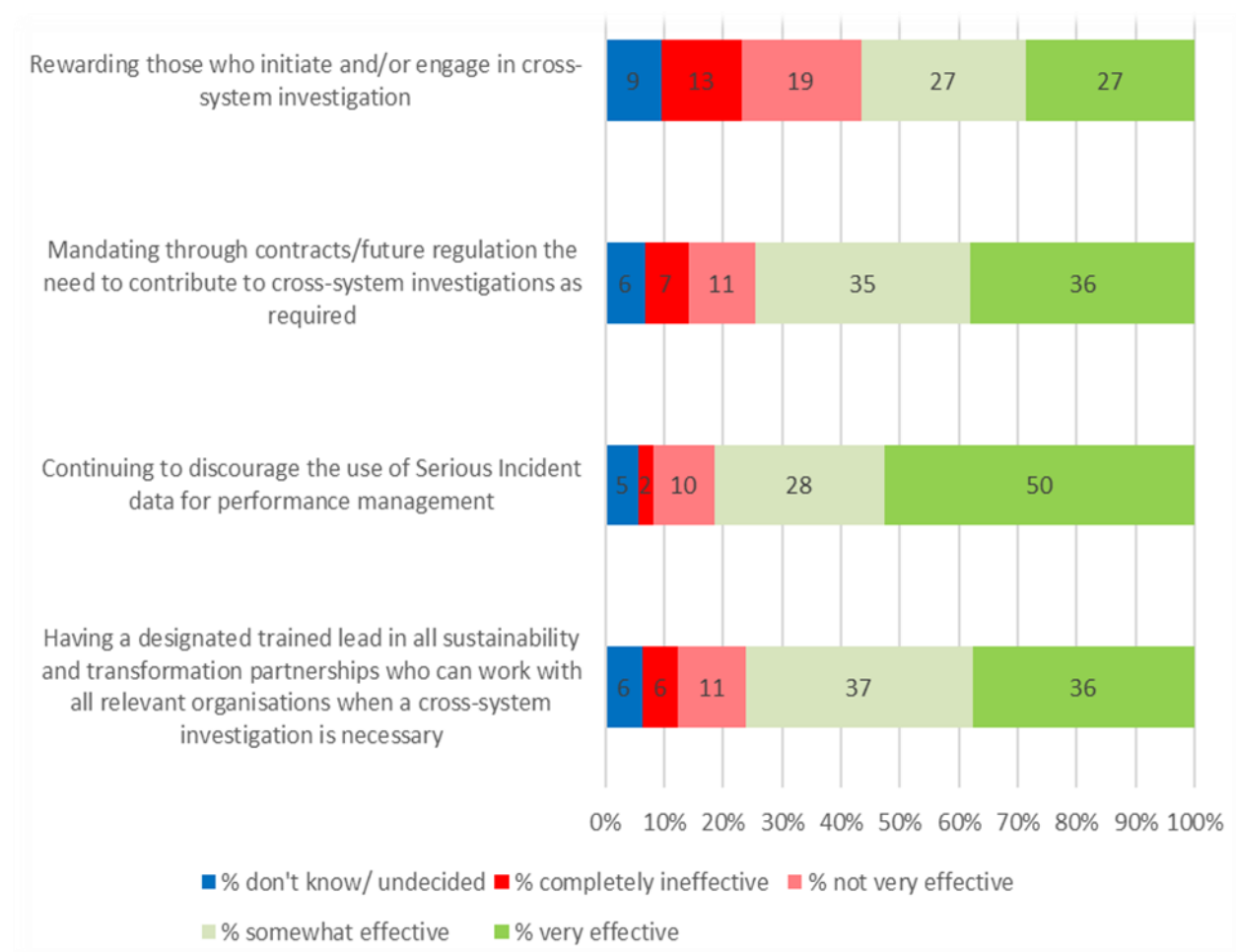
organisation) that is held to account if queries are raised with regards to the management and quality of the investigation process.

- 4.3.5. Currently improvement resulting from a Serious Incident investigation does not need to be described in Quality Accounts. Participants suggested that making this a requirement could engage NHS boards in the output of the investigation process and encourage focus on improvement rather than process.
- 4.3.6. Participants also highlighted the importance of organisational ‘maturity’ in relation to patient safety (that is, how well systems and process support openness, transparency and improvement), stressing that “there is a spectrum of how people would respond based on maturity”. Help developing organisational maturity may be needed to support implementation of guidance and any new standards.

5. Supporting cross-system investigation

5.1. Survey question (MCQ)

Respondents were asked to indicate how effective the following suggestions could be in supporting cross-system investigation.



5.2. Summarised free text comments

- 5.2.1. The suggestion to continue to discourage the use of Serious Incident data for performance management received the most positive response. Comments revealed that pressure to complete an investigation within 60 working days and performance management against the number of Serious

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Incidents reported prevents cross-system investigation: "...there is a culture of mistrust between organisations combined with a competitive edge. This does not encourage cross-system communication".

- 5.2.2. The suggestion of having a designated lead in all sustainability transformation partnerships (STPs) also received a positive response. Respondents suggested that a lack of skill and time to support cross-system investigation is a key issue. CCGs are trying to support cross-system investigation in some areas but they also do not always have staff with enough time or the right skills. Some respondents reflected on other processes requiring cross-system working, such as the mortality review process (particularly the Learning Disabilities Mortality Review; LeDeR), where lack of time and resource has resulted in delays and reviews not being completed.
- 5.2.3. Several models were suggested to support cross-system investigation: appointment of trained and independent investigation chairs; employment of professional investigators; trained investigation co-ordinators within CCGs or STPs (there was some debate about where expertise should reside); funded government department; recruitment of a national pool of experts. Aspects of the Child Death Overview Process were cited as helpful for supporting cross-system working. Several respondents indicated that a dedicated budget would be needed to support cross-system leads, and possibly a strategy to prevent the lead from being overwhelmed or merely managing a 'pleading mailbox'.
- 5.2.4. Making the patient the focus, not the organisation, was also suggested – that is, where did the patient go and which part of their journey do we need to focus on? Not which organisation needs to investigate?
- 5.2.5. People, relationships and process were noted as essential to supporting cross-system working. Some respondents suggested picking a theme or incident type (eg deterioration of elderly patients) for a cross-system improvement programme that could help to build relationships and a shared sense of purpose, rather than waiting for an incident to occur to test this.

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- 5.2.6. Facilitated reflection meetings with different organisations were suggested as was the establishment of a national forum for identifying and debating cross-system issues. Publication of good work was also recommended.
- 5.2.7. The suggestion to require cross-system investigation to be considered each time a Serious Incident is declared, and the reasons why/why not to be included, received mixed feedback; while some respondents thought this could be a helpful prompt, many believed it would introduce another layer of administration and further bureaucracy (which would not benefit many incidents).
- 5.2.8. The suggestion to reward those who initiate and/or engage in cross-system investigation was considered to be the least effective suggestion. Some respondents felt that rewards could be useful providing they were “quality improvement focused”, eg funding a cross-system improvement project or secondments to support cross-system working. However, many felt that incentives should not be used to encourage participation in and initiation of cross-system investigation as this should be part of normal/expected practice as stated in current guidance. Others suggested that rewards would be an intrinsic part of cross-system working: “rewards occur naturally when information is shared and learning can be achieved”, “celebration of success is a more cogent factor to support cross-system investigation”. Respondents suggested that when incentives are used, capacity and focus to achieve the target may be time limited – lots of resource is put into ‘ticking a box’ but not into achieving sustainable change and improvement.
- 5.2.9. Caution was expressed about applying contractual levers: while some respondents recognised that these could help with enforcement, there were concerns this approach may not “yield positive impact on quality” and “positive levers may be more effective than contractual and other sanction-based approaches”. Contracts and rewards may mean lead investigators form an alliance/allegiance with one organisation over another.
- 5.2.10. Respondents highlighted potential tensions between improving cross-system investigation and the suggestion to develop an organisational investigation strategy where the number and type of incident each trust will investigate is agreed in advance (see Section 3.2.2 above).

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- 5.2.11. Some respondents recommended clearer guidelines about cross-system investigation, with roles and responsibilities better defined. Learning from Public Health England quality assurance teams for national screening programmes provided useful insight into the role of the RASCI (responsible, accountable, support, consult, inform) model and the value of regional and national expertise to support decision-making and co-ordination of investigation associated with complex incidents.

5.3. Feedback from national workshops

- 5.3.1. Participants highlighted a conflicting message to be honest and transparent but also to maintain low rates of reporting, as otherwise external organisations will seek to 'manage' or demand assurance. This means organisations are reluctant to report incidents unless they absolutely must.
- 5.3.2. Pressure to complete the investigation within 60 working days also prevents joint working because individual organisations are performance managed on this and joint working often adds complexity, meaning timeframes are breached.
- 5.3.3. Participants highlighted the current lack of capacity in terms of both time and skills to support cross-system work and suggested this was a bigger limiting factor than issues associated with information sharing and confidentiality.
- 5.3.4. Concerns were expressed about the development of recommendations and action planning at the end of the investigation process: it can be difficult for an organisation 'taking the lead' in an investigation to make recommendations to another organisation. Participants suggested this needs to be a collaborative process and that oversight of action delivery needs to focus on systems not organisations to support partnership working.

6. Ensuring appropriate time and expertise

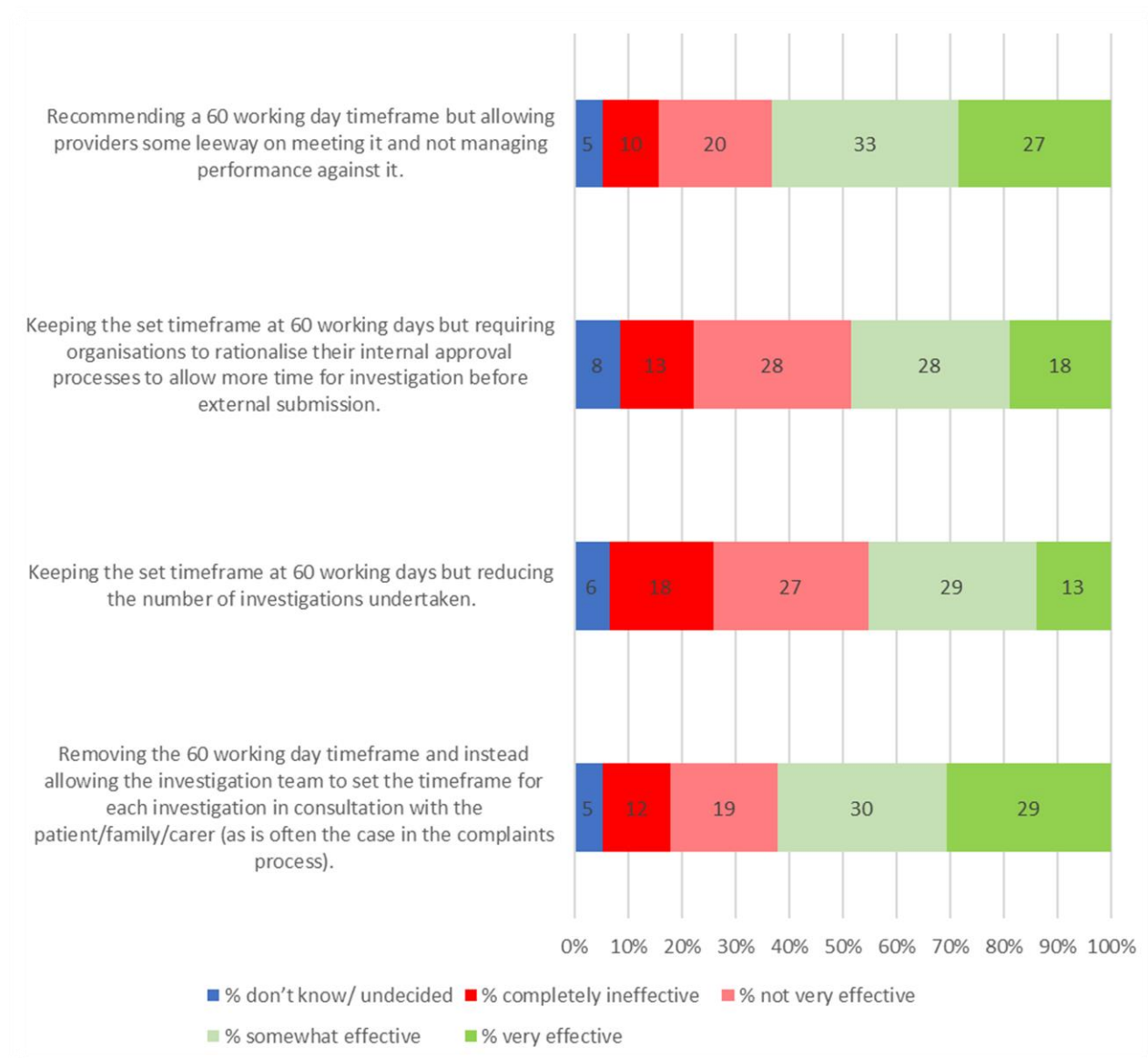
6.1. Survey questions (MCQs)

6.1.1. Respondents were asked to indicate how effective the following suggestions could be in helping to ensure appropriate expertise is dedicated to investigation.



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6.1.2. Respondents were asked to indicate how effective the following suggestions could be in helping to ensure appropriate expertise is dedicated to investigation.



6.2. Summarised free text comments

6.2.1. The suggestion that organisations have a designated and trained head of investigation was the most positively received. Clarification was sought about what the head of investigation would need to be trained in – that is, if

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the head of investigation were a nurse or doctor, would they be considered 'trained'.¹

- 6.2.2. Respondents were also in favour of protecting time for investigators to undertake investigations. The suggestion to have a flexible investigation team (that is, staff who manage investigations alongside other roles but have dedicated time to undertake investigations) was considered potentially more effective than having a dedicated team (that is, investigators with no other roles/responsibilities), largely because of concerns about the ability to resource such a team but also about isolation and deterioration of clinical skills. This opinion contrasted with that from the workshops (see Section 6.3).
- 6.2.3. Problems caused by the strict 60 working day timeframe were also highlighted. Often this is not enough time to complete an investigation, especially when the incident involves more than one team, department or organisation. Some patients and families need more time to feel able to contribute to an investigation.
- 6.2.4. Concerns were raised about changing timeframes. Respondents suggested that having no set timeframe could delay the start of an investigation and then allow it to drag on indefinitely. Generally, stakeholders favoured an approach that included a timeframe such as: agreeing a timeframe against a plan and monitoring this with patients and families; or having a national timeframe (with extra time for action planning) but not performance managing providers against this.
- 6.2.5. Respondents highlighted the significance of the lack of nationally available/ accredited training. Currently no standards have been set around training. Respondents also highlighted the need to consider what counts as 'expert/expertise' in investigation. Some of the most expert investigators in NHS providers and commissioners have only had two days of training.

6.3. Feedback from national workshops

- 6.3.1. The focus on completion of investigations within 60 workings days was highlighted as one of the most significant issues. Performance against the

¹ Note: 'Trained' in this context means trained in investigation so any other qualification is not sufficient on its own.

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60 working day timeframe for investigation completion seems to have become the preoccupation of both providers and commissioners, and this is now undermining investigation quality. Some suggested that a focus on completion was necessary because “there was a time when hundreds of investigations were still ‘open’ many months and even years after an incident had occurred”. Participants suggest that over the last four to five years there has been an effort to resolve this and we need to ensure that investigations are still completed in a timely way.

- 6.3.2. Many participants were in favour of focusing on the quality of the investigation. Concerns were raised about problems meeting a patient’s and/or family’s expectation if there were no national timeframe to act as a guide. Family representatives confirmed that compliance with 60 working days has little meaning and, providing patients and families are involved and informed about progress, the exact number of days was a secondary concern. The families and patients we spoke to repeatedly said their primary concern was good quality investigation that includes them.
- 6.3.3. Participants discussed how organisations currently resource investigation teams. Most rely on staff with other roles to undertake investigations. Some reported reluctance to be assigned the ‘lead investigator’ role because of the significant workload this entails. Some have appointed dedicated investigators and investigation teams with no additional responsibilities. This allows focused work and enables people to develop skill and experience. The general sense was that having dedicated investigation teams is the best approach, providing such teams are appropriately resourced. Participants highlighted that other factors could still undermine the quality of investigation (eg pressure to meet deadlines, lack of support from the leadership team, a legalistic approach). This emphasises the need for systematic change.
- 6.3.4. Access to training was a significant concern. Many organisations rely on in-house training from staff who have been doing investigations or who were trained a long time ago. Currently training has to be resourced from external companies and organisations must do their own checks on its quality. Participants suggested that nationally accredited training would be beneficial.

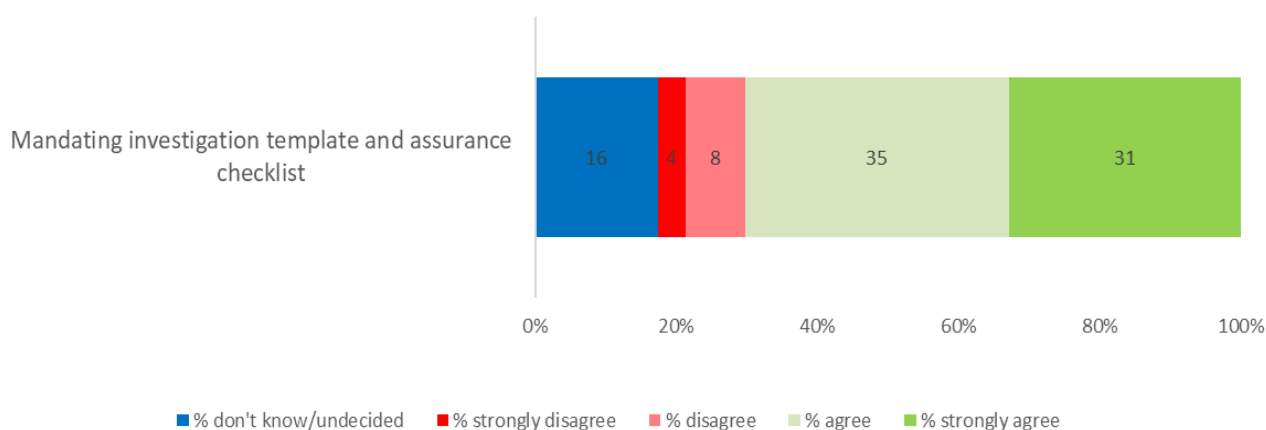
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- 6.3.5. Workload pressures were discussed alongside skills and expertise: “investigators are becoming deskilled, demotivated and you have to question how long you can survive doing the job”.
- 6.3.6. Interest was expressed for developing networks/connections with neighbouring organisations to support investigation, either by sharing good practice or by helping to provide an ‘objective eye’. Such arrangements are not well established except in a few areas.
- 6.3.7. Stakeholders suggested that mandated standards around training and backfilling time to support investigation could help put investigation “on an equal footing” with other roles in the NHS. Currently investigation is seen as something almost anyone can do.

7. Support uptake of evidenced-based approaches

7.1. Survey question (MCQ)

Respondents were asked to indicate how effective the following suggestions could be in supporting uptake of evidence-based approaches.



7.2. Summarised free text comments

- 7.2.1. Respondents gave mixed views about mandated report templates and assurance checklists; generally, they agreed these could be helpful but were wary of “over-reliance on standardised tools, without critical thinking processes”.
- 7.2.2. Respondents suggested a need to get the basics right, such as better definition and use of investigation language: “there are basic ABCs that transcend all industries and they are not complicated”.
- 7.2.3. Lack of training and expertise were highlighted again. Respondents suggested that there is a need to professionalise this area of work and stressed the need to invest in people to develop the right skills and

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expertise: for example, “report writing is a skill that needs to be learned and cannot be enforced through a template alone”.

7.2.4. Many respondents expressed an interest in learning from the HSIB.

7.3. Feedback from national workshops

7.3.1. Discussions focused on the need to set standards for investigation and investigation training across the NHS.

7.3.2. Participants suggested dedicated time for investigators (who have had appropriate training, exposure and experience) or standing investigation teams would improve uptake of an evidence-based approach.

7.3.3. Standard/accredited training for investigators and methods to support board awareness/understanding were also recommended.

8. Principles for investigation

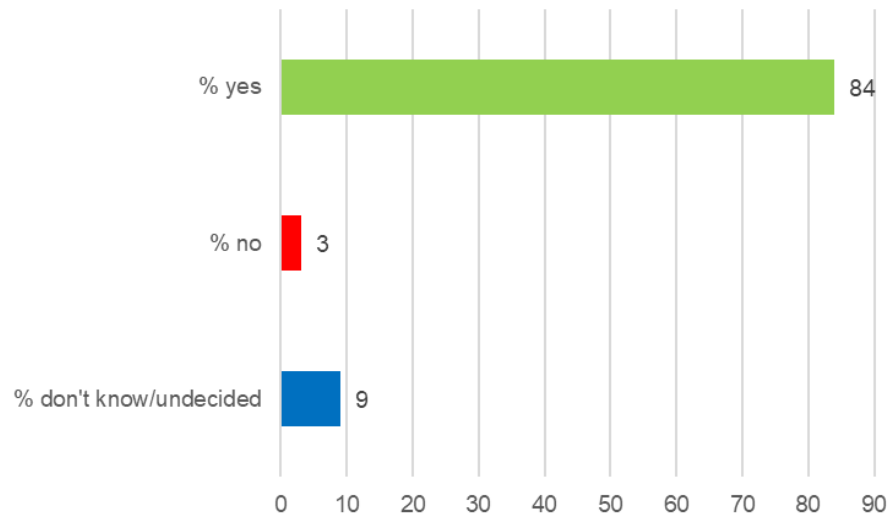
8.1. Survey questions (MCQ)

Please see the suggested principles below.

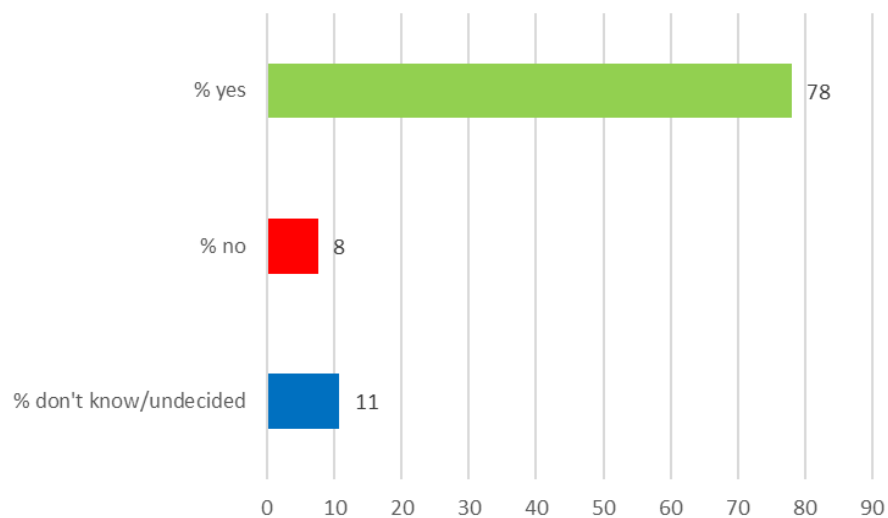
Strategic	Boards focus on quality of output, not quantity. Resources are invested to support quality outputs. Boards recognise the importance of findings. There is a culture of learning and continuous improvement.
Preventative	Investigations identify and act on deep-seated causal factors to prevent or 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: <ul style="list-style-type: none">• 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.

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



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



8.2. Summarised free text comments

8.2.1. Respondents suggested that examples of how principles are realised and why they are important would be useful in clarifying their rationale at a practical level.

8.2.2. Respondents generally supported a single set of principles for good practice that all NHS providers, commissioners, regulatory and supervisory bodies must follow.

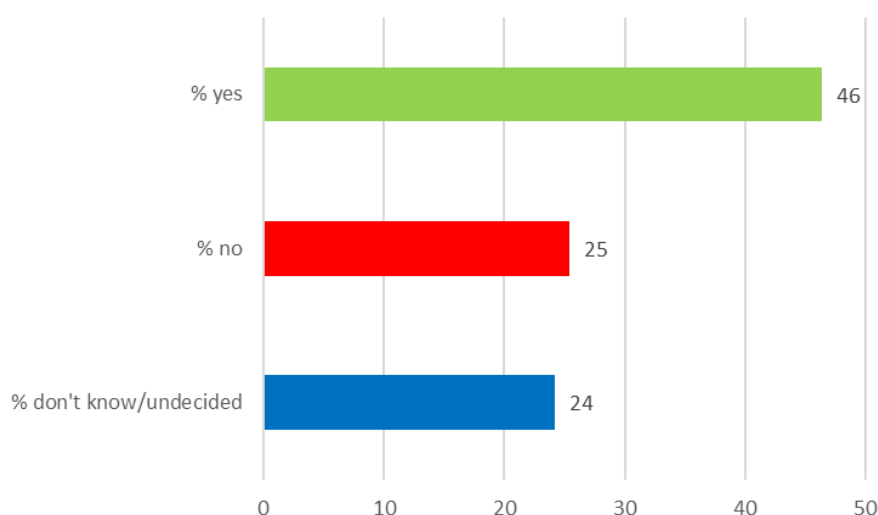
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- 8.2.3. Revision of some existing terminology was recommended “as words like investigation, statements, witnesses are all loaded with legal implications and do not fit with the prime objective of learning”.
- 8.2.4. Many suggested that investigations could be improved by developing and giving access to a library of well-conducted investigations and reports.
- 8.2.5. Comments highlighted that courage and leadership will be required to effect changes to established investigation practice.

9. Changing the name of the Serious Incident framework

9.1. Survey question (MCQ)

- 9.1.1. 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?



9.2. Summarised free text

- 9.2.1. Opinion about changing the name was divided. Some respondents thought a name change is essential (along with changing terms such as 'root cause analysis', 'investigation' and 'incident' as all have negative connotations). They suggested 'rebranding' to emphasise learning and improvement. "It often frightens patients/relatives/carers when receiving a letter or report with the wording 'serious'. I believe it also confuses them and causes unnecessary stress".
- 9.2.2. Respondents also suggested that the term 'Serious Incident' is not meaningful to all provider types (eg primary care) and the new framework/name could resolve this.

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- 9.2.3. Other respondents were indifferent, implying that the name does not matter because it is the behaviour/culture that is important.
- 9.2.4. Some respondents thought a name change would risk confusion and “change fatigue”, and be perceived as “changing labels rather than substance”. Several respondents asked us to “stop changing things”. Others pointed out that name changes take a long time to embed and are somewhat pointless; some organisations are still referring to ‘SIRIs/SUIs’, although a more fundamental change might be more obvious.
- 9.2.5. Those who supported a name change suggested that the name should focus on collaboration, learning and improvement.

10. Next steps

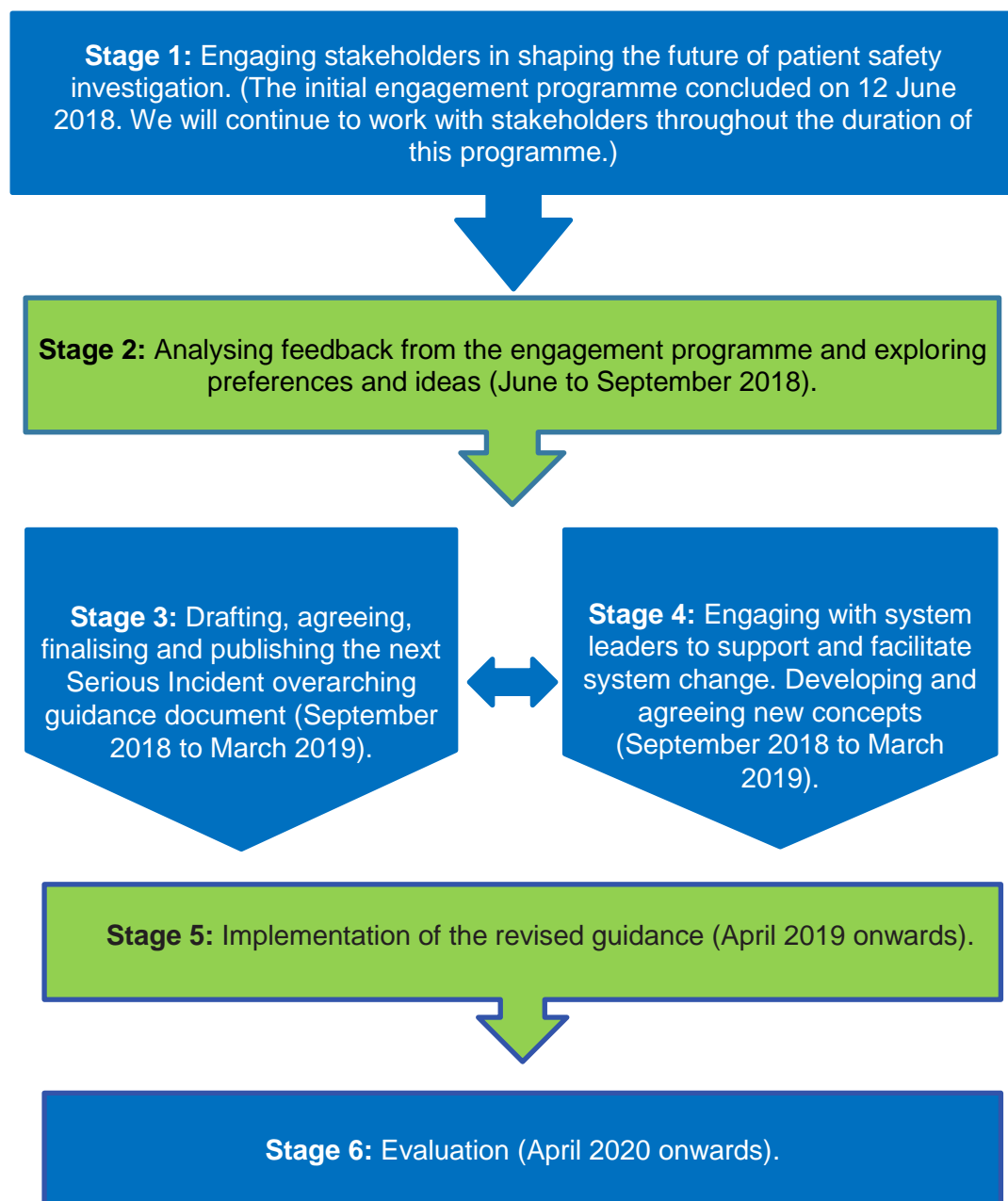
This engagement has provided invaluable insight into the issues associated with Serious Incident management and how improvements might be achieved. This is thanks to the significant amount of time and effort more than 400 people have spent preparing and sharing thoughtful feedback with us – for which we are extremely grateful.

We will use this information over the next six months to develop and test new ways of working for Serious Incident management (as outlined in Figure 1 below). We will use an agile approach to iterate and align this work with other key programmes where there may be interdependence, such as work led by the HSIB, the development of the Patient Safety Incident Management System and the Learning from Deaths work programme. We will provide further information on our engagement webpage.

Please contact Patientsafety.enquiries@nhs.net if you have any further questions or queries.

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Figure 1: Key work programme phases



Appendix 1: Type of representation

	No selection made	I am responding as an individual	I am responding on behalf of a group/team/department	I am responding on behalf of a patient, family or carer	I am responding on behalf of an organisation	Total
Acute care provider (inc clinical and non-clinical staff)		81	15		27	
Ambulance provider (inc clinical and non-clinical staff)		2	3		2	7
Care Quality Commission		1			1	2
Charity		1			2	3
Clinical commissioning group	1	22	8		24	55
Community care provider (inc clinical and non-clinical staff)		12	4		3	19

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	No selection made	I am responding as an individual	I am responding on behalf of a group/team/department	I am responding on behalf of a patient, family or carer	I am responding on behalf of an organisation	Total
General practice (inc clinical and non-clinical staff)		5	1		1	7
Member of the public		21				21
Mental healthcare provider (inc clinical and non-clinical staff)		44	10	1	10	65
NHS England		10	1		2	13
NHS Improvement		3				3
NHS Resolution					1	1
Patient, carer or family representative		2	1	1		4
Patient, carer or family member		21		11		32
Pharmacy (inc clinical and non-clinical staff)					3	3

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	No selection made	I am responding as an individual	I am responding on behalf of a group/team/department	I am responding on behalf of a patient, family or carer	I am responding on behalf of an organisation	Total
Prison healthcare (inc clinical and non-clinical staff)		1			1	2
Public Health England			1			1
Royal college					5	5
Specialised tertiary care provider (inc clinical and non-clinical staff)		5	1		3	9
No selection made	3	16	6		10	35
Total	4	247	51	13	95	410

Separate responses were also received from: HSIB, Royal College of Nursing, Royal College of Psychiatrists, General Medical Council, Health Education England, Professional Standards Authority, Medical Defence Union and London Fire Brigade. We have incorporated their comments in the summaries of free text comments for each engagement topic.

Appendix 2: Response summary

This table summarises the responses to the suggestions surveyed in relation to each engagement topic area. (Note: 'blank responses' are the reason many of the responses do not add up to 100%.)

How effective would the following options be for supporting and involving patients, families and carers?	% don't know/ undecided	% completely ineffective	% not very effective	% somewhat effective	% very effective
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 its requirements and if it is not, raise this with the organisation (with support from their key point of contact who organisations are currently required to provide).	1	3	6	38	49
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.	1	5	14	37	39
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.	3	16	19	34	24

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How effective would the following option be for supporting and involving staff	% don't know/ undecided	% completely ineffective	% not very effective	% somewhat effective	% very effective
Requiring organisations to have dedicated and trained support staff who listen to and advise staff on their worries and concerns following incidents.	2	2	9	30	54
Requiring completion of a formal assessment 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.	8	12	17	30	30
Requiring those making judgements about the need for individual action to demonstrate up-to-date training and understanding of just accountability.	3	5	10	34	45
How could the Serious Incident framework best support more effective use of investigation resources?	% don't know/ undecided	% completely ineffective	% not very effective	% somewhat effective	% very effective
Continuing to discourage the use of prescriptive Serious Incident lists as a tool for reporting.	7	6	16	39	28
Setting minimum resource requirements for an investigation team.	4	5	14	39	34
Setting a nationally agreed minimum number of investigations for each organisation (based on size of organisation) so that each organisation can plan how it achieves this number with the appropriate resources to deliver good quality outputs.	7	40	25	14	10

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Requiring organisations annually to develop an investigation strategy that identifies and describes which incidents will be investigated and how their investigation will be resourced.	4	15	19	34	25
Stating that incidents do not always have to be investigated if an ongoing improvement programme is delivering measurable improvement/reduction of risk.	4	9	13	34	37
Providing decision aids and record-keeping templates that help determine which incidents should be fully investigated.	2	4	7	41	42
Providing information on other processes for managing incidents that may be appropriate for certain types of concerns/issues raised.	4	1	5	40	44
What changes could be made to the assurance processes to better foster an environment for learning and improvement?	% don't know/ undecided	% completely ineffective	% not very effective	% somewhat effective	% very effective
Providing clear descriptions about roles and responsibilities.		2	12	41	38
Requiring a designated trained person in provider and commissioning organisations to oversee the investigation process.	2	3	9	34	50
Setting minimum training standards for boards and those signing off reports.	2	1	7	30	56
Introducing a standard quality assurance tool to support sign off.	3	3	9	38	45
Increased involvement of families at sign off.	5	7	12	31	41

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What changes could be made to the framework to identify and facilitate cross-system investigations?	% don't know/ undecided	% completely ineffective	% not very effective	% somewhat effective	% very effective
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.	5	4	15	40	32
Having a designated trained lead in all STPs who can work with all relevant organisations when a cross-system investigation is necessary.	6	6	11	37	36
Continuing to discourage the use of Serious Incident data for performance management.	5	2	10	28	50
Mandating through contracts/future regulation the need to contribute to cross-system investigations as required.	6	7	11	35	36
Rewarding those who initiate and/or engage in cross-system investigation.	9	13	19	27	27
How could the Serious Incident framework best ensure that the necessary expertise is devoted to investigation?	% don't know/ undecided	% completely ineffective	% not very effective	% somewhat effective	% very effective
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.	3	4	12	30	47
Requiring each provider to have a dedicated team of trained lead investigators with no duties in that organisation other than	3	11	17	24	41

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investigation. Additional clinical or managerial expertise should be sought as required on a case-by-case basis.					
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 lead investigators to conduct 20 investigations a year.	4	12	14	35	29
Requiring each provider to have a trained head of investigation who selects, supports and oversees patient safety investigation management processes.	3	2	7	29	53
Requiring a trained head of investigation oversight for commissioning organisations.	6	3	9	31	46
How could the Serious Incident framework best ensure that the necessary time and expertise are devoted to investigation?	% don't know/ undecided	% completely ineffective	% not very effective	% somewhat effective	% very effective
Removing the 60 working day timeframe and instead allowing the investigation team to set the timeframe for each investigation in consultation with the patient/family/carers (as is often the case in the complaints process).	5	12	19	30	29
Keeping the set timeframe at 60 working days but reducing the number of investigations undertaken.	6	18	27	29	13
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.	8	13	28	28	18
Recommending a 60 working day timeframe but allowing providers some leeway on meeting it and not managing performance against it.	5	10	20	33	27

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