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Extended Research Article

Co-designing and testing the learn together guidance to support patient and family involvement in patient safety investigations: a mixed-methods study

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers. It also contains descriptions of bereavement and suicide.

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This article

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Abstract

Background: There are multiple reasons for involving patients and families in incident investigations. Fiscally, costs due to clinical negligence claims approximate £4 billion annually. Logically, patients and families provide important information about patient safety incidents. Morally, involving harmed patients and families helps address their concerns. However, little United Kingdom-based evidence was available to support systematic involvement.

Objective: To co-design processes and resources to guide the involvement of patients and families in incident investigations at a national and local level, and to test these processes to understand their impact upon experience, learning and likelihood of litigation.

Design and methods: A mixed-methods programme of research was undertaken. Stage 1 comprised a scoping review of evidence for the experience of patients/families in incident investigations, and a documentary analysis of 43 National Health Service Trust incident investigation policies. Stage 2A extended this with 41 qualitative interviews with patients/families, healthcare staff and investigators. Stage 2B synthesised previous data to develop common principles and programme theory. Stage 3 involved a 6-month co-design phase with a 'co-design community' of > 50 stakeholders. In stages 4 and 5, co-designed guidance was evaluated in a 15-month ethnography, within four National Health Service Trusts and the national independent investigatory body. Twenty-nine investigations were followed in real time, including 127 interviews and 45 hours of observation. Four final co-design workshops supported iterations to the final guidance and website. A substudy explored meaningful involvement in, and learning from, investigations following suicide via interviews and a qualitative survey involving 32 people (healthcare staff, policy-makers and managers; people bereaved by suicide).

Findings: Stage 1 found stakeholders valued involvement, but it was not well supported by local policy, even though it likely reduces litigation. Stage 2A found a need for navigational support, and support for other needs. In stage 2B, 10 common principles and a programme theory were developed, emphasising the aim of reducing compounded harm, alongside promoting organisational learning. In stage 3, four draft guidance booklets and a training session were developed. Stage 4 found these to be feasible, with stakeholders positive about involvement, and generally agreed that it aided organisational learning. The guidance supported systematisation of involvement and encouraged relational working, but wider organisational challenges were highlighted. The substudy found that suicide was regarded as somewhat different to other safety events. Meaningful involvement was complicated by a range of factors and should be decoupled from postvention support.

Limitations: Undertaking research during the pandemic may have impacted sample representativeness in stage 2A. Ethnically minoritised and lower socioeconomic groups were under-represented across the programme.

Future research: Research should explore how people from minoritised groups experience investigations and any required adaptations to the approach. Research should also explore the possibilities for 'harm-centred' rather than 'incident-centred' responses to safety.

Conclusions: Investigations are complex, relational processes. Our guidance was found to be feasible, with stakeholders being positive about involvement and the impact on organisational learning. It may help to reduce the significant and long-lasting experience of compounded harm for patients and families. However, involvement may always be challenging due to the divergent needs of patients/families and organisations.

Study registration: This study is registered as Current Controlled Trials ISRCTN14463242.

Funding: This award was funded by the National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research programme (NIHR award ref: 18/10/02) and is published in full in *Health and Social Care Delivery Research*; Vol. 13, No. 18. See the NIHR Funding and Awards website for further award information.

Contents

List of tables

List of figures

Glossary

Family In cases where it is not possible to involve the patient (e.g. where the incident has led to a death) or where an individual wishes for support from others close to them, family may be involved. Sometimes termed next of kin or an emergency contact, there is no legal basis or clear rules surrounding who could or should be involved. Family may mean anyone who has a direct and close relationship to the patient, including but not limited to that person's spouse, adopted family member, their closest living blood relative or a friend.

Incident Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving health care. The rationale for identifying and reporting patient safety incidents is to support health services to learn from mistakes and to take action to reduce the likelihood of recurrence.

Investigator This term is used to describe anyone working to investigate and/or liaise with patients and families. This may be someone employed solely to investigate, or someone who investigates alongside another role such as a clinical role patient safety role or something else. They may also be referred to as an engagement lead or a family liaison officer.

Involvement Often, engagement and involvement are terms used interchangeably. However, Patient Safety Incident Response Framework makes an important distinction between the two. This is because Patient Safety Incident Response Framework sets out a number of learning response types that healthcare organisations in England can draw upon, only some of which offer opportunities for involvement, but all of which should be underpinned by engagement. Engagement is a general term that refers to everything organisations do to communicate and work with patients and their families within the processes that follow a patient safety incident. For example, disclosing the incident through the Duty of Candour, providing an apology and explaining what will happen next. Irrespective of the incident response type used according to Patient Safety Incident Response Framework, and regardless of whether the patient or family chooses to be involved in the investigation or not, staff should always seek to engage. However, involvement is a more specific term that refers to activity relating to supporting the explicit investigation aims. For example, understanding what happened from the patient and family perspective to support learning and seeking feedback on a draft version of the investigation report. Involvement opportunities, such as these may only be appropriate for certain response types (e.g. patient safety incident investigations).

Postvention Refers to activities that reduce risk and promote healing after a suicide death.

Restorative approach A voluntary, relational process where all those affected by an adverse event come together in a safe and supportive environment, with the help of skilled facilitators, to speak openly about what happened, to understand the human impacts, and to clarify responsibility for the actions required for healing and learning.

List of abbreviations

CQC	Care Quality Commission
EDI	equality, diversity and inclusion
HSIB	Healthcare Safety Investigation Branch
NHSE	National Health Service England
NIHR	National Institute for Health and Care Research
PFAG	Patient and Family Advisory Group
PPIE	patient and public engagement and involvement
PSIRF	Patient Safety Incident Response Framework
RQ	research question
SAG	Staff Advisory Group
SIF	Serious Incident Framework

Plain language summary

Around 10,000 patient safety incidents resulting in severe harm or death happen every year within the English National Health Service. As well as the burden of harm for patients and families, the cost of legal claims is large. Involving patients and families in investigating incidents may help to clarify why something went wrong. It can also help make sure that investigations answer their questions. However, there was a lack of evidence to help people investigating incidents do this well. This research aimed to develop and test processes to guide the involvement of patients and families in incident investigations, to improve learning for organisations, and the experience of patients and families.

We spoke to patients and families, healthcare staff, and people who investigate incidents about their experience of investigations. We also looked at policies from National Health Service Trusts. We identified 10 'common principles' that could help people investigating incidents to involve patients and families meaningfully. Then, with over 50 people (patients/families, staff, investigators, managers) we developed new involvement guidance (https://learn-together.org.uk/). We tested this guidance over 15 months in 29 investigations. One further small study also looked at investigation effectiveness after a death by suicide, and who should be involved.

Everyone valued involvement and agreed it helped learning, but current guidance did not support it. Being part of an investigation was emotional and complicated, so information to help people understand and be involved was important. The testing of our guidance found that it supported investigators to involve patients and families, but the organisational systems they work in can make involvement difficult. Investigations after suicide are thought to be different to other incident investigations, and that support for bereaved families should be made available.

The Learn Together guides may support involvement of patients and families, but investigators need to be trained and supported properly to make it work.

Scientific summary

Background

The burden of patient safety incidents is significant. Fiscally, 10,000 are estimated to occur annually within the UK, and costs associated with clinical negligence claims and their administration approach £4 billion per year. Some of these claims are thought to result from the experience of incident investigations themselves, emphasising the need to improve how patients and families are involved. Involving patients and families is also important logically, due to their well-established role in patient safety. Evidence from the USA has shown that patients and families can identify contributory factors to patient safety incidents, which if gathered, may support better organisational learning. However, at the time of the award, evidence from the UK was limited, with no known studies from the UK exploring the process of involving patients and families in incident investigations, no evidence that this leads to improved experience for those involved, improved learning or reduction in the likelihood of litigation, and no UK-relevant structured processes for how to systematically undertake successful involvement. The proposed research programme aimed to address these gaps, with the following overall aim:

To co-design processes and resources to guide the role of patients/families in incident investigations at a national and local level, and to test these processes to understand their impact upon experience, learning and likelihood of seeking legal recourse.

Further funds were awarded during the programme to explore the perceived utility of investigations following suicide. Within mental health care, incident investigations are the primary source of exploring risk, as well as understanding factors contributing to or surrounding suicide, and how to prevent recurrence. However, there are currently no known UK-based studies exploring local investigations following suicide, and how they contribute to organisational strategies to prevent incidence. Further, given the established links between familial isolation and suicide, what meaningful involvement means within such investigations is complex, with no known UK-based studies exploring who should be involved.

Stage 1: understanding the current landscape

Objectives

RQ1: What is the current involvement of patients and families in incident investigations?

Methods

This stage comprised two studies. First, a scoping review of the qualitative literature explored the experiences of patients and families within incident investigations, and what prompts decisions to litigate. Three databases were searched, followed by independent screening of title and abstracts (20% double-screened). Data were extracted from included studies, before undergoing a narrative synthesis. Second, we conducted a documentary analysis of policy documents referring to the involvement of patients/families in incident investigations. A random sample of 103 NHS Trusts (50% of all trusts in England) were approached, supplemented with searching trust websites. A total of 43 documents were sourced and submitted to a qualitative documentary analysis, with particular attention to how involvement of patients, families and staff was described, and how this was presented in the context of the whole document.

Findings

Evidence from across these two studies suggests that all stakeholders value patient and family involvement in incident investigations, but that this is not facilitated or supported by local policy. Staff found involvement easier when guided by clear policy and systematic processes, which can be flexibly applied. If patients and families felt involved, they were less likely to pursue litigation.

Stage 2A: in-depth interview study

Objectives

RQ2: What is the experience of patients and families who have been involved in an incident or incident investigation, and what might have influenced decisions to litigate?

RQ3: What is the experience of front-line healthcare staff and investigators who have been involved in an incident investigation, and what might have influenced decisions to litigate?

RQ4: What are the views of front-line healthcare staff and investigators on the potential involvement of patients and families in incident investigations?

Methods

A qualitative semistructured interview study was conducted with patients/families, healthcare staff, legal staff and investigators. We invited participants via (1) communication from partner sites, (2) charitable organisations, (3) social media, (4) snowball sampling. One hundred and seventeen people registered interest and 42 participated (18 patients/families, 7 staff, 16 investigators, 1 legal representative). Data were analysed using an inductive reflexive thematic approach.

Findings

Patients and families reported starting an investigation with cautious hope, before realising that they lacked power, knowledge and support to navigate the system. For some, this ultimately resulted in feeling compelled to pursue litigation. Staff experienced similar injustices, such as exclusion and lack of support. All stakeholders need help understanding what an investigation is, system navigation assistance, and tailored short- and longer-term support. Investigating was also found to be skilled 'work' requiring adequate training, resources and infrastructure support to balance competing priorities.

Stage 2B: synthesis, and development of common principles and programme theory

Objectives

RQ5: What are the common principles necessary for involving patients and families in incident investigations?

Methods

A three-phase analysis and synthesis was conducted on data from stages 1 and 2A. The inductive analysis phase involved creating short descriptive reports for each of the previous three studies. An abductive analysis phase based on three foundational theories and approaches created a new analytical framework to support the development of the draft common principles and narrative programme theory. A synthesis phase ran parallel with the first two, bringing them together through a series of analytical workshops.

Findings

We developed 10 common principles for meaningful involvement. The juxtaposition of existing theories illuminated new insights. First, that organisational learning is not the only desired outcome for incident investigations, with patients and families (and sometimes staff) reporting the need for restoration and repair. Second, investigations can be part of reparation, but when they fail to address the needs of stakeholders arising from investigations, it can compound the harm of the original incident. Our programme theory further developed these insights to propose how guidance and processes might better support involvement and reduce compounded harm.

Stages 3A and 3B: co-designing new processes and guidance

Objectives

RQ6: How might these common principles be reflected in local and national processes for involving patients and families in incident investigations?

Methods

We conducted a longitudinal, largely remote co-design process, informed by the UK Design Council Double Diamond for Innovation. Co-design activities comprised two large stakeholder events bookended by a series of three co-design workshops that ran in three parallel workstreams, reflecting (1) acute settings, (2) mental healthcare settings and (3) national independent investigatory body setting. A 'co-design community' of > 50 stakeholders was formed, with members invited to participate in all activities. A range of innovative co-design activities were used to build relationships and trust and support generation of ideas.

Findings

The co-design phase had two main outputs. First, we collectively co-designed new guidance, underpinned by the common principles and programme theory, to support investigators to involve patients and families in incident investigations, in ways that may reduce compounded harm. Second, we developed a community of co-design partners that not only supported generation of new guidance but also further iterations in stage 5, and provided credibility for, and dissemination of, the final programme outputs.

Stages 4 and 5: implementing, evaluating and iterating co-designed processes and guidance

Objectives

RQ7: Are co-designed processes for involving patients and families in incident investigations feasible and acceptable to patients, families, healthcare staff and investigators?

RQ8: How do co-designed processes influence incident investigations in terms of depth of learning, recommendations, action plans and decisions.

Methods

A 15-month focused ethnography was conducted across four NHS Trusts, and within maternity investigations undertaken by the national investigatory body. We trained 49 investigators in the new guidance, before working with 16 investigators within 29 real-time investigations. We undertook 127 remote qualitative interviews (92 semistructured, recorded interviews, and 35 ethnographic interviews) at different investigation touchpoints, with investigators, patients/families and staff. A duration of 44.5 hours of non-participant observation was undertaken, including investigator training and site-based meetings. Analysis proceeded using an inductive approach. First, an adapted version of pen portrait methodology brought together all data into individual cases at the level of the investigation, along with contextual organisational summaries. Following this, we conducted a multicase analysis using a reflexive thematic approach, with the investigation case as the unit of analysis, in conjunction with the organisational summaries. Following the ethnography, a series of four final workshops were convened with co-design partners and other stakeholders to discuss findings and agree to the required iterations to the final guidance.

Findings

Stakeholders were almost universally positive about meaningful patient and family involvement, and generally agreed that it could aid organisational learning. The co-designed guidance supported systematisation of involvement, as well as encouraging the relational element, with a key enabler being the rollout of the Patient Safety Incident Response Framework (PSIRF). There is a need for formal recognition and support for the complex challenges different stakeholders face as they navigate the system procedurally, relationally and emotionally. Organisational infrastructure needs to be aligned to support investigators to meet the multiple needs of investigations, and the stakeholders involved in them. Our revised guidance was reorganised around the 'Five-Stage Process', which centres the needs of patients

and families to be heard and their experiences dignified at the start of the investigation, followed by flexibility in involvement throughout.

Additional funding: exploring meaningful involvement in, and learning from, investigations following suicide

Objectives

RQ9: Do stakeholders involved in incident investigations following death by suicide believe they contribute to organisational learning, and risk management and suicide prevention strategies?

RQ10: How do we define meaningful involvement in investigations to prompt learning following death by suicide?

Methods

We conducted a qualitative study combining interviews and a qualitative free-text survey. Semistructured interviews were conducted with staff, managers and policy-makers with experience of investigations following suicide. Purposive sampling was employed, with recruitment undertaken via social media and approaching policy-makers directly. A fully qualitative survey was developed to explore the experience of those bereaved by suicide, of the investigation and other processes that follow. The survey was based on the stage 2 findings and further developed with a family representative. The survey was distributed via social media, charities relating to suicide, and the Care Quality Commission (CQC). Data were combined and analysed using reflexive thematic analysis.

Findings

Fourteen interviews were conducted, and 18 survey responses were received. Seven themes were generated. Investigations were found to have both explicit and implicit purposes, causing confusion and limiting their effectiveness in achieving learning and improvement, and supporting families. Suicide was largely regarded as different to other safety events, due to variability in treatment and care standards, the ability to control risk, and distribution of care across settings and time. What constitutes meaningful involvement was both similar to that in the wider programme but different, in part due to the fact that people who die by suicide may have a long history of receiving care, and the complexity of familial dynamics. Investigations need to decouple learning from the provision of postvention support. However, even once decoupled, we suggest that the needs of families might always be at odds with the organisational driver of learning and improvement as the principal aim of investigations.

Conclusions

Incident investigations are complex, relational processes, which have the potential to either repair or compound the harms from patient safety incidents. Our co-designed processes are feasible and acceptable, and support more comprehensive and systematic involvement of patients and families in investigations, and the learning that arises from them. Importantly, they might support the reduction in the significant and long-lasting effects of compounded harm for patients and families, although this study design cannot establish this. Investigations are complicated by divergences in the needs of different stakeholders involved in investigations, often relating to their purpose and focus. Navigating this complexity requires skilled, well-supported investigators, who work with an organisational infrastructure flexible enough to allow them to individualise their approach.

Contributions

This programme of research has resulted in several important contributions to research, methodology and theory.

Empirical contributions

This programme represents the first known research to co-design evidence-based guidance, and evaluate it in real time, from the perspectives of the multiple stakeholders. Further, in developing a programme theory we have provided a blueprint for the development of future frameworks that can adapt to local or changing contexts.

Theoretical contributions

This programme built on existing theories and approaches to develop a new understanding of, and evidence for, the concept of 'compounded harm' – the harm resulting from the experience of processes that follow a patient safety incident. Our evaluation also illuminated the difficulty with eliminating compounded harm entirely, given the divergence between the needs of organisations to learn, and the human need for accountability, understanding and reconciliation between those affected.

Methodological contributions

This programme produced two important contributions to co-design methodology. First, we expanded the understanding of how co-design might be undertaken with policy-makers, and the benefits of this approach. Second, we have outlined an innovative approach to co-designing policy, where evidence was moved into policy and practice at the point of need – in this case, during a significant national policy shift.

Limitations

There are two principal limitations to the work presented here. First, the programme commenced just ahead of the pandemic, which impacted the stage 2 interview study particularly in terms of the potential representativeness of the sample. However, given the similarity in experiences of investigations between stage 2 (interview study) and stage 4 (ethnography), we believe the sample was unlikely to be unusual. Second, and more significant, is our difficulty achieving a sample across studies that is representative of healthcare populations. In particular, we struggled to connect with or hear from ethnically minoritised people or those from lower socioeconomic groups.

Recommendations

1. Policy and procedures need to formally recognise that there are multiple purposes for responding to a safety incident and that organisational learning is only one of these purposes.
2. The relational work of involving patients, families and staff is important, but complex, and needs to be resourced, valued and recognised within policy and processes.
3. When embedding processes for involving and engaging patients and families in incident investigations and responses, organisations need to first seek to understand how this is currently done and seek to adapt current organisational infrastructure to support them.
4. Organisations should undertake ongoing monitoring of processes for involving and engaging patients and families, which centre their experiences, as well as objective outcomes, such as subsequent complaints and litigation.
5. Research should explore how current approaches to involving and engaging patients and families in incident responses might be different for people from minoritised and underserved groups, and what adaptations might be required.
6. Research should explore the possibilities for 'harm-centred' rather than 'incident-centred' responses to safety, and how this might address the seemingly intractable divergences in the needs of patients, families and organisations.

Study registration

This study is registered as Current Controlled Trials ISRCTN14463242.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research programme (NIHR award ref: 18/10/02) and is published in full in *Health and Social Care Delivery Research*; Vol. 13, No. 18. See the NIHR Funding and Awards website for further award information.

Chapter 1 Background and rationale

Chapter outline

This chapter describes the problem to be addressed, the way in which the research programme aimed to address it and the significant shifts in the NHS policy landscape that influenced the programme, as well as a short description of the theoretical approaches underpinning and informing the research. Finally, we outline the additional research funding received in Year 3 of the award (see *Chapter 8*).

Background and introduction

The burden of patient safety incidents and litigation

When the programme was awarded, incident identification and investigation in NHS organisations was guided by a policy called the Serious Incident Framework (SIF).[1] This policy, published by NHS England in 2015, defined serious incidents in health care as 'adverse events, where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified'[1] (p. 7). In the UK, reported serious incidents (causing severe harm or death) were estimated to be around 10,000 annually.[2] In 2016–7, clinical negligence claims totalled £1.7 billion, with £1.8 billion to administer and settle claims, and long-term liabilities in the region of £65 billion.[3] These figures highlighted two key issues: first, the significant burden of litigation on health service finances, and the psychological and physical burden for those involved in pursuing claims; and second, the need to improve the process of learning from serious incidents to reduce their incidence.

The reasons why patients and families pursue claims are complex,[4] but at the time of the award, there was a paucity of empirical evidence. A significant proportion of litigation is recognised as warranted and necessary, due to the life-changing or life-limiting effects of serious incidents.[5] However, in their 5-year strategy (2017–22) NHS Resolution stated that some litigation was driven by frustration, motivated by poor experiences of complaints or investigation processes.[6]

In this strategy, they proposed a model of patient and family involvement in complaints and investigation management, based on principles of early intervention, openness and engagement. They posited that involving patients and families earlier in investigation processes would both reduce costs of administering claims as well as divert claims pursued in search of explanation or acknowledgement.[6] These principles were shared by NHS England in their guidance on incident investigations within the SIF,[1] the National Quality Board in their guidance on Learning from Deaths,[7] and the Duty of Candour.[8] It was clear therefore that at a policy level, openness with, and involvement of, patients and families in processes following serious incidents was a high priority. However, the Care Quality Commission (CQC) found in their review of incident investigations that only 12% of investigation reports clearly indicated involving patients or families,[9] suggesting that this policy drive had not translated into changes in practice.

While NHS Resolution proposed that early involvement may reduce complaints, their own data suggested that only 30% of claims start with a complaint.[10] Empirical work had also found no link between complaints and litigation rates.[11] This suggested that focusing only on complaints to reduce the costs of litigation was unlikely to be effective.

How might patient and families improve incident investigations?

Over the past decade, a growing evidence base has demonstrated that patients and families can and do support patient safety in several ways. First, it is now established that patients and their families can support the identification of patient safety concerns and incidents[12] that other error detection methods (staff reports, case note review) do not access.[13] Further, patients and families can also support patient safety proactively by providing information on contributory factors to future patient safety incidents,[14] and through continual monitoring of their care and 'stepping in' when it fails or is suboptimal.[15] It is clear therefore that patients and their families are a key source of information that could help healthcare organisations monitor, measure and manage the safety of care.

Despite the building evidence and policy directives for patient and family involvement in patient safety initiatives and incident investigations, at the time of the award, empirical evidence for the impact of involvement upon investigations and their outcomes was limited. Two US studies had explored experiences of patients and families and their ability to comment on factors contributing to the incident,[16,17] finding that, on average, they were able to identify three contributory factors. This suggested that patients and families could act as a key source of information to investigations. These data were used to develop a tool [IMproving Post-event Analysis and Communication Together (IMPACT) Tool] for structuring conversations with patients and families after an incident, to gather information to be used in investigations.[18] However, the tool was not implemented or tested in healthcare organisations. Another US study proposed a process for involving patients and families in root cause analysis,[19] but this was not evidence-based and again had not been tested in practice.

Within the UK, little evidence was available. One paper had discussed the potential role for patients and families in investigations, suggesting that their unique perspective on incidents and services could support both analysis and recommendations.[20] However, while evidence directly exploring the role of patients and families in incident investigations was limited, the wider literature on patient and family involvement in patient safety initiatives described above provided the rationale for doing so. Put simply, patients and families represented an untapped resource for investigations, particularly where events have unfolded over time (e.g. diagnostic error or delay), where they represent the only common denominator across multiple healthcare presentations.[21] Evidence at the time of the funding award therefore suggested that patients and families could, and arguably should, be involved in incident investigations. While some research and commentary had explored the potential challenges and opportunities for such involvement, there was a fundamental lack of empirical evidence, and in particular, no evidence-based tools or guidance to support involvement in practice.

The current research

In summary, at the time of the award, there were no known studies from the UK exploring the process of involving patients and families in incident investigations, no evidence that this leads to improved experience for those involved, better learning or reduction in the likelihood of litigation, and no UK-relevant structured processes for how to practically achieve successful involvement. The proposed research programme aimed to address these gaps, with the following overall aim:

To co-design processes and resources to guide the role of patients and families in serious incident investigations at a national and local level, and to test these processes to understand their impact upon experience, learning and likelihood of seeking legal recourse.

The proposed research programme was believed to be important for three reasons. First, for those involved in a serious incident – staff as well as patients and families – the processes following disclosure can be traumatic and result in psychological trauma, poorer health, absence from work and difficulty contributing to society.[22,23] Thus, exploring how to improve the experience and transparency of investigatory processes for all stakeholders was desirable both in moral and fiscal terms. Second, improving learning from serious incidents may reduce the likelihood of future events,[24] thus reducing the need for further investigations, and the likelihood of harm to future patients and families. Finally, for patients and families to act as partners, and be involved in the safety of their care, it is vital that there is public trust in the processes that follow a serious incident. Thus, this research might help to improve transparency and trust in investigation processes.

The changing national policy landscape

At the time of funding, the policy underpinning incident investigations was the SIF.[1] Within Methods of the policy, it outlined how:

> *The needs of those affected should be a primary concern for those involved in the response to and the investigation of serious incidents. It is important that affected patients, staff, victims, perpetrators, patients/victims' families and carers are involved and supported throughout the investigation[1] (p. 37).*

The policy goes on to outline some points of guidance as to how this might be achieved, including the need for the personnel involving patients and families to be appropriately skilled, the need to involve patients and families in setting the terms of reference, and that they should be given the opportunity to contribute their evidence to the investigation. However, as discussed in the previous sections, despite mandating the involvement of patients and families in incident investigations, this did not appear to have translated into routine practice.[9]

At the beginning of the programme, we were informed that the NHS England patient safety policy team were in the process of consulting stakeholders about a revision of the policy underpinning how patient safety incidents should be responded to by healthcare organisations. Following this development period, the final policy, the Patient Safety Incident Response Framework (PSIRF), was published in August 2022.[25] To ensure that the guidance and processes aligned with the context of this new policy, we began regular, 3-monthly 'check-in' meetings with the NHS England patient safety policy team, starting in Autumn 2019. This ongoing discussion led to an enduring and productive relationship with the policy team. Two policy team members attended all co-design workshops within stage 3, helping us shape the 'Learn Together' approach (as it became known), and exploit the new opportunities afforded by the incoming patient safety policy. Importantly, it also led to the research team inputting directly into the new PSIRF policy through a novel collaborative approach between researchers and policy-makers. This collaboration is described more in *Chapter 9*.

Theoretical underpinnings

The overarching 'grand theory' for this work was the organisational accident model.[26] This theory proposes that learning from patient safety incidents can facilitate the identification of latent factors that exist in organisations that can contribute to the future safety incidents. It shaped the proposal through focusing the research questions (RQs) on the potential for patients and their families to add to the development of knowledge about an incident, through their involvement in an investigation.

Aside from this general theoretical foundation for how patients and their families might contribute to organisational learning, there was a distinct lack of theorising on how they might be involved, and what this would change. As mentioned above (see *Background and introduction*), at the time of funding, we drew on the NHS Resolution 'approach to early intervention',[6] which proposed that involving patients and families earlier in investigation processes would impact positively on important outcomes, such as complaints and litigation. Therefore, for the initial proposal, we brought together the organisational accident model, and the NHS Resolution early intervention approach, to broadly suggest that earlier involvement of patients and families in investigation processes might both address some of their needs such that further action would be unnecessary and contribute positively to organisational learning.

As described in *Chapter 5*, through the course of the programme, and in part due to the emergent findings from stages 1 and 2, we began to explore the potential for a third theory to inform our work. This theoretical umbrella can be practically described as 'restorative approaches', and it encompasses a range of approaches and methods, which are beginning to be discussed and applied across healthcare settings both nationally and internationally. These approaches come from restorative justice theory, which is defined as:

> *… as a relational way of responding to … wrongdoing or similarly harmful episodes, whereby those with a personal stake in the harm come together, in a safe and respectful environment, usually with the help of skilled facilitators, to speak truthfully about what happened and its impact on their lives, to clarify accountability for the damage that has occurred, and to resolve together how best to promote repair and bring about positive changes for all involved*[27] *(p. 178).*

Through collaboration with a member of our oversight committee (Jo Wailling), and learning from New Zealand's restorative response to surgical mesh harm,[28] we incorporated this approach into our wider programme. In particular, we used it to explore the assumption that the aim of investigations is simply for organisational learning, as espoused by the organisational accident model, within the abductive analysis undertaken to develop the common principles for meaningful involvement, detailed in *Chapter 5*.

Additional funding

In Autumn 2022, we were awarded further funding from the National Institute for Health and Care Research (NIHR) to address additional research questions related to the wider programme but specific to mental healthcare settings. Through our discussions with our participating NHS organisations and the Patient and Family Advisory Group (PFAG) (see *Patient and public involvement and engagement*/*Equality, diversity and inclusion*), it was clear that there were perceived differences in the involvement of patients and families in patient safety incident investigations within mental healthcare settings, particularly when there had been a suicide. Further, our discussions highlighted that, especially for suicide in the community, investigation scope seemed to be limited to the extent to which organisations had met standards of care. Such a limitation seemed to be too reductive for the espoused aims of investigations to support risk management and prevent future suicide. Therefore, in response to the invitation from the funder to extend our research, we devised a further study to complement but not duplicate the focus of the wider programme (see *Chapter 8*).

A note on terminology

During the programme, and due to the changing policy landscape, the terminology surrounding the processes that follow a serious incident, and the triggering of an investigation, changed. Up until the publication of the PSIRF in August 2022, the investigations that we were aiming to enhance involvement within were called serious incident investigations. Following the publication of the new policy, this terminology changed to patient safety incident investigations, although the expectations of the investigation process itself remain largely unchanged. Therefore, for the purposes of this report, we use the term ‘incident investigations’ throughout.

Chapter summary

This chapter has explored the extant evidence and theory relating to the involvement and engagement of patients and families in serious incident investigations, and outlined the changes to important policy that influenced the programme. In the next chapter, we explore how the research programme addresses the research aim, and specific research questions, and how the changing policy and research landscape was accommodated within changes to the protocol.

Chapter 2 Study overview and changes to protocol

Chapter outline

This chapter outlines the main stages of the programme of research, and how they pertain to the research questions. Further, we present a table of the changes to the proposed plan of work, and the reasons for these changes.

Study overview

Figure 1 provides a visual overview of the original programme of work. The research programme was designed to answer eight research questions, with a further two added following the additional funding. *Table 1* presents the research questions, their methods and which chapter they are reported in.

Study partners

This programme partnered with five collaborating organisations throughout, from conception of the idea through to designing the study and securing the funding, supporting the data gathering at multiple stages, and ultimately, acting as case study sites for evaluating the co-designed guidance and processes. These sites were two acute care hospital trusts, and two mental healthcare trusts (all based within Yorkshire) and the national independent investigatory body, the Healthcare Safety Investigation Branch (HSIB). For the purposes of this report, the four hospital sites are anonymised, except for their inclusion (where permission has been given) within the acknowledgements. As the only national independent investigatory body, HSIB cannot be effectively anonymised. However, they have provided the permission to be named, and for consistency, are provided with a pseudonym within stage 4 (see *Chapter 7*).

We were also supported throughout the programme by two important stakeholder groups. The first was a PFAG, which comprised patients or relatives who had experienced harm as a result of health care. The second was a Staff Advisory Group (SAG), which included staff, managers and legal representatives. Both groups provided an important source of advice and guidance throughout the programme. Their specific contributions are detailed in each chapter and summarised in *Chapter 9*.

Changes to protocol

Both pre-emptive changes, in preparation for working during COVID-19, and responsive changes to challenges that were occurring during the study stage were made to the protocol. Other changes came about organically as part of the co-design work. *Table 2* summarises these changes.

Chapter summary

This chapter summarised the planned work, the study partners and the main changes to the protocol. The next chapter presents the combined findings from stage 1.

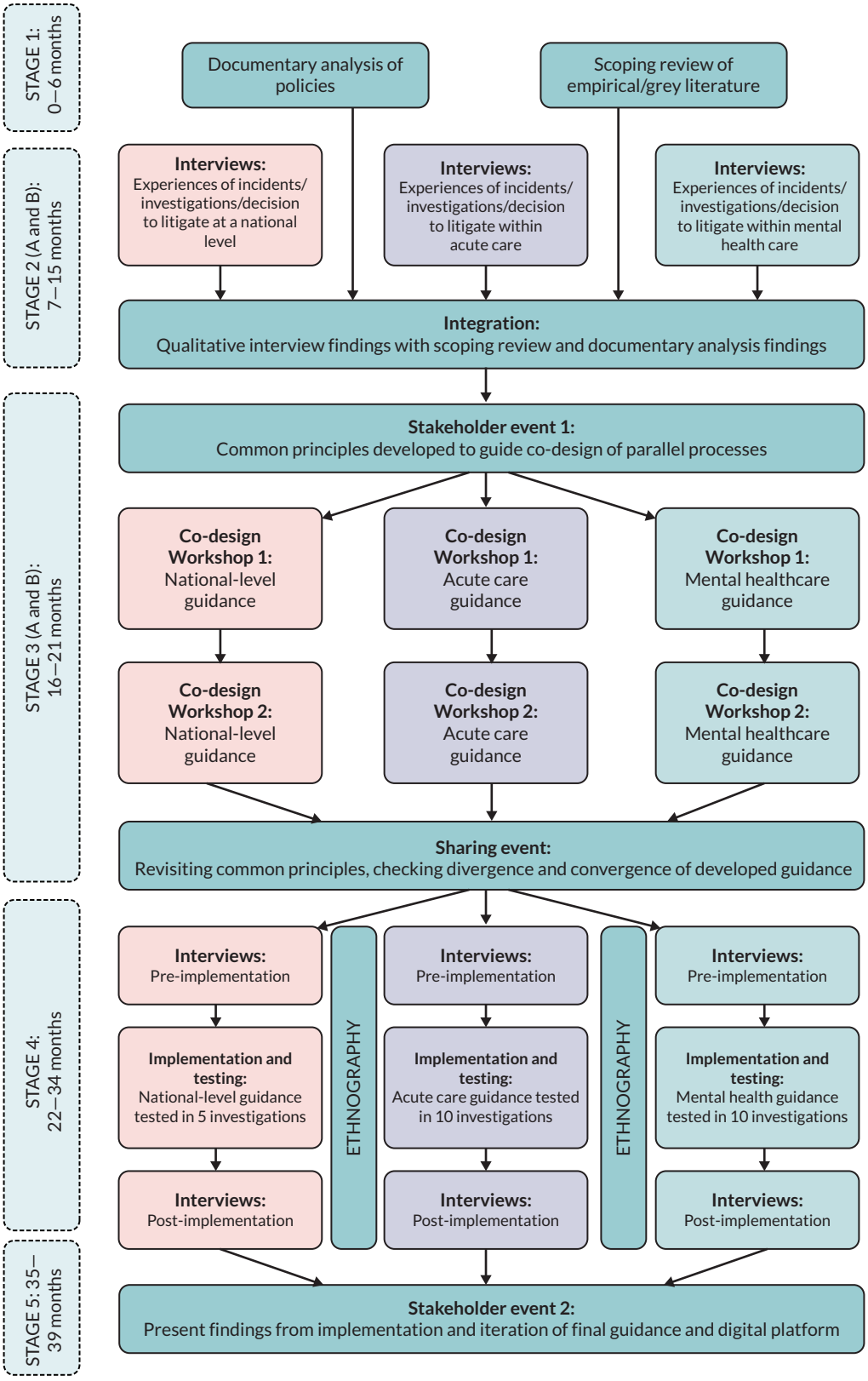

FIGURE 1 Research programme overview.

TABLE 1 Summary of research questions, study design and the chapter in which they are detailed

Questions	Study stage and design	Chapter
1. What is the current involvement of patients and families in incident investigations?	Stage 1 – Scoping review and documentary analysis	3
2. What is the experience of patients and families who have been involved in an incident, or incident investigation, and what might have influenced decisions to litigate? 3. What is the experience of front-line healthcare staff and investigators who have been involved in an incident investigation, and what might have influenced decisions to litigate? 4. What are the views of front-line healthcare staff and investigators on the potential involvement of patients and families in incident investigations?	Stage 2A – In-depth interview study	4
5. What are the common principles necessary for involving patients and families in incident investigations?	Stage 2B – Synthesis/integration of findings, development of common principles and programme theory Stage 3A – Stakeholder event to present and develop the common principles	5
6. How might these common principles be reflected in local and national processes for involving patients and families in incident investigations?	Stage 3B – Co-design of three parallel processes and resources for guiding patient and family involvement in incident investigations	6
7. Are co-designed processes for involving patients and families in incident investigations feasible and acceptable to patients, families, healthcare staff and investigators? 8. How do co-designed processes influence incident investigations in terms of depth of learning, recommendations, action plans and decisions?	Stage 4 – Implementing and evaluating co-designed processes and guidance in live investigations Stage 5 – Refining and final iteration of processes and digital platform	7
9. Do stakeholders involved in incident investigations following death by suicide believe they contribute to organisational learning, and risk management and suicide prevention strategies? 10. How do we define meaningful involvement in investigations to prompt learning following death by suicide?	Mental health substudy – interviews and qualitative survey study	8

TABLE 2 Summary of changes made to the original protocol

Stage	Original plan	Rationale for change	Change	Impact of change
3A	To hold an in-person stakeholder event	Government restrictions on social distancing were in place at the time of running the events	To hold virtual sessions	We were able to hold the event that otherwise would not have been possible
3B	To hold a series of in-person co-design workshops	Government restrictions on social distancing were in place at the time of running the events	To hold virtual sessions	We were able to hold the workshops that otherwise would not have been possible
3B	Development of a process flow and decision tree to guide involvement	This changed partly due to the new PSIRF recommending involvement within all incident response types, and also due to co-design activity shaping the nature of the emergent guidance and processes	Information resources and supporting materials	Resources could fit within the new policy, and represented the collective views of the co-design community
4	To consent patients and families into the ethnography study at the start of the investigation Staff at the hospital consenting patients and families into the study	Low consent rate into the study from patients and families Additional layer of administration creating additional staff burden	To deliver the co-designed guidance and processes as usual care and consent patients and families later in the process Researchers to consent patients and families into research	Allowed patients and families to do one thing at a time: engage in the investigation process first and consent to research later directly with a researcher

Chapter 3 Understanding the current landscape

Chapter outline

This chapter presents a synthesis of two studies that collectively answered the following research question:

RQ1: What is the current involvement of patients and families in serious incident investigations?

Within this we aimed to:

1. Explore patient and family experiences of the process of investigations;
2. Uncover why patients and families decide to litigate;
3. Gain an understanding of different approaches to engagement across Trusts in England;
4. Identify best practice for patient and family involvement across Trusts in England.

Two pieces of research were conducted to address these research aims and questions. The first was a scoping review of the qualitative literature addressing the first two aims above. The second was a documentary analysis of NHS acute and mental health policy documents focusing on the latter two aims. These two pieces of work were used to inform the development of common principles for patient and family involvement (stage 3A) as well as guiding subsequent research stages.

Existing publications

This chapter has been adapted with permission from authors of two papers.[29,30] Both papers are Open Access articles distributed in accordance with the Creative Commons Attribution (CC BY 4.0) license, which permits others to copy, redistribute, remix, transform and build upon this work for any purpose, provided the original work is properly cited, a link to the licence is given, and indication of whether changes were made. See https://creativecommons.org/licenses/by/4.0/. As our published work reported on wider stakeholder engagement in investigations, for example, with staff and investigators, we report abridged summaries which focus specifically on our originally posed questions about the current involvement of patients and families in incident investigations.

Methods

Scoping review

A scoping review of qualitative research was considered the most suitable approach to explore and summarise the emerging evidence and answer the research questions. Full methodological details are available in our published paper.[29] The search strategy was iteratively developed in collaboration with the project steering group and the PFAG. The search comprised four search strings combined with AND relating to (1) population, that is, patients and families, and three separate strings relating to elements of the concept, that is, (2) serious incidents, (3) investigations and (4) involvement (each combined with OR). The electronic search was run across three databases [OVID Medline (1946–present), APA PsychInfo (1806–present) and CINAHL] followed by independent screening of titles and abstracts (with double-screening across 20% of records) according to criteria. Criteria stipulated that articles must explore the involvement of patients and/or families in serious incident investigations in secondary care, mental health or maternity settings in any country. Studies conducted in purely primary or community care or where death occurred outside of the healthcare setting or was deemed unrelated to a serious incident were excluded. Papers not published in the English language or before the year 2000 were also excluded. Forward and backward sampling of eligible articles via Connected Papers (www.connectedpapers.com/), an online tool that generates relevant articles based on citation and bibliographic coupling, continued until no new articles were found. *Figure 2* provides a visual summary of the number of articles screened and included according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

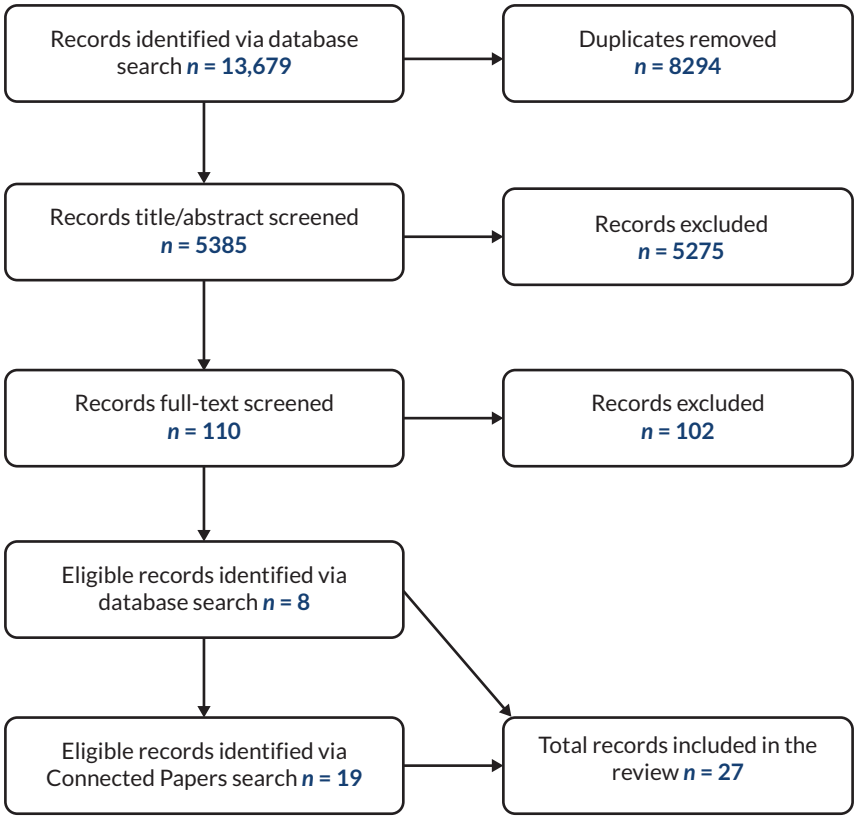

FIGURE 2 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

Data were extracted from eligible articles based on the study details, population and study design. Data were then summarised and described using a narrative synthesis method.[31,32]

Documentary analysis

In 2019, we randomly sampled 103 (representing 50% of all) acute non-specialist and specialist trusts and mental health trusts in England to take part in this study. From these sites, we requested any policy documents making reference to the involvement of patients/families and healthcare staff in incident investigations from trust governance, risk management and patient safety teams. This approach, combined with searching for publicly available online trust polices, identified 43 policy documents. These represented 19.4% of acute non-specialist and specialist trusts and 25% of mental health trusts. The three-stage approach to qualitative documentary analysis[33] was used: *skimming*, *reading* and *interpretation*. Three researchers identified relevant and meaningful excerpts of text within policy documents, to understand which parts of the document were explicitly and implicitly linked to involvement. We were particularly interested in how trusts outlined the process of involvement for patients, families and healthcare staff in their policies, and more generally how the policy documents were constructed and information about involvement represented within the wider context of the document. A more focused re-reading of the policy documents was then carried out by the same three researchers to explore the meaning. To ensure a level of objectivity (fair representation of the policy documents) and sensitivity (representing and responding to subtle cues to meaning), several analysis sessions were held where the research team (including all authors) came together to discuss meaning, structure the emergent findings and refine the headline findings. The analysis was not structured around an existing theoretical framework, thus our exploration of the concept of involvement within the policy documents was wholly inductive.

Findings

Scoping review

Twenty-seven articles were included in the review, published from 2003 to 2020, and these were based in the USA, Australia, UK, the Netherlands, Norway and New Zealand. Most represented patient and family experiences across

general hospital care settings. Only one study focused on investigations in a mental health setting. The evaluation of patient and family involvement interventions was the focus for 16 studies, with the remaining 11 studies being observational. Interventions primarily focused on early open disclosure approaches (*n* = 7 studies), with one reporting on reconciliation through engaging patients and families in the process of organisational learning.

The experiences, values and needs of patients and families

Many patients and families reported physical, financial and/or emotional vulnerability during investigations which was furthered by inadequacies in processes. Experiences of processes included expectations not being made clear, inappropriate disclosure of unexpected outcomes, none or insincere apologies, lack of support, being denied opportunities to meet with involved staff and delays. Most patients and families valued being involved, and the way they wished to engage varied. Most felt that formal face-to-face interaction was authentic and respectful, whereas others preferred less intrusive methods that gave emotional space to process information. In general, most preferred to be asked about their needs rather than them be assumed.

Some patients and families who felt involved in transparent investigation processes reported being less likely to pursue litigation, whereas others felt the need to fight for progress, using methods, such as 'threatening litigation'.[34]

Within studies reporting on maternity investigations, parents reported concerns of information being withheld, not knowing how to be involved, lacking understanding of formal processes and medical jargon, and a sense that meetings were taking place without their knowledge. Most valued continuity of care and wanted to meet the staff, but this was not always possible. Parents also expressed difficulties with returning to the hospital where the event had happened and often wanted support at meetings from a spouse, relative, social worker, chaplain and/or nurse. Most parents wanted to be heard, and their needs met through tailored and sensitive investigations rather than rigid processes. Key considerations included meeting locations, purpose and attendees, language and cultural factors, and parental desire for involvement including method and timing of communication. Examples included finding terms such as 'resolution' insulting in this context as a baby death could never be 'resolved', flexibility in the timing of formal follow-ups to allow parents time to grieve, holding meetings with a clear purpose and shared understanding and recognising that not everyone wanted an apology but prefer a personal remembrance.

Almost all wanted to receive information and give feedback to staff regarding topics including the chronology of events leading up to admission and death, cause of death, treatment, autopsy, generic risk, medical documents, withdrawal of life support, ways to help others, bereavement support, and what to tell other family members. Parents found follow-up meetings useful as they were able gain answers which helped to alleviate self-blame.

In the one study which focused on mental healthcare settings, involvement was useful for families to access aftercare to assist grieving, allow them to provide useful knowledge about wider contextual information outside of the hospital, and some suggested that it reduced the likelihood of litigation and escalation in other ways.

The experiences and benefits of patient and family involvement from the perspectives of key stakeholders

Staff largely viewed serious incident disclosure as a moral and professional duty; however, this was made more difficult when multidisciplinary team input was absent, workload and staff turnover were high, and investigations did not integrate with wider patient safety improvement efforts. Despite the availability of policy to guide staff during an investigation, staff still faced difficulties in communicating with patients/families. In maternity services, this included managing parents with unanswerable, unexpected and repeated questioning, parent anger and vulnerability, and challenges of parents demanding additional investigations that were not possible. Staff were unsure about who should initiate and facilitate meetings with parents. Some felt that each incident needed an individual staff member to take the lead and act as a single point of contact who could streamline processes and build trusting relationships. It was also important to consider the job title of the person liaising with parents and how it might be perceived. Other challenges included prioritising investigations alongside competing demands, limited resources, lacking communication between obstetric and neonatal teams, unallocated time in their job plans, and busy workloads. Staff also highlighted various needs including access to adequate training to help prepare for, deliver and follow-up on investigations, and needing to feel supported centrally, organisationally and by immediate management and colleagues. Although some staff perceived

that patient/families could sometimes hamper investigations due to insufficient knowledge, staff mostly perceived that patient and family involvement could improve investigation quality (e.g. by providing clinically useful information), promote an open culture and help to ensure the safety of future care. Staff were critical of what they deemed to be a tokenistic approach to family involvement, particularly in the latter stages of investigations once conclusions had been made. Many also felt that the investigation reports were too narrowly focused.

Documentary analysis findings

We aimed to gain an understanding of different local policy-led approaches to patient/family and healthcare staff engagement across Trusts in England and to identify best practice. We found that direct reference to support or involve those affected by safety incidents was distinctly lacking. Specifically, there was an absence across all policies of specific justification or guidance to inform those leading investigations as to *why* and *how* to include involvement in the investigation process beyond the scope of formally sharing their experience. Therefore, we were unable to identify best practice.

In policies that expressly directed continued involvement of patients or family members, and recognised potential support needs, involvement was described as a passive process as opposed to providing a moral or epistemic justification for active involvement and contribution to learning.

> *Patients and their families are to be told about patient safety incidents that affect them, receive appropriate apologies, are kept involved about investigations and are supported to deal with the consequences.*
> *… there is early, meaningful and sensitive engagement with affected patients and/or their families/carers from the point that an SI is identified, through investigation and action planning, to closure of the incident. Information should be shared in line with Being Open and Duty of Candour Policy.*

For those policies that did reference some level of active engagement, this was generally based on a 'contribution' rather than being more actively involved throughout the investigation process.

> *When the Lead Investigator for the SI has been identified the patient or relatives will be offered involvement in the investigation to include their perspective of the SI. This can be in written form or by being offered a face-to-face meeting by the investigation team.*

The tone when referencing involvement often represented a specific directive such as Duty of Candour or complaints and litigation that was represented as a passive process of information delivery to which to be adhered. Examples are shown below:

> *Ensure Duty of Candour requirements are fulfilled.*
> *Managers will, in the case of an incident involving a patient, inform the patient and their carer or relatives of any incident as soon as possible in line with the Duty of Candour policy.*

Involvement and support where referenced was often positioned at the end of policy documents. This positioning combined with a relatively heavier emphasis on roles and responsibilities (on average 33% of a policy document) as compared with stakeholder involvement or support (on average 3% of a policy document) suggests a hierarchy of importance within policies.

Discussion

What is clear from the evidence presented in these two studies is that all stakeholders value patient and family involvement in incident investigations but that this is not facilitated or supported by local policy. Our review of patient and family involvement specifically identified that staff found involvement easier when guided by clear policy and structured but flexible processes. Furthermore, when patients and families felt involved, they were less likely to pursue litigation.

At the time of conducting these two studies, the SIF[1] was national policy. This framework did refer to patient and family involvement, specifically being informed of the event in a timely open and honest way (aligned to the 2014 Duty of Candour legislature), having access to 'necessary' information, informing the terms of reference, providing evidence, accessing the findings and viewing the final report. However, evidence from the two studies reported in this chapter demonstrates that local policy did not capture or build on these recommendations so that practice and therefore patient and family experiences of investigations were sub-optimal.[12,13,35,36] Local policy, however, did reflect national policy in two key ways. The positioning of information guiding patient and family involvement in national UK policy was predominantly towards the back of the policy document suggesting a hierarchy of importance. Similarly, the tone of the national policy document was somewhat passive and could have been interpreted locally as providing a single offer of involvement rather than a guiding process whereby patient and family involvement was valued and supported throughout.

Although the main focus for our first review was patient and family experience, it is important to consider staff views and experiences. Barriers to disclosure, honesty and transparency such a fear, blame, and lack of skills and training need to be addressed through national policy that sets the tone for cultural change through organisations. Similarly patient and family involvement presented as a passive approach within policy cannot be expected to meet their needs.

Chapter summary

This chapter has described what is currently known about patient and family involvement in incident investigations, from the extant empirical literature, and local organisational policies. In the next chapter, we explore the experiences of investigations from the three key stakeholder groups: patients and families, healthcare staff and investigators.

Chapter 4 Stage 2A: In-depth interview study

Chapter outline

This chapter presents the methods and findings from stage 2A of the study which involved in-depth interviews with key stakeholders focused on their experiences of patient and family involvement in serious incident investigations, including decisions to litigate. This chapter addresses research questions (RQs) 2–4:

RQ2: What is the experience of patients and families who have been involved in a serious incident, or serious incident investigation, and what might have influenced decisions to litigate?

RQ3: What is the experience of front-line healthcare staff, investigators and legal staff who have been involved in a serious incident investigation, and what might have influenced decisions to litigate?

RQ4: What are the views of front-line healthcare staff, investigators and legal staff on the potential involvement of patients and families in serious incident investigations?

Methods

The study received favourable ethical approval in July 2020 (REC ref: 20/EE/0133) and interviews took place between September 2020 and April 2021. Decisions at each stage of the study, including development of the study protocol, were done in consultation with the PFAG, SAG and steering group. Specific examples of their involvement include refining the eligibility criteria, developing recruitment material and advising on when to stop recruitment.

Recruitment

A targeted sampling approach aimed to recruit participants in four key ways, via: (1) a personal invitation letter, general communication method or snowball sampling study partner sites (see *Chapter 2*); (2) advertisement via relevant charitable organisations (Care Opinion, AvMa, Harmed Patients Alliance); (3) advertisement via social media or (4) word of mouth. People were invited to respond and register their interest with the research team by e-mail, and were then sent a copy of the detailed information sheet (in easy-read where preferable) and assessed for eligibility according to criteria, which stipulated that participants must: be > 16 years old, have experienced a 'serious incident' and subsequent investigation within a healthcare setting as defined by NHS England, experienced the serious incident > 1 year after consenting to take part, have no ongoing police or legal involvement relating to the serious incident, and have capacity to consent.

One hundred and seventeen people registered their interest in taking part (see *Figure 3* for participant flow), 98 people were assessed for eligibility, of which 66 were eligible to take part. Telephone conversation to assess eligibility followed a detailed semistructured guide and due to the sensitive nature of the topic, participants were signposted to personalised sources of support where necessary. A total of 42 participants had capacity to consent and took part in the study. Our decision to stop recruitment was guided ethically, wanting to avoid unnecessarily causing distress to non-eligible people, consenting participants and the research team. With a caveat of assumed limited participant diversity, this decision was also made based on collaboratively feeling that we had 'understood enough' and 'heard enough'.[37]

Interviews

Forty-two eligible people with lived or professional experience of incident investigations took part in individual semistructured interviews with one of four researchers (LR, KL, SMcH, RSE). Interviews were supported by a topic guide which enabled avenues of conversation to remain focused on the research questions, while also allowing flexibility to capture wider topics of interest, including exploring topics most important to participants themselves. The topic

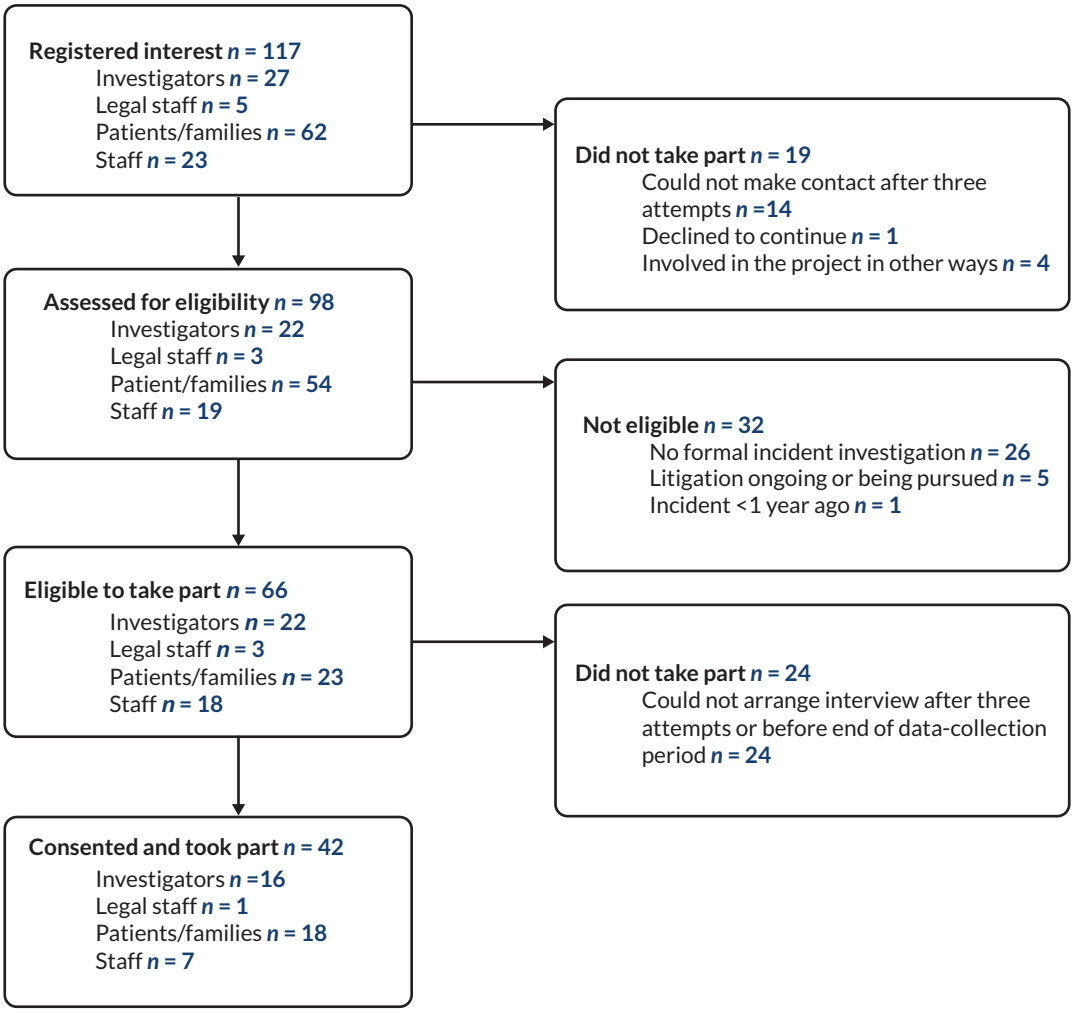

FIGURE 3 Participant flow of people with lived or professional experience of incident investigations who were interviewed.

guide was tailored for each stakeholder group; however, all questions centred on experiences of incident investigation processes, their thoughts and feelings about, and experiences of, involvement, and their experiences of processes that surround or are linked to incident investigations, including decisions to litigate. The topic guide was developed based on the focus of the research questions, the exploratory nature of the study and also to reflect the findings detailed in *Chapters 3* and *4*. With guidance and support, participants were also given the option of producing and sharing a timeline.

This was thought to help to organise and structure their thoughts, and ensure that they were able to share details of events that were most important to them personally, as well as helping the researcher to understand the order of events during the interview.[38] Three patients/relatives chose to produce and shared a timeline purposefully for the interview. Many others brought along relevant documentation to use as a personal prompt for their interview, but did not share that with the research team. Interviews took place virtually due to COVID-19 restrictions, held via Zoom (Zoom Video Communications, San Jose, CA, USA) (n = 36), Teams (n = 2) or telephone (n = 12) and were video- or audio-recorded. Interview duration ranged from 25 minutes to 2 hours 32 minutes (average 1 hour 27 minutes). Due to the sensitive nature of discussion, researchers followed a detailed distress protocol, which aimed to support both participants and the research team prior, during and after the interview. This included signposting participants to relevant sources of support, and debriefing as a research team following each interview, led by a researcher with a background in counselling (RSE). The aim of the interviews was to understand both the context within which the processes for supporting meaningful patient/family involvement in incident investigations will operate and support the further development of the programme theory to underpin the co-designed processes.

Analysis

Data were auto-transcribed via Zoom or Teams software initially where possible, and checked by in-house admin support, transcribed in-house or outsourced to TypingWorks. An inductive reflexive thematic approach was taken to analysis,[39] aiming to develop overall findings representing the commonality of experience across the stakeholder groups, and explore divergence. Weekly 'data sessions' were held with researchers who had conducted the interviews to reflexively discuss initial impressions, and develop a descriptive account based on patterns of meaning and similarities and differences within and between participants and stakeholder viewpoints. Three researchers then focused specifically on a stakeholder perspective (LR – patients and families, SMcH – investigators, RSE – clinical staff) to elucidate the descriptive account, and ensure that it was grounded within the data, as well as a researcher from the wider team (GL) focusing on transcripts across all stakeholder perspectives.

This involved reading each transcript to become immersed within the data, and making descriptive notes in the margins, as well as highlighting significant quotes and summarising key details of each account, before independently and collaboratively collating ideas analytically. Further discussions were held with the wider research team, including qualitative experts (LS, JW) to develop, evidence and refine the themes until a consensus was reached.

Findings

The interview analysis is presented in four main parts: part 1, experiences of patients and families; part 2, experiences of clinical staff; part 3, experiences of investigators; and part 4, decisions to litigate.

Part 1: Experiences of patients and families

The 18 patients and families interviewed comprised patients directly affected by the safety incident themselves (7), as well as parents (7), children (2), a sibling (1), a spouse (1) and an uncle (1). Their experiences related to investigations in acute care (13) and mental health care (5), although some spanned multiple settings. Incidents included delayed or misdiagnosis (6), surgical error (4), maternity related harm (3), suicide (3), drug error (1) and unexplained death (2). Two incidents also formed part of larger-scale investigations or inquiries, and one was completed by an independent investigatory body. Themes relating to the experience of patients and families are detailed below.

Theme 1: Cautiously hopeful

In the aftermath of an incident, patients and families described an overwhelming sense of vulnerability, largely emotionally, as they or their loved ones were harmed while under the care of a healthcare service they inherently trusted.

> *I was very distressed. I find myself quite a resilient person. I can manage my emotions quite well. But I think I was very, very vulnerable in that situation.*
>
> *Patient*

For some, communication relating to the investigation felt like an adversarial formality from the outset, and for others, formal recognition of the incident exacerbated fear. However, most came from a position of cautious hope. People desperately wanted to feel able to put their trust in the health service again, and for some good to come of the investigation.

The fact that an investigation was taking place brought reassurance, a sense of opportunity to validate their experiences and comfort at the potential of gaining clarity about what happened. This was despite a sense of mistrust already being fostered for some, where attempts to escalate had not been listened to, when formal acknowledgement of the incident could have been made sooner, or where there were histories of fractious relationships, delays and poor communication.

> *During the time of my mum being looked after, she was not listened to and also as a family we weren't listened to, so it felt like an opportunity, finally, to be listened to.*
>
> *Relative*

This required strength, as many felt that there was no longer space to express emotion, distress or anger. Taking great care to manage their feelings, people wanted to present in a manner that would be perceived reasonable.

> *I put a lot of thought into it, even though, you know, I did feel angry and upset, I tried to make sure that the letter wasn't aggressive or pointing the finger.*
>
> *Patient*

Due to the range and complexity of emotions that patients and families experienced, alongside coming to terms with the immediate and longer-term implications of what had happened, their ability to reach into the system was often limited.

> *When you're low like that you don't know what to do, you don't know how to raise issues, you don't know where to go … To start with I did nothing. I was just likely completely dumbfounded.*
>
> *Patient*

Instead, most described expectations of the system to proactively reach out and support them in due course. On that basis, most placed their good faith in the polite people they encountered in a hope that knowledgeable staff were progressing the investigation with their needs in mind. How that good faith was handled then laid the foundations for how their relationship with the healthcare organisation would continue. Over time, most felt that the trust was broken.

Theme 2: Overwhelmed by indistinct processes

Some patients and families had difficulties disentangling their experiences of care and the investigation. Others raised concerns of history repeating as the issues seen in care became intertwined with the investigation. Having never been through such process before, some felt unable to comprehend that an investigation was taking place or what that meant in practice.

> *The words might have been mentioned once, but I never really understood what serious incident meant. I didn't know what the investigation would mean … very minimal information … I wasn't asked to be included in the investigation at all. I didn't even know that was an option.*
>
> *Patient*

Investigations also often ran alongside other inter-related processes, with unclear remits, as well as their own overlapping timelines. Ambiguity surrounded simultaneously receiving ongoing care, liaising with multiple care providers and conducting personal research to make sense of what had happened. Some were also involved in processes, such as coroner's inquest, appeals, police investigations, patient advice and liaison services, formal complaints, funeral planning, pursuing litigation, public inquiries and independent investigations, among other things and the demands of life. This was particularly complex in cases dealing with death, or where needs were being addressed across multiple care providers, requiring complex liaison.

> *We were getting drip-fed information, and because there were so many different agencies sort of involved … the whole thing's really, really difficult. Really difficult. Because I just don't think that anyone has sort of, really helped us at all …. We were grieving. No one actually realised.*
>
> *Relative*

Theme 3: On the side lines of organisational agendas

Over time, patients and families were not necessarily able to articulate how or why they felt that they were not being levelled with, but experienced widening power gaps, the breaking down of therapeutic relationships and investigations working to organisational agendas.

> *I didn't have the information or knowledge to explain exactly, and my eyes started filling up … when you know inherently there's something wrong because you can hear enough information but you can't join all the dots, nobody's joining the dots for you.*
>
> *Patient*

Feelings of naivety, demoralisation and betrayal by the health service they once held in high esteem over-rode as that they themselves had to 'work' to be heard, with an underlying sense of injustice. Muddling through a complex system with limited knowledge, resource and power, designed without their needs in mind, they felt that their good faith was later taken advantage of. Alongside unclear expectations, this meant that everything became a challenge at a time they needed support.

> *This sort of dragging, everything taking a very long time feels deliberate in that they hope it will just go away, or that the whole process will be too long, traumatic and awful for a family that they'll just give up.*
>
> *Relative*

People felt that processes were strategically 'unseen', behind closed doors, and denied real scrutiny. In the meantime, some blamed themselves for the outcome or felt made to question their own memories and realities, leaving them more vulnerable than before.

> *You begin to believe that you're making it up somehow. I remember that at one point thinking 'well if no-one's believing me, it must be my fault' and of course it wasn't, and even if it was then I needed help, you know. But I just thought I was going mad. I was made to feel like a pathetic little woman.*
>
> *Patient*

This was experienced as an exploitation of power imbalance in favour of the healthcare organisation, who most felt unable to stand up against when in disagreement. Some persisted, whereas others with limited power, strength, assertiveness, systems intelligence and social capital withdrew feeling discriminated. Some also raised concerns for others who may be defeated by the process due to social inequality.

> *They did say that they would be able to investigate it more if I wanted to. But at this point … I just felt a little bit defeated by it all …. You are left with lots of questions but it's almost that you kind of resign yourself to it's just how it is.*
>
> *Patient*

Particularly damaging for patients and families was feeling disillusioned by a lack of compassion, not feeling heard and experiencing an unwillingness to fully acknowledge or take accountability for the potentially profound impacts of what happened, despite that being something that some desperately wanted.

> *I was sort of dealing with a life changing event at the same time as dealing with this, people just lying and being mean.*
>
> *Patient*

Many also felt that the organisation insufficiently provided support in the aftermath and longer term. Compassionately attending to these needs was considered basic steps to making amends when something had gone wrong, grounded in a need for openness, transparency and candour. These disorienting experiences jarred with underlying assumptions, and shattered understandings and expectations of what caring organisations were set up to do.

> *There should just be so much more compassion, empathy, putting the family at the heart of the investigation, that their needs are being seen to … they didn't sort of really check or ask if we needed support … it feels pretty basic.*
>
> *Relative*

Theme 4: Awaited report compounding harm

Patients and families waited in anticipation of the investigation report, marking a key point in the process and contributing to compounded harm. Generally, people appreciated that staff input was important, but felt

that more weighting was given to protecting the organisation and staff accounts, rather than considering all perspectives. Reports were also described as disheartening, disrespectful, dishonest, paying lip service, defensive, lacking empathy and avoiding accountability. Patients and families also felt that they insensitively delivered unexpected information which indicated ambivalence, and that the organisation had lost sight of the affected family, devaluing the experience they had been through, as well as lacking acknowledgement of the questions they had raised.

> *The report doesn't really even sort of acknowledge the fact that she died …. Small things like typos which maybe in another context you would let go … at various points they refer to her as Mr … in this context feels just really disrespectful.*
>
> *Relative*

Frustration was also felt as the report was then felt to be accepted as an objective truth, with no right to discuss, reply or refine what had been written. It was often considered too late to become meaningfully involved and influence the report in the ways many would have liked to with hindsight. The few that were happy with the report felt that it was not designed with them in mind but for the organisation.

> *It's purely a review of the clinical practice that's taking place … once it's been published and released, the trust do take on board concerns that the family may have regarding the content of the report, but it cannot be changed.*
>
> *Legal staff*

Following receipt of the report, some were offered bereavement support, funeral planning advice, counselling service access, and signposted to relevant charitable organisations. Others were invited to meet with representation from the healthcare organisation to ask any outstanding questions. However, offers of support were not universal, and some felt they were tokenistic or inaccessible. Instead, some sought to build informal relationships with others who had experienced similar situations, and developed support networks via social media.

Theme 5: Being left to pick up the pieces

Once investigation reports were published, there was a general sense that it was the end of the process for the organisation, leaving patients and families to pick up the pieces, sometimes with their life in turmoil.

> *I needed some help … I just got a reply back saying, these are our findings, you know, the process is over now.*
>
> *Patient*

Experiencing a heightened sense of fear, confusion and disorientation, many still suffered due to bereavement, loss of career, lifelong disability, loss of identity, ongoing care needs, disruption of family dynamics, fear of revisiting services, generalised fear of health care, difficulty processing what happened, and mental health decline. In addition to the impacts on them personally, people also had concerns for the mental toll it took on those around them, as well as considering what they had lost by investing their time and energy into the process, sometimes over a long period of time. For some, life became an all-consuming effort to get answers to their questions and help to prevent the same thing happening to others, which was described as an exhausting, emotional and lonely journey that continued to have a ripple effect on their life.

> *I had to sort of step back and take a breath, and when I looked around me after all the years I'd spent … intensely engaged in this, but the rest of my life crumbled around me … it broke me, if I'm honest.*
>
> *Relative*

People also reflected on being drip-fed information, leading to more questions they felt compelled to gain answers to via activities, such as liaising with clinical experts, regulatory bodies and members of parliament, as well as sourcing relevant information including recent reports and policy linked to the incident.

> *I've had cause to touch base with the police, with home office pathologists, with countless regulators … I have spent hundreds of hours watching live surgical procedures … I reckon I could take a decent stab at performing this procedure …*

> *We are kind of forced into the level of detail that no normal person outside of medicine would ever have to get involved in, but you're forced down that route in order to understand.*
>
> *Relative*

The sense that opportunities to learn were neglected also contributed to compounded harm, as some felt that their experience was of no consequence. Some perceived that this was due to procedural constraints, whereas others evaluated that the organisations chose to circumvent the real issues that needed attention. Others raised concerns of arbitrary recommendations that did not indicate organisational learning would take place, and one patient described how they had to revisit the same care setting again for a similar procedure, and witnessed first-hand that a recommendation had not been actioned.

> *It makes it feel that what you've gone through hasn't been completely in vain … I just feel that yes I went through this and anyone else can go through it again afterwards, it's, you know, no-one's learnt anything from it.*
>
> *Patient*

Part 2: Experiences of clinical staff

The seven clinical staff interviewed worked within acute (n = 5) or mental health settings (n = 2). Themes relating to the experiences of clinical staff are detailed below.

Theme 1: Well-entrenched fear

In some circumstances, it was immediately apparent to healthcare staff that an incident investigation would take place regarding the care that they had provided, invoking shame, blame and fear of what that meant for the patient, as well as their reputation and the security of their professional position. Often continuing to work clinically in the immediate aftermath, staff described a lack of time and mental space to process their experience in preparation to report the incident and share their account as part of the investigation. Other times, staff were made formally aware of the investigation and patient outcome retrospectively by management, sometimes perceived to be delivered insensitively, with lacking support and emotional help having lasting impacts on them.

> *I've still got the email … but it's just the tone of it is just, I remember just thinking, 'what the bloody hell is going on?' … It was just like being hit again at every stage, there was so much harm that was caused … I still can't talk about it this far on without, as you see, being in floods of tears. I don't know when that harm will stop.*
>
> *Staff*

Some also described experiences of learning of investigations informally via colleagues or patients, which felt particularly jarring, humiliating, blaming and isolating, with perceptions that they were being talked about, and that their professional capabilities were being questioned. This was sometimes later made explicit by interventions, such as additional supervision and training.

> *It was almost a case of, the nursing staff, you know, had almost been told, oh, just be careful of this one. So it felt very isolating, very difficult to even do anything because I felt very scrutinised after it.*
>
> *Staff*

Worries surrounded limited opportunities to give a full and true account of their experience, that their written or verbal account of events would be later misconstrued and ambiguity about how the information they provided would be later used or disregarded. The general feeling was that the core goal was to protect the organisation, rather than to learn or to support staff.

> *It was really difficult for me because it wasn't a case of this is in your best interests or whatever, it was more of it's in the best interests of your employers, the Trust, or my manager … professionally I felt very compromised.*
>
> *Staff*

Some also reflected on not having the opportunity to become involved in an investigation relating to their care, and that the lack of information resulted in distress.

> *There was a huge meeting, MAPPA (Multi-Agency Public Protection Arrangements), social services, health, child and family services. Everybody and his granddad was invited apart from myself. And the outcome of that meeting was that there was no case to answer from anybody involved, any of the professionals. That resulted in me resigning … I walked away from my job and it had a serious impact on my mental health at the time … there's no other word for it, they deliberately kept me away from the investigation.*
>
> *Staff*

The incident grading system also contributed to confusion for staff, with some unsure why similar incidents were and were not investigated and how the investigatory system linked to other processes, such as formal complaints and litigation. Adding complexity, was the relationship between staff and investigators, as they were likely to work for the same organisation. For some, it was perceived an unfair and biased system, combining accountability and ambiguity. Staff described the longer-term impacts this had on their well-being and job satisfaction, contributing to decisions for some to avoid working in certain settings or ultimately leave their role.

> *I had such a terrible experience that really scarred me, to the point of wondering for a while, whether I still wanted to be a doctor. It scarred me that deeply … it's coming up three years … I'm still living the ramifications now, of how it was handled what happened and how it made me feel … it was horrific, it was absolutely horrific. It meant that day-to-day I hated going to work, I absolutely dreaded it. I love my job, but I hated it with a passion.*
>
> *Staff*

Theme 2: Support as an indulgence

The provision of support for staff following safety incidents varied. Some described feeling well supported by management and colleagues which largely happened informally, whereas others carried the emotional burden of being investigated alone, feeling isolated, confused and angry.

> *Not one person at any point asked me if I was okay … I'm lucky to have friends and family … but my God, they could have ended up with a very, very different outcome, had I not had support. And that really angers me … It's really important that we don't traumatize already traumatized staff further.*
>
> *Staff*

Generally, staff felt that there was an assumption that they should be well versed in the uncertain and high-risk nature of the environment they worked in, and so investigation processes were an inevitability of their career. Because of the normalisation of events with perhaps life-altering or life-ending circumstances for patients and their families, some staff felt that seeking formal support was an unnecessary indulgence for them. Perhaps more jarring for mental healthcare professionals, staff worried about struggling with their own mental health, with concerns about how taking up offers of support may be perceived, as well as having limited time to access it alongside their busy clinical role.

> *They weren't assuming any responsibility for supporting me … I became isolated, it was really difficult for me. My colleagues made life difficult … they treated me like I was some sort of, er, mental health case myself … I lost a lot of friendships … II took a year off … I just needed to get away, and I was quite unwell for about six months after … I did have to get some counselling.*
>
> *Staff*

In the absence of support, one staff member described personally setting up their own peer support group, providing dedicated space and time for staff to discuss the impacts incidents had on them.

> *We just meet every month and people can just come and talk about grief, it's just for staff, it's not for patients … and have some sort of marking, some sort of ceremony … around naming people and coming together as stuff and permission giving to express grief around losses that we've had … You talk about your values of caring and compassion and, but we have to embody it … how can we look after each other to be facing these really difficult things.*
>
> *Staff*

Theme 3: Separated from the patient and family

Some staff valued contact with patients and families following incidents and felt it was a naturally caring instinct to support them. However, they were often kept separate, as communication was then made via those leading the investigation. This systemic response which was thought to be designed to protect staff, inadvertently fostered unresolved feelings, guilt and apprehensions of unknown outcomes, as well as fear of how events may unfold if they came into contact informally. These fears later surfaced for some as they met with the family after a delayed period in emotionally charged environments, such as coroner's court or future inquiries.

> *When you get that phone call of, say, someone's taken their life or someone's been killed, if you've been working with them you just want to go and see them … often then the managers come in and then they're the ones that have contact, because it just goes into the policy … I think sometimes it's a protective thing for the staff … you can feel that's been taken out of your control and maybe you would like that phone call.*
>
> *Staff*

Some sought their own ways to connect with the patient or family directly, such as communicating via e-mail or attending the funeral. Others indirectly connected with them, via methods such as lighting a candle in their name.

> *We went to the funerals, I actually spoke at one funeral, so I was really deeply involved with the family … but not in the input of the report or the investigation … it must be confusing, I think, for relatives … another team, getting involved. Like who are you? And especially when you're in the middle of grief.*
>
> *Staff*

Without an ongoing relationship, staff were sometimes left in limbo unaware of the outcome of the investigation, or found out long after the episode of care via the coroner. Others felt that reports were a 'tick box' exercise, defensive, failed to get to the bottom of issues, unfairly blamed individual staff, and did not facilitate learning, leading to queries about their purpose.

> *I personally struggled with the report … for me it didn't dig deep enough. There was so much information under the system, questions that didn't get asked … we looked at all the NICE guidelines around psychosis, oh, tick, tick, tick, she was offered medication, she was offered this, she was offered that, oh, we've got nothing to learn then, really … was it because maybe we weren't naming, really, what was going on? I do think a lot of is linked to that they've got to protect themselves, a lot of it is about litigation for the trust.*
>
> *Staff*

Part 3: Experiences of investigators

The 16 interviewed investigators worked in an acute setting (n = 3), mental health setting (n = 7), national setting (n = 5), or worked across settings as a bank investigator (n = 1). Themes relating to the experience of investigators are detailed below.

Theme 1: Feeling ill-equipped and unsupported

Investigators reflected on histories of not involving patients and families, but it being something that they felt was the right thing to do. Nevertheless, being the human face following healthcare harm was emotionally burdensome, with risk of burnout and suggestions that the role was potentially unsustainable long term.

> *Sometimes engaging with families is very challenging. They may be angry, and that's linked to their grief, they may have lost faith in our trust, or the NHS per se, and that may come across as anger directed at possibly the only person who's actually contacted them since the death of a loved one.*
>
> *Investigator*

The extent to which investigators felt supported organisationally and adequately equipped with the appropriate skills and knowledge was deemed important, but generally gained little attention. However, this varied within and between individual investigators, organisations and settings.

> *It's handed over to an investigator and it's then, right, you get on with this … there's no proper support.*
>
> *Investigator*

Investigators sometimes completed work alongside a demanding clinical role with little or no training, feeling that they needed more support with factors including dealing with the array of emotions experienced by patients and families, report writing and preparation for coroner's court or inquest, among other things.

> *People are trying to do it when they've got a spare hour, which means they take longer, there's no consistency from one report to the next.*
>
> *Investigator*

However, in a national context, the independent investigatory body had well-established processes, in which investigators were solely employed to focus on investigatory work, with relatively high investment in training and support, of which most spoke positively about.

Theme 2: Pushed and pulled in different directions

Investigators found their role messy and entangled, forcing them to take on a multifaceted identity. Alongside their own attitudes and beliefs, they juggled motivations from different stakeholders they were responsible for co-ordinating. This included patients and families, but also staff, legal teams, governance structures, and wider local and national policy directives. Motivations were made both explicit and unspoken, including: finding out what happened, learning, preventing litigation, defending organisational reputation, protecting the professional position of staff, healing, and using time and resources effectively. As a human being, it was impossible to remain truly objective, but instead they experienced isolating internal conflict and were made to regularly challenge and question their own positionality, balancing factors such as power, morals and their perception of the greater good, all within the context of organisational culture and with limited authority and autonomy.

> *It's just having an awareness that I'm not in this to win. This isn't me getting the better of somebody. It is listening to a distressed family who've lost a loved one and understanding what their concerns are.*
>
> *Investigator*

Investigators described being caught between advocating for the patient or family, who they had sometimes fought hard to gain the trust of and built up a meaningful relationship with, and speaking on behalf of the organisation, who they often felt came from a position of defensiveness.

> *I was really trying to be an advocate for this family. It got escalated quite high up, through our head of midwifery into the governance lead for the area. It basically was a blanket, 'no, that's the end of the report and that's it', and it was awful, it was absolutely awful. Working like that, where the family obviously were not happy and there were things I wanted changing.*
>
> *Investigator*

Some suggested that the mismatch in priorities was driven by a culturally engrained fear of litigation or blame for individual staff and teams, as well as wider reputational concerns. Other suggested that there was a lack of clarity surrounding whose role and responsibility it was to engage with the patient and family, and lacking a support system for them to do it well.

> *I find it really difficult because whose responsibility is it to liaise with people? Is it my responsibility or is it actually the Trust's team that manage this process's responsibility because I don't think it should be the investigator.*
>
> *Investigator*

Some were frustrated by empathising with and raising the concerns of patients and families, only to have them shut down by the system. Examples included timelines of communication, meaningfully contributing their experience to the report, widening the scale and scope for learning and providing tailored support.

> *Those concerns weren't part of the actual purpose of the investigation. When I tried to then report that it was, no, you can't include that in the report because that's not the subject of the investigation. And the lady actually specifically said to me, you know, no-one has involved me in this, you're ringing me up with this process I knew nothing about, no-one's involved me, no-one's listened to me, no-one's talked to me. So I found the whole thing really difficult.*
>
> *Investigator*

Working in this role, some were keen to express their impartiality, which was perhaps made easier in a national context, despite some questioning what it meant to be truly independent. To facilitate this, some went to great lengths to detach themselves from the organisation they were employed by, such as building rapport with the patient and family and making a conscious effort to work remotely. However, this perhaps exacerbated their loneliness.

> *I work for the same trust and in which we cared for their loved one and that loved one isn't here anymore, and I completely understand their reticence to trust me … is quite an isolated role, you know, I'm not part of the team. I mean, technically I am … but even before COVID I would be working at home for most of the time. I like that distance … because I need to look at things objectively.*
>
> *Investigator*

A key part of their role was negotiating and managing expectations, both practically and emotionally, in terms of what the investigation would and would not be able to achieve. Divergence tended to be illuminated when sharing the investigation report, and worlds collided.

> *In terms of involving the family, it would be at the end of the report process. So we'd have done the investigation. They might not have even known an investigation was going on, or the in's and out's of it … I remember sitting in meetings offering this final report, and the family being very upset. We hadn't achieved anything in terms of trying to answer family's questions, we hadn't even asked them what the questions were.*
>
> *Investigator*

Here, investigators felt trapped under conflicting pressures and forced into a position of certainty, despite messy realities with conflicting accounts and gaps in their understanding of what happened. Neatly packaging this complexity into a simple and coherent narrative which resonated with everyone's experience and advanced opportunities for learning was difficult. Ultimately, some investigators felt that nobody's needs were being met in favour of elusive 'organisational needs'. They were left questioning what purpose an investigation was serving if patients/relatives were experiencing compounded harm, staff were fearful, and the healthcare organisation was not visibly learning or improving. This was signified by the repetitious and inevitable nature of investigations and a lacking confidence in that recommendations would be implemented.

> *So you can't go back to the family and say, right, I've done this, this is what's going to happen because you've got no idea whether any of its actually going to happen. I know we'd like to think that once we've done it everything that you suggest is going to happen but you know full well that … some things will and others won't.*
>
> *Investigator*

Part 4: Decisions to litigate

Themes relating to the decisions to litigate from the perspective of all stakeholders are detailed below.

Theme 1: Instigating adversarial relationships in fear of litigation

Patients and families sometimes got the sense that staff trying to work out their legal stance or instigated adversarial relationships by taking a defensive and formal tone to communications. This jarred with how they had been communicated with by caring professionals prior to the incident, as well as their expectations of support, empathy and compassion in the aftermath, fostering a sense of injustice.

> *It's all so cloak and daggers, isn't it. Professionals are so scared that if they admit anything they're going to get done, and so everyone's so hush-hush about it and it's wrong, it should be so much more open.*
>
> *Patient*

Over time, it felt that the organisation went to great lengths to defend themselves illuminated by investigation reports, placing investigators in lonely positions which challenged their morals.

> *I find the process of preparing reports frankly adversarial. I think the whole set-up of the way this is managed is really unfriendly.*
>
> *Investigator*

Fear also manifests as absent or insincere apology, as staff and investigators worried that conversations would be difficult and that it would be misconceived as admitting liability, yet it brought long-awaited relief for those who did receive it.

> *There's the misconception that we can't say sorry. Saying sorry doesn't mean there is a blame attached to that, that's saying sorry, you know we cared for this person for 10 years, we're really sorry the person died whilst in our care. There's a lot of fear in involving the family, or apologizing because it gets confused with some sort of admission of blame or liability and, won't the family be upset and how will I deal with that?*
>
> *Investigator*

Some felt that this was due to an unfounded assumption that all patients were out to seek financial compensation, which did not resonate and minimised their human experience and the impacts of harm.

> *It's very easy to be entrenched and be like, oh, you know, the patients that complain are sort of money grabbing, rather than actually, this patient is suffering … I think the NHS needs to do a bit more listening, but unfortunately listening isn't a metric that they can measure.*
>
> *Patient*

All stakeholders perceived fear of litigation as a barrier to rebuilding trust, transparency, and ultimately, learning.

> *It's so in the bones in the NHS, so, so much practice is defensive … it's so in-ground in our system, and I can really understand that, especially because I've just been investigated. You know, and we, you can be struck off, so I can really understand it, but I think it can get in the way, again, of meaningful conversation and dialogue, because of this fear of litigation … so much time now is spent protecting the system.*
>
> *Staff*

Theme 2: Legal involvement changing the investigation

Where patients and families did initiate legal involvement or it was clear that there would be legal processes surrounding the incident such as coroner's court, there was a further shift in tone, with sense that any informal communication had broken down. Despite investigators feeling that, as a right, legal involvement should not change the investigation, communication often went through additional layers of scrutiny and meant that different members of staff became involved. Patients and families felt that language was more contrived and that they experienced additional delays as a result.

> *I kind of handed over communication to the legal team, that was when everything kind of went quiet and then there was this big delay in getting a report back to us, so personally I feel like it was, that influenced communication going forward.*
>
> *Relative*

Investigators reflected on not being able to build meaningful relationships in those circumstances.

> *I think it's sad because if there are solicitors for the family, I think the trust are obliged to have our trust solicitors … it's escalated to a different level and makes it less personal.*
>
> *Investigator*

One patient reflected on seeing statements written by clinical staff in later processes, which were not communicated due to legal processes stripping them out of the report, removing an opportunity to heal.

> *I did see, as part of the legal case, what they'd written, and what the doctors themselves had written was a lot more caring than anything that I'd come across in the letter. And I did feel an element of sadness that, you know, that had been stripped away.*
>
> *Patient*

Theme 3: A forced route to feeling heard

Perusing litigation was often not financially motivated, or a decision taken lightly, but was considered an avenue people were forced down in hope to be finally heard, gain answers to their questions, and receive some recognition for what had happened and its impacts.

> *When I did, you know, seek legal advice, that wasn't something that was a small decision, it was a massive decision. I just felt like it was the only way. I wanted to have a proper investigation and I just wanted them to take notice.*
>
> *Patient*

Some felt that outside of a legal case, there was nobody with the power needed to help them piece together the many, small pieces of the puzzle. Others reflected on what was perceived unnecessary distress, having to go through the legal process, and that the organisation could have taken simple steps to avoid forcing them down that route.

> *If this was a mistake that had been immediately acknowledged and admitted to in the spirit of the duty of candour as it should be, this probably wouldn't have even been a clinical negligence claim. Don't get me wrong, we'd have been a bit p'ed off but we'd have got past it, you know, we recognise that, hey, we're all human.*
>
> *Relative*

From an investigator perspective, some empathised and encouraged patients and families to escalate their concerns, sensing that it was the only way that their needs could be met.

> *I got told off for this. We'd done the actual investigation, we'd got a final report and the father wasn't happy … I felt I had no option but to ask him to resubmit it as a complaint … they would have had a point of contact … it would be looked at by our head of governance … a better process than we had for the actual investigations where we didn't involve the family … the matron would have a family meeting where we'd go through and literally all the questions were answered, and if the family weren't happy about anything then it would be looked at.*
>
> *Investigator*

On gaining legal advice, some found the unhindered communication a refreshing contrast to a process that was seemingly out to question their realities. Instead, this was the first time they felt heard.

> *That was the first time that somebody had just listened and then taken it all in … that validation just helps you … if we hadn't had that we would be just doubting ourselves and our recollection of things.*
>
> *Relative*

There was an acknowledgement that pursuing litigation required capital, both financially and mentally, to allow people to repeatedly revisit what happened, while also suffering potentially life-changing consequences, or grieving. This sense of powerlessness led some to choose not to raise a legal claim.

> *At one stage I was so upset by the whole thing I felt like taking legal action but I was very aware that the NHS is a very large organisation and, you know, that it was little me against them. I didn't feel like I wanted to take it on … I felt like I was in the boxing ring with my hands tied behind my back. And I felt desperate.*
>
> *Relative*

Some also raised concerns for others, due to social inequalities.

> *It discriminates against people who don't necessarily have the ability or the support around them to pursue it … have the intelligence and have the drive to go through the compensation process.*
>
> *Patient*

Discussion

To our knowledge, this represents the first UK-based study to examine the views of key stakeholders collectively (patients, relatives, investigators, healthcare staff and legal staff), to explore their experiences of involvement and what might have influenced decisions to litigate.

This study supports the theoretical underpinnings of the organisational accident model[26] in suggesting that patients and their families have valuable things to share relevant to safety and provides much needed evidence to highlight the key things that patients and families may need within the English healthcare system when involved in an incident investigation, and also the factors that contribute to compounded harm.[40] In basic terms, what patients and families might need following something going wrong in health care has been explored in other countries over the last two decades.[41–43] Evidence suggests that these needs are often wide-ranging, and specific to individual circumstances; however, at the crux of it are human beings, relationships between them, and the physical, emotional and/or financial impacts they are experiencing. Where these needs are not met, this can feel at odds with basic expectations of what caring organisations are set up to do. Much of the compounded harm experienced by patients and families was arguably easily avoidable, and aligned with a compelling argument made by Bismark and Peterson,[41] to suggest that there is a need to go back to basics in health care, and warrant these human experiences with a human response. In addition, where these needs are left unmet, it may result in additional complaints and litigation – supporting the NHS Resolution 'approach to early intervention',[6] which proposed that involving patients and families earlier would impact positively. It could be argued therefore that meeting these needs is both a moral duty of health services, and the various agencies that support them within the policy and regulatory landscape, and an important intervention to alleviate the significant financial burden of unnecessary legal claims.

Understanding and acknowledging this moral duty has emerged slowly over the past two decades. In 2009, the Being Open Framework was launched, followed by the Duty of Candour being enshrined in legislation in 2014.[44,45] Further, the right to an apology, support through an investigation regarding any complaint of poor quality or unsafe care, and the commitment to learn from any complaint or investigation and improve services in response to that learning are now explicitly written into the NHS Constitution within England.[46] In some ways, this moral duty to support people after healthcare harm could be regarded as a simple extension of the duty of care of services to patients and families experienced before healthcare harm. In short, the same concepts applied to healthcare provision should remain in the aftermath of something going wrong. However, perhaps more complex to change it the wider cultural and systemic barriers faced by investigators with limited knowledge, training and support, which all stakeholders perceived to be driven by fear.

Interestingly, while the focus of this study was primarily patients and their families, we found striking similarities between the way that patients and families, and staff felt. Throughout the investigation process, both groups reported feeling overwhelmed, excluded, ill-equipped, unsupported, uninformed and ultimately experienced compounded harm.[40] This builds on existing literature focused on the perhaps controversially labelled phenomena of 'second victim', describing the emotional difficulties experienced by staff following healthcare incidents.[23,47–50] Our evidence further suggests that not only do incidents themselves result in harm for staff, but the processes that follow have the potential to exacerbate the harm experienced. For this reason, we proceeded to develop co-designed processes which mirrored the patient and family resources for staff. In consultation with the PFAG and SAG, we recognised that this was a problem too important to ignore, despite not falling within the original remit of the research programme.

Finally, one key limitation of this study is the self-selecting nature of participants perhaps attracting those with particularly negative experiences to take part. As a research team, we were mindful of that moving into stage 3 co-design and drew upon the experiences of the steering group, PFAG and SAG to ensure that guidance was not being produced to support a subset of patients, families and staff only.

Chapter summary

This chapter presented the interview study findings where we found that patients and families often start investigation processes from a point of cautious hope, expecting the organisation to want to listen and learn from what happened as well as supporting them to heal. However, they later come to realise that they lack power, knowledge and support to navigate the system to meet those needs, with risks of disproportionately affecting those most vulnerable. In addition, some perceive that they are intentionally excluded, illuminated by the investigation report that becomes available late in the process, leading them to feel forced to meet their needs elsewhere such as pursuing litigation. Staff also experience similar injustices, such as exclusion, lack of support and shame. To avoid this fractious cycle of involvement ultimately resulting in compounded harm seemingly driven by fear, all stakeholders need a collaborative understanding of what an investigation is and is not, as well as system navigation assistance, and sensitive tailored support short and long term to deal with the incident, but also the ripple effects on people's lives. Interpersonal relationships must be centred. Equally, the challenging role of investigating needs to be recognised as skilled 'work' requiring adequate training, resources and support, as well as support to navigate through the multidimensional balancing act of competing priorities and sensitive discussion, to avoid people feeling forced into pursuing litigation.

Chapter 5 Stage 2B: Synthesis, common principles and programme theory

Chapter outline

This chapter focuses on stage 2B of the study which sought to synthesise the findings from stages 1 and 2A, and develop a foundation for stage 3 co-design, through the development of common principles for how patients and families should be meaningfully involved in incident investigations. Further, we sought to expand our emergent programme theory for how the co-designed guidance and processes might impact on experience, including decisions to litigate.

This chapter therefore specifically addresses RQ5: What common principles are necessary for involving patients and families in incident investigations?

Methods

Between January and April 2021, we conducted a three-phase analysis and synthesis of the qualitative data drawn from stages 1 and 2A using first inductive and then abductive analytical approaches, to create meta-level findings that could be taken forward to the stage 3 co-design phase. Analysis was both descriptive and conceptual. The descriptive, inductive analysis allowed for an understanding of 'what was said' while a higher, conceptual-level analysis provided an interpretation of what this meant for the involvement of patients and families in serious incident investigations. Our research questions focus the analysis first upon patient and family experience and decisions to litigate. However, we remained open to explore what elements might be crucial to integrate across the set of findings to move forward into stage 3.

Phase 1: Inductive analysis

To prepare for the synthesis of the findings, short descriptive reports were created for each of the three studies: the documentary analysis of policy and the scoping review in stage 1, and the interview study in stage 2A. For the interview study data, due to the volume of interviews and purposive sampling by group, a short report was created for each of the three groups represented: patients and families, healthcare staff and investigators. Each report was created by the lead researcher on each of the three studies and shared within the team for refinement and agreement. These reports were inductively generated as a precis of findings, and as such had variable structures. Examples of the short reports can be seen in *Appendices 1* and *2*. The reports were shared ahead of synthesis workshop 1.

Phase 2: Abductive analysis

Our analysis then moved to an abductive phase to extend the inductive analysis and support the synthesis of our three data sources to create the common principles and further develop the working programme theory. Abductive analysis is an approach to qualitative data analysis that involves an interplay or middle-ground between inductive and deductive-type reasoning. It resembles an iterative cycle of analytical reasoning, in that ideas and themes identified within the empirical data are used to develop concepts and propositional statements, which are then related back to the existing literature and theory to determine whether they are plausible and whether they confirm, extend or question the existing evidence. This then generates additional questions and theoretical ideas about the field of enquiry that are then examined through further analysis of the data.[51]

Underpinning theories

The overarching 'grand theory' for this work was the *organisational accident model*.[26] However, through our scoping review (stage 1) and interview study (stage 2A), it became clear that this lens was limiting in its focus only on

organisational learning, at the expense of the relational experience of investigations and the potential for compounded harm. Therefore, we sought to augment our understanding of the phenomena of patient and family involvement in incident investigations, through the application of an additional theoretical lens, from a group of approaches which can loosely be termed *restorative responses*.[27] As described in *Chapter 1*, restorative approaches are gaining increasing interest internationally, as a potential alternative approach to responding to healthcare harm.[40] In contrast to a systems safety approach, which emphasises organisational learning and prevention of future harm as the motivation for investigations, a restorative response focuses on those who have been harmed or who are affected by the harm, what their needs are, who is responsible for meeting those needs, and only after these are addressed is the question of prevention of future harm.[28] Finally, in writing the original proposal, our working programme theory had been based on that proposed by NHS Resolution *as the basis of their approach to early intervention*.[6] However, at the time of application, this had not been interrogated empirically. Therefore, in this phase of the analysis, we were interested in exploring the espoused, nuanced links between the temporal experience of processes following patient safety incidents – the identification and disclosure of the incident, involvement in the investigation, and the final report and next steps – and decisions to litigate.

Analysis procedure

We created an analytical framework based on the three theoretical lenses, which is illustrated visually in *Figure 4*. First, we were interested in the role for, and experience of, patient and family involvement in the creation of organisational learning. Second, we were interested in the needs that are created for patients and families due to the experience of a patient safety incident, but importantly, also the experience of the investigatory process itself, and the potential for that experience to compound the initial harm and dictate further action (such as complaints and litigation). Finally, we were interested in the temporal aspects of the investigatory process, and whether the needs for learning and repair were different across the phases of an investigation, and across the different 'stakeholder' groups who are involved in the process and practice of investigations: patients and families, healthcare staff and investigators.

The research team and qualitative co-applicants (GL, LS, JW, JL) met in several intense analysis sessions in order to conduct the abductive analysis. Based on the content of the short reports developed from the inductive analysis and researchers' own knowledge of the field, the analysis team discussed each theoretical lens in relation to the empirical

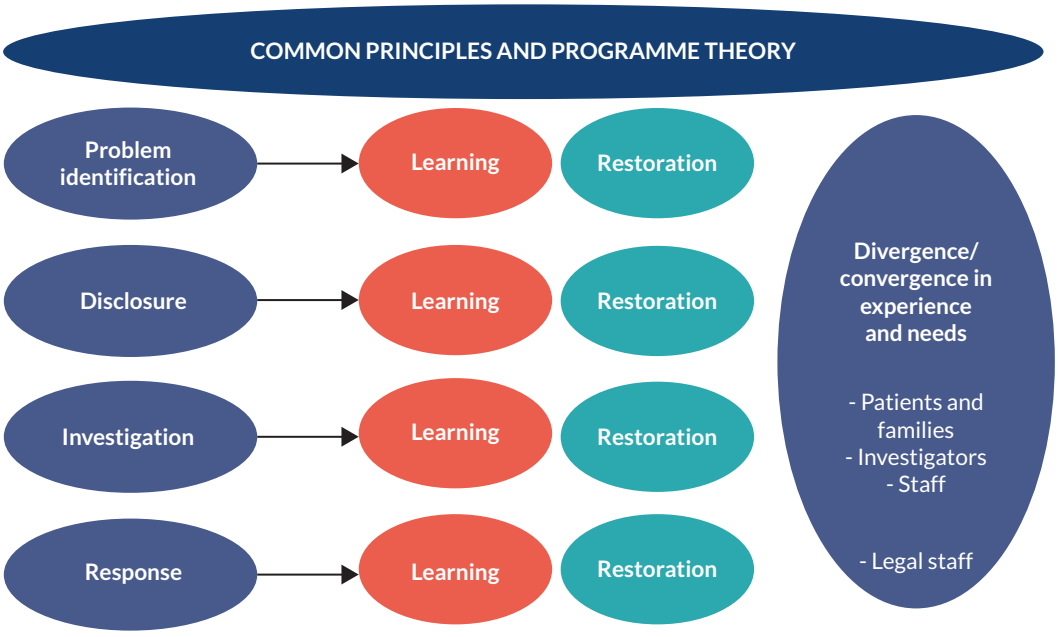

FIGURE 4 Abductive analytical framework.

data. This involved reflecting on the overlaps and divergence between the three theoretical notions. From this intense analytical work, the abductive analysis framework (see *Figure 3*) was constructed and findings were written up which paid attention to the core constructs of the common principles and programme theory.

Phase 3: Synthesis

This phase ran concurrently with the first two, supporting an ongoing synthesis of the inductive and abductive analysis, to more fully develop: (1) the draft common principles for meaningful involvement; and (2) a working programme theory to explain why enacting these principles through the subsequent co-designed processes, might lead to changes in patient/family experience, learning and decisions to litigate. *Figure 5* illustrates the chronological order and content of the analytical phases, and how the workshops were used to direct and undertake the synthesis of these analyses to develop the common principles and the narrative programme theory.

Three workshops were undertaken between March and April 2021, comprising the core research team, and the four qualitative and co-design co-applicants (GL, LS, JW, JL). These workshops were bookended and punctuated by the analysis phases, which provided data for each workshop in turn. All workshops had an agenda and desired outputs agreed in advance.

Workshop 1

Ahead of this workshop, attendees were provided with the short reports of the previous studies from Phase 1 of the analysis. During the workshop, these reports were discussed, and the team identified the key foci of the integration. The abductive approach using the three forms of theoretical framing was agreed, and plans were made for Phase 2 of the analysis.

Workshop 2

Ahead of this workshop, attendees were provided with the draft abductive analysis of the needs for the different stakeholders, based on the temporal breakdown of the investigation stages. During the workshop, this analysis was discussed and revised to create the final version, and to reflect on what this meant for the working programme theory. Finally, a set of sensitising questions (*Table 3*) was agreed to support the development of the common principles based on the analysis of temporal variation in stakeholder needs. Between synthesis workshops 2 and 3, the core research team worked individually to create first drafts of their suggested set of principles, based on these sensitising questions.

Workshop 3

Ahead of this workshop, attendees were provided with the draft common principles created by core research team members. These were discussed, convergence and divergence explored, and a final set of 10 principles agreed to go forward into stage 3 co-design for further exploration and ratification. The working narrative programme theory was discussed and revised. Following the final workshop, the two final drafts of the common principles and working programme theory were agreed among the workshop members.

Developing the programme theory

Following the work of Davidoff and colleagues, who explicated the role of theory in improvement work in health care,[52] we sought to develop a programme theory to both guide the co-design of the processes in stage 3 and guide the foci of the ethnography in stage 4. In developing the theory, we were particularly interested in delineating the *who*, *what*, *when and how* of the proposed guidance, based on our collective evidence. Our intent was therefore for this to be a working theory that would form the basis of ongoing discussion, reflection and iteration as the research proceeded through stages 3–5 of the programme. Further, given that we were entering into stage 3 co-design that would specify how the principles would be enacted, and in what form, we chose to use the form of a narrative account of the working programme theory, rather than a diagrammatic logic model.[52] In particular, we were concerned that development of a visual logic model might overtly prescribe the potential 'form' that the 'functions' (outlined in the draft common principles) would take, which would be antithetical to a co-design ethos.

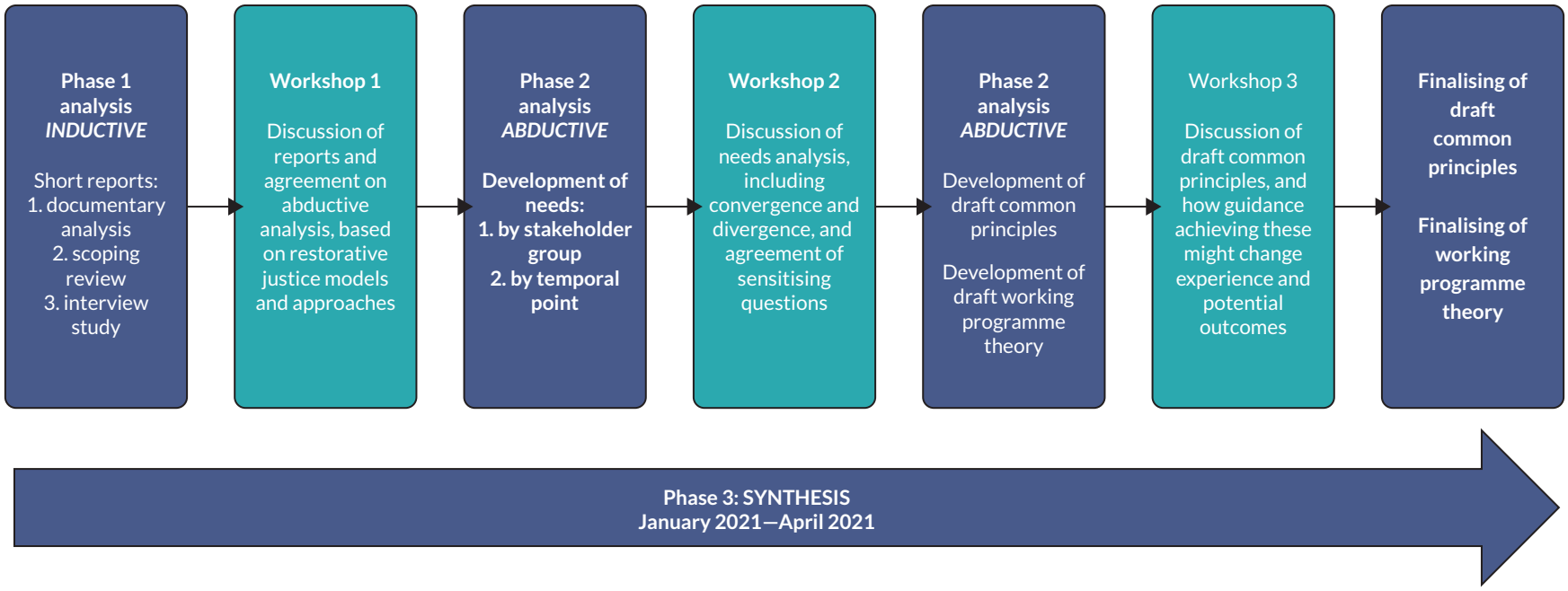

FIGURE 5 Analysis and workshop timeline.

TABLE 3 Draft common principles to help people investigating incidents to involve patients and families meaningfully

Sensitising question	Common principle	Description	Illustrative examples	Summary description for stage 3 co-design
What do sincere and meaningful apologies look like?	Make apologies meaningful	Apologies should show understanding of the potential impact of the incident on the individuals involved, not be followed up by excuses or reasons. An insincere or ill-timed apology can feel insulting. Demonstrating accountability in an apology suggests a commitment to learning which sets the tone for everything that follows.	Patient or family insulted at receiving a delayed apology, or perceived 'non-apology'. Receiving a letter or call with apology and feeling like it is just covering the organisation. Feeling that excuses are being made for what happened straight after the apology is made making it feel meaningless and impersonal.	Rather than offering excuses, demonstrate understanding and a commitment to learn what has happened and why.
Can a standardised process fit all?	Individualise your approach	Involvement in investigations should be flexible enough to accommodate different needs and adapt to changing needs over time. Clear expectation setting is important to set out a realistic approach that can appropriately respond to individual differences. At a human level, the harm of not doing so can have long-term effects beyond any harm caused by the initial incident.	Patients who cannot be involved because they are still undergoing treatment (e.g. a missed cancer diagnosis investigation but the patient is still undergoing cancer treatment). Death of daughter by suicide and parents are desperate to connect with the organisation in a positive way to share their experience about positive care and potential for improvement.	Involvement should be flexible and adapt to changing needs. Set realistic expectations.
How can we be sensitive to timing?	Be sensitive to timing	Being sensitive to timing, and the individual experience of time following an incident, can support meaningful involvement for all. Outlining the expected timeline of the process at the beginning of the investigation will prepare those involved and allow discussion of potentially sensitive dates. Insensitivity to timing can re-traumatise and be a barrier to involvement.	Family liaison officer making notes of important dates to avoid contact in opening meeting, or asking how and when patients and families would prefer to be contacted. The negative impact of the final report being received by the family on the day of their baby's funeral.	Investigations can feel like they are happening slowly, quickly, or at insensitive times. Investigators need to manage time carefully.
Are we still under your care?	Treat people with respect and compassion	Everyone involved in an incident investigation should be treated respectfully. There should be a duty of care to everyone involved in the incident and subsequent investigation, and opportunities provided for open communication and support through the investigation's process. Overlooking the relational elements of an investigation can shatter assumptions about the organisation and can lead to a complete breakdown of trust.	Patients feeling that the tone of the organisation changed immediately on discharge following an incident that they had flagged up. Communication being stopped at the point of discharge, and the subsequent incident report not being reflective of what the patient felt happened. Staff members involved in incidents as patients feel shocked about perceived organisational defensiveness and being shut out of the investigation process. Feeling ostracised by other staff members.	Harm can happen through the experience of the investigation, and how people are treated within it.
Whose needs are being served?	Strive for equity	Investigations are important for organisational learning but should also address the needs of those involved. Organisations should understand the potentially life-changing impact of an incident and the subsequent investigation process on patients, families, and staff, and be sensitive to their needs. The process can feel discriminatory or adversarial if the organisational agenda is prioritised above all others.	Staff would like the opportunity to talk to patients and families about what happened, but are advised not to by the organisation. The mother of a woman who died by suicide wanted to meet with the staff at the organisation to share learning, but the Trust legal team prevented the meeting for over a year, and when it did happen it was presided over by senior organisational staff.	Investigations allow organisations to learn, but if their agenda is prioritised over patients/staff, the process can feel discriminatory.

continued

TABLE 3 Draft common principles to help people investigating incidents to involve patients and families meaningfully (*continued*)

Sensitising question	Common principle	Description	Illustrative examples	Summary description for stage 3 co-design
What is an incident investigation?	Provide guidance and clarity	Clarity during the investigation process can be achieved through meaningful involvement and support of those involved. Those outside health services, and even some within in, do not know what an investigation entails, or why the incident is being investigated. Patients and families can feel powerless and unequipped following an incident, and the use of jargon at the initial stage sets the scene for the investigation as a nebulous concept.	Patients not knowing what an incident investigation is or that they have been through one. Patients and families confused at the amount of jargon in the report. Some give up reading it, or just accept it because they did not understand it.	Patients, families and even staff can all be confused by what an investigation actually entails.
Are you learning if you are not listening?	Listen	The intention of an investigation as a process for learning is well-meaning. Providing the opportunity for everyone involved to share their experience of the incident, where they wish to do so, better supports this 'learning' rhetoric. All sides will always have an imperfect view individually, but collective understanding builds a more comprehensive picture which can support learning. The commitment to learning is questioned where involvement is not central to the investigation process.	Patients and families are sometimes not involved in the investigation even when they try to be. They can feel actively excluded and that the organisation do not want to listen to, or learn from them, even though they have a lot of information to provide that could contribute to learning.	If there is a true commitment to learning, then everyone involved should have the opportunity to share their experience.
Is litigation a route to feeling heard?	Be collaborative and open	An investigation process that is collaborative and open with information, and provides answers, reduces the chance of using litigation as a route for being heard. The decision to litigate is a difficult one, but often feels like the only way to get these answers. Organisations must not assume that litigation is always about a payout or blame.	Patients and families feeling that they want a 'proper' investigation, so decide to pursue legal routes. Patients and families feeling that the organisation has closed ranks, so feel forced to pursue litigation. Patient and families advised to pursue litigation to cover costs of increased care after incident. Some investigators advise families to claim, especially after serious harm to baby, even though they are meant to be impartial.	People who feel involved are less likely to need to seek other routes to be heard (e.g. complaints, litigation).
Are not we all in this together?	Respect humanity	Acknowledgement that these are emotional events for everybody is important. Everyone involved will have a human response. Investigations should aim to understand and embrace different human responses, not strip away the humanity in the process.	Staff often do not find out that an investigation is happening, or only through informal channels rather than official routes. They may not find out the outcome of an investigation, leaving them feeling like an insignificant cog in a wheel. Family liaison officer role is an independent advocate for the patients and families. Where people are bereaved, they will often ask about the person who has died where appropriate, which helps families to process their emotions.	Investigations should embrace and accommodate different human responses.
Is your 'truth' also my truth?	Acknowledge subjectivity	Investigations should start with the assumption that how different people experience the same incident will differ, and each will have their own subjective 'truth'. People will feel meaningfully involved when they are able to share their 'truth', and where they do not feel one subjective 'truth' is being prioritised over others.	Final report arriving to patient and family – feels like it is talking about someone else. Partly different versions of the same truth, but also concerns of falsifying information, collusion, covering backs, etc.	Each individual will experience the same incident in different ways. No one truth should be prioritised over others.

Findings

This section presents the findings from the analyses and synthesis, in the form of the two objectives of stage 2B: (1) the developed draft common principles and (2) the narrative account of our working programme theory.

Draft common principles

Table 3 presents the final version of the draft common principles that were agreed ahead of the stage 3 co-design. The table presents the sensitising questions posed, the final version of the common principles that the question represents, a description of the principle, and illustrative examples from the reports and abductive analysis of stakeholder needs. In conjunction with the design researchers leading the stage 3 co-design activity, the description for each principle was reduced slightly, to support presentation in the materials and stakeholder events.

Working programme theory

At this stage, we were not seeking to prescribe the form of the new approach to the involvement of patients and families in serious incident investigations. So, for this draft narrative account we present the findings based on the following format: (1) the desired outcome of the new approach; (2) who needs to be involved; (3) what needs to be done; (4) when should it be done; and (5) how should it be done.

1. The desired outcome

It was clear from the synthesis of the evidence that organisational learning was not the only desired outcome of incident investigations for all stakeholders. Data generated from the interview study and scoping review demonstrated that patients and their families who experience patient safety incidents have a range of needs that arise, with only some of those being related directly to the incident itself – for example, physical health needs or financial compensation to support costs associated with ongoing physical or psychological health. For patients and their families, and in some ways healthcare staff too, there was a second purpose of an investigation, relating to their need to be restored or 'repaired', in part through the process of being involved in a collective sense-making of the incident. Additionally, our synthesised findings suggest that being listened to, heard, and having their contributions and experience both valued and dignified by the investigation process was an important part of the potential restorative impact. Importantly, our findings suggest that when patients and families are not involved in investigations in ways that they need and want to be, and where their needs are ignored or minimised, organisations can compound the initial harm. That is, the initial harm from the incident can be made worse, or in some cases eclipsed, by the harm generated from investigations that do not meet these dual needs – for learning, and for restoration and repair. Therefore, the explicit desired outcome of the approach and guidance to be co-produced in stage 3 is to reduce compounded harm.

2. Who needs to be involved?

Our evidence synthesis suggests that while the desired outcome is to reduce compounded harm for the patient and their family, through the process of the investigation, the key actor in the new approach will be the investigator. The investigator sits at the heart of the investigation and is the fulcrum for co-ordination of involvement and engagement activity. The investigator is the principal link between the organisation and the patient and their family, following the duty of candour.

3. What needs to be done?

The investigator needs to balance the needs of the organisation to learn, alongside the needs of the patient and family to get answers to their questions and feel that their experience has been given the time to be shared, listened to, and dignified. Their witness to what happened should be valued as credible information to sit alongside other sources of evidence. To undertake this important role, investigators need to be trained, have sufficient capacity, and be supported by the wider organisational system.

4. When should it be done?

This approach needs to be flexible, with the ability to be person-centred, that is, able to accommodate the different needs of individual patients and their families. The nature and success of the early contacts by the organisation, and then the investigator, are likely to be perceived by the patients and their family as setting the tone for further contact through the investigation, and so should be prioritised.

5. How should it be done?

Without prescribing the components of the new approach ahead of the stage 3 co-design activity, the common principles provide a starting point from which the materials and guidance will be developed. However, it is likely that information for the patient and family to support their navigation through the novel (to them), potentially re-traumatising, and often confusing investigation process will be an important component. Further, the approach needs to recognise the relational nature of investigations, and that they are not just 'fact-finding' processes to establish and objective 'truth'. The tensions involved in reconciling different data sources and perspectives on the same event need to be recognised and made visible for all involved. Finally, the new approach needs to prioritise and promote transparency and seek to create processes that lead to equity in outcomes.

Discussion

Our analysis and synthesis of the evidence from stages 1 and 2A have developed 10 principles foundational for meaningful involvement. In applying (and juxtaposing) the organisational accident model[26] and restorative approaches,[27] we have illuminated that organisational learning is not the only desired outcome of incident investigations. Indeed, for patients and families, and to some extent healthcare staff, there is a second purpose, relating to their need to be restored or 'repaired', and that the investigation itself is an important part of this reparation. Specifically, our analysis has described how not addressing the needs arising from the investigation can result in *compounded harm* – that is, harm arising from the processes that follow the initial incident. Our working programme theory builds on this, which proposes that guidance to support patient and family involvement needs to be designed to reduce compounded harm, that the key role is the investigator, who should be trained and supported to balance the organisational needs with those of patients and families. The new guidance needs to be flexible and person-centred, and provide navigational support, which recognises the relational nature of involvement in investigations and the importance of transparency.

Our findings both support and build on existing literature. During the programme, interest has been growing internationally in research, policy and practice, in what the foundations are for patient and family involvement in processes that follow incidents, and in particular, incident investigations. For example, Healthcare Improvement Scotland has recently published a set of eight recommendations to underpin better involvement,[53] emphasising open communication, and person-centred approaches, which are consistent with our findings. However, these recommendations were developed through one perspective only – that of patients and families. Our approach here has been to speak to all stakeholders throughout the process of examining the phenomenon, to base our principles in the realities of enacting involvement, while meeting the needs of patients and families. An example of this is the inclusion in our principles of 'acknowledge subjectivity', which recognises that investigations cannot identify 'objective truth' but try to reconcile multiple sources of information, and sometimes conflicting accounts. Such a principle is important if investigators are to avoid raising expectations of patients and families that their information will be prioritised over other sources – an expectation, which when not met, might lead to compounding their harm.

Finally, our work is the first to develop an explicit programme theory underpinning the development of guidance to support better involvement of patients and their families. Further, this programme theory has been based on the juxtaposition of two theoretical approaches, which has led to a new 'mid-range' theory,[52] describing how involving

patients and families in investigations in ways that address their multiple purposes might reduce the likelihood of compounded harm, and present an opportunity to repair through a collective process of sense-making.

Chapter summary

This chapter presented the synthesis of findings from stages 1 and 2A, the development of the common principles, and our working programme theory.

Chapter 6 Stages 3A and 3B: Co-designing new processes and guidance

Chapter outline

In this chapter, we present work related to stages 3A and 3B, where we co-designed new processes and guidance to support patient/family involvement in investigations. We describe the co-design process, management of ideas, outcomes, and challenges and to address the following research question:

RQ6: How might these common principles be reflected in local and national processes for involving patients/relatives in incident investigations?

Due to the iterative, non-linear processes contained within co-design, this chapter deliberately takes a slightly different format, reflecting the process as it unfolded.

Changes to the protocol

Due to national COVID-19 restrictions in 2021, we made changes to our protocol. First, instead of face-to-face meetings, we adopted a multichannel approach using phone, Zoom and Miro to work with co-design partners. Miro is an online, web-based project and design collaboration tool that allowed us to document the co-design process, record the stakeholder interactions and contributions, and to support input to the co-design process between the various stakeholder interactions. We provided drop-in (Zoom) training sessions in how to use Miro throughout the duration of the co-design work. The Miro board was structured around a 'landing' frame that included a welcome message, some basic user navigation controls and tips, and directions towards other 'frames' on the broad, where each frame hosted different information or activities. This approach allowed multiple people, with different experiences of co-design, to work together productively across both time and space. We also worked with experts in large digital-based events to deliver two 'bookend' stakeholder events.

Second, based on earlier experiences of co-design during the pandemic, the Lab4Living design team developed a modified series of co-design interactions that alternated online group interactions with individual activities for people to carry out in their homes or workplaces to the individual activities inviting co-design partners to reflect individually on specific design prompts, before sharing their reflections and evolving ideas with others via the online group interactions or via the Miro board.

Methods

Overview

This co-design process was, at the design level, informed by the UK Design Council Double Diamond for Innovation.[54] We drew on other frameworks such as NIHR CLAHRC SY[55] with its design focus and NIHR INVOLVE[56] with its relational focus. Combining these with our years of co-design experiences, the Lab4Living team developed its own framework (*Figure 6*) to guide its co-design practice.

Developing the co-design community

To undertake the co-design, we formed a virtual 'co-design community' with representation from patients, family members, healthcare staff, investigators, family liaison officers, policy representatives, legal staff, academics, researchers and designers. As detailed below, part of the co-design process broke into smaller workstreams to focus on different contexts. Some co-design partners attended multiple workstreams. The mental healthcare workstream included 21 co-design partners, the acute care workstream 30, and the national independent investigatory body workstream 22. The subsequent four development sessions were drop-in open invitation. Roughly 17 people attended each of these. *Figure 6* illustrates the proportion of different stakeholders involved at each step of the process.

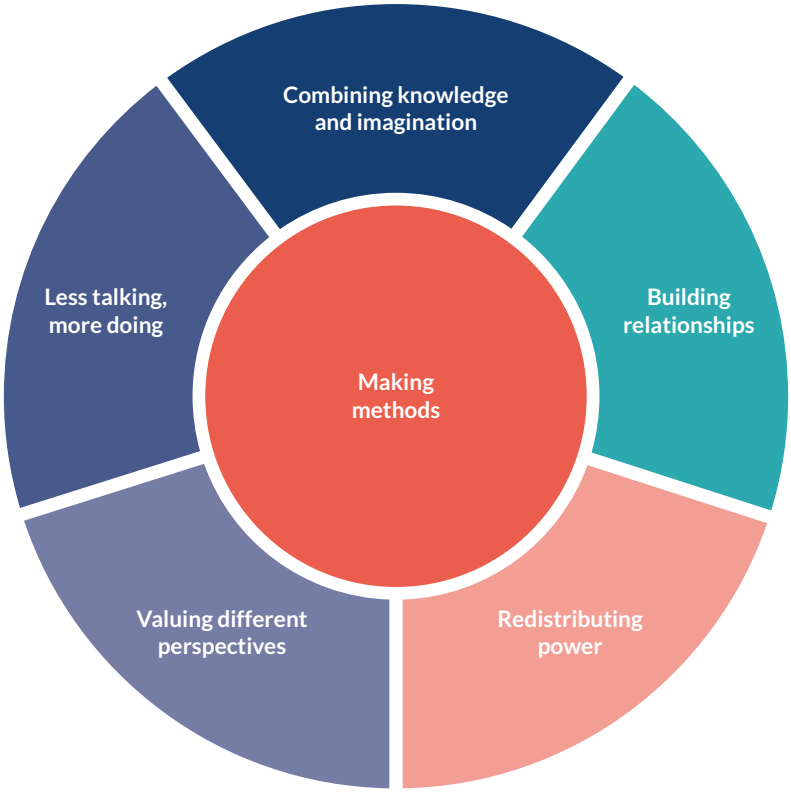

FIGURE 6 Lab4Living co-design framework.

The design team (JL, RP, Chris Redford) and research team (JOH, LR, SMcH, RSE) collaborated throughout this process ensuring that research evidence was fed into the co-design activities, and feasible, actionable outcomes that could be evaluated were derived. There was considerable close, interdisciplinary working, and some healthy tensions between these two teams.

Planning the co-design interactions and activities

Co-design activities were structured around the following process: two large stakeholder events 'bookending' a series of three co-design workshops that ran in three parallel workstreams. The three parallel workstreams reflected different contexts of incidents and investigations: (1) in acute hospitals, (2) in mental healthcare settings and (3) the national independent investigatory body. These three distinctions were decided a priori at the funding application stage, based on known differences in the incidents that occurred in these three settings, the resources available to investigate them, and the degree of influence we had to effect change in these settings (i.e. feasibility to implement findings).

Draft outlines for co-design sessions were prepared by the design team following discussion with the research team. These outlines were iteratively refined with the research team and the PFAG. Kaleidoscope Health and Care (digital events facilitators) were involved in iterative planning for the stakeholder events beginning and closing stage 3.

Co-design should include all perspectives and the co-design activities and outcomes should be based on collective experiences *and* on evidence obtained from research. To do this, we wanted to (1) build and sustain relationships and trust between all co-design partners, the research team and the design team and (2) provide the evidence from our research phase in an accessible format that enabled people to make sense of it in relation to their own experiences, and give them an insight into others experiences. In the planning and preparation for the co-design interactions and activities, we were mindful of the emotional investment for all, the probability of oppositional viewpoints and the potential for wide differences in expectations about what could or should change.

Co-design interactions and activities

Figure 7 illustrates the initial co-design process, activities and proportions of different stakeholders in each. We describe each step in more detail below.

Step 1: 'Handshake' and Rebuilding Investigations Kit

Step 1 included two posted interactions: The 'Handshake' and 'The Rebuilding Investigations Kit'. Both kits were designed to fit into a letterbox sized, A5 or A4 boxes, printed in colour and professionally bound. The obvious care and unique content implied a significant time investment, demonstrating we valued the process and our partners.

'*The Handshake*' introduced and prepared people for the whole process. This included a Handshake Booklet (*Appendix 3*), creative origami activity, and tea bag. In calling this '*The Handshake*' we considered the experience of meeting in-person for the first time: greeting, identifying and welcoming. We attempted to re-create elements of this via deliberate design decisions in the content and form of this pack. The tone of the booklet was simple, accessible and friendly. It included team photos, putting faces to names and humanising the team (identifying). It presented a process and informed what would be provided and expected. The choice of the origami activity was deliberate, as we wanted people to use their hands to make something. Such activities help to move ideas beyond words into tangible representations to think about them differently. This origami helped familiarise people to what would be coming. The tea bag along with the postal and boxed nature of this interaction was intended to mimic gift experiences. In relation to the Lab4Living co-design framework, this pack started the process of building relationships, sharing power and getting people doing things.

The *'Rebuilding Investigations Kit'* (see *Appendix 4*) was posted approximately a week later, developed by the design team with the research team. It was an interactive presentation of the synthesised evidence. It walked each co-design partner through a narrative of a patient safety incident and subsequent investigation. The activity required the co-design partner to lay out the incident narrative in 'channels' corresponding to each character in the incident (patient, patients' adult son, nurse, ward manager, institution). Once laid out this way, differences in how the event was experienced could be seen in relation to each other, building appreciation that different perspectives can be true. Subsequently in this activity, co-design partners adopted the role of investigator and made choices that modified the narrative of the investigation, changing evidence they gained access to and ultimately their understanding of the incident. This highlighted how some perspectives can become 'silenced', distorting the narrative, and resulting in a form of narrative injustice.

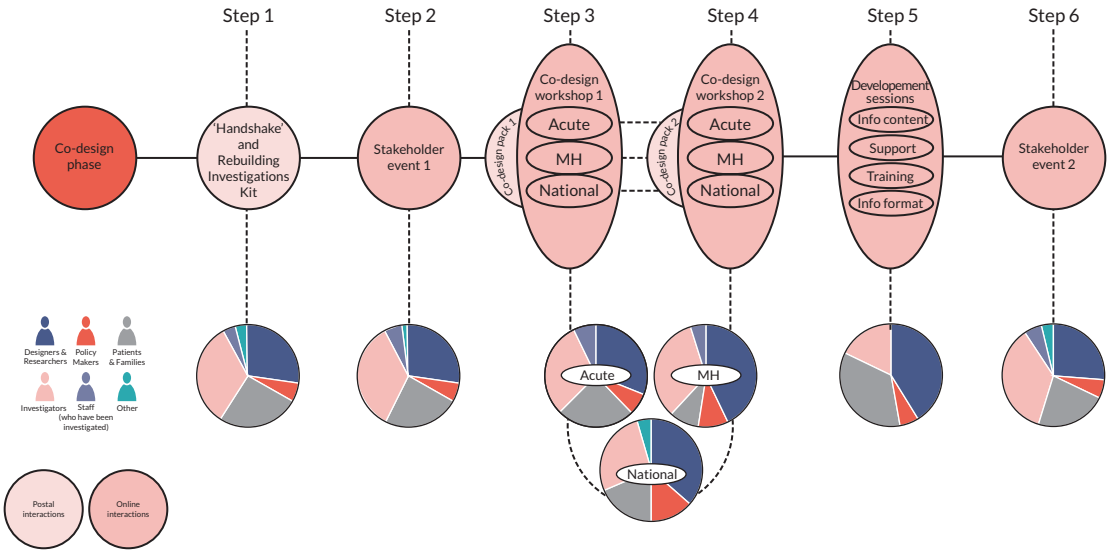

FIGURE 7 Co-design process and activities. MH, mental health.

Co-design partners were intended to do this as a reflective, individual activity, taking roughly 1 hour. Feedback indicated that some families completed the activity together and some co-design partners repeated it, making different investigator choices and reaching different conclusions.

In relation to the Lab4Living co-design framework, this activity communicated knowledge (research evidence) in an interactive, sense-making way and built appreciation for different perspectives our co-design partners would bring. The kit continued the theme of less talking and more doing by encouraging co-design partners to externalise thoughts, engaging with the kit's physical components.

Feedback from co-design partners stated this activity 'opened them up' in 'non-threatening ways', perhaps best summed by a quote from a family representative who said:

> *It was the first time [in 15 years] I had felt sympathy for staff.*
>
> *Family representative*

Step 2: Stakeholder event 1

The community met for the first online stakeholder event in April 2021, to share and iterate the 10 'common principles', discuss the research findings within the Rebuilding Investigation Kit, and define a common goal. This event (along with preceding activities in step 1) brought people together, built relationships and created conditions to take their own place within the co-design team.

Kaleidoscope Health facilitated both stakeholder events (steps 2 and 6), enabling the research and design team members to sit 'alongside' co-design partners, all of us responding to activities and prompts in the same way. This aimed to shift power among the co-designers and researchers. In relation to the Lab4Living co-design framework, this continued the process of building relationships, introducing, and examining the surrounding knowledge (research evidence) and sharing of power (by sharing knowledge).

Steps 3, 4 and 5: Co-design workshops 1 and 2, and development sessions

Six virtual workshops ran May to August 2021 (2, mental health care; 2, acute care; 2, national independent investigatory body) focusing on needs and ideas generation. In these context-specific workstreams, we considered what would work best in each separate context. Each workshop was proceeded by a co-design kit posted to participants before workshop 1 and 2. Each kit contained individual reflective exercises supporting co-design partners to gather their thoughts in preparation for the next online workshop.

The workshops were followed by four development sessions iteratively refining shortlisted ideas. We brought the three workstreams together for these to compare ideas. We looked at similarities and differences to understand whether they had a common base or were fundamentally different due to context. The co-design group recognised that there were similarities and important variations between mental health care and acute contexts. For example, investigations in mental health contexts often related to suicide in the community. It also seemed that mental health investigations frequently involved a greater number and diversity of stakeholders such as social care providers, primary care providers, police, education providers, employers, coroners, etc. However, it was decided to deliver the same solution in both settings, and evaluate these distinctions as we did not, at that stage, understand these differences sufficiently for a design response. The maternity investigations led by the national independent investigatory body had very different resources, a more consistent approach to investigations, dedicated investigators, and family engagement staff, and had previously conducted work-developing approaches to engage patients and families in investigations. These important distinctions lead to solution variations in the national workstream.

Initial identification of solution concepts

These broad areas of solution concepts arose from the workshops:

1. Support Café
2. Information:
    a. Physical/printed
    b. Digital/website
    c. Online chat/advice

3. Investigation training resources (for investigators and organisations about involving patients and families in investigation processes)
4. Improvement centre (collating and implementing recommendations)
5. Team approach to investigations (support for investigators)
6. Patient-led investigations

These labels encompass a complex set of concepts. For example, Support Café was not a physical café, but rather a 'one-stop-shop' provision of a menu of support (practical, physical, emotional, cognitive, legal, 'technical') for patients and families experiencing an incident and subsequent investigation, and those who had historically experienced such events. 'Café' represented informality and even conviviality about the support as opposed to formal support provision (e.g. professional counselling, guidance, etc.). This did not exclude professional support but emphasised peer-to-peer and lived-experience support.

Ideas around Information were separated into different media or channels to accommodate differences in design, production, implementation, and on-going maintenance and associated implications, costs and resources.

Concepts taken forward and developed

From the outset of the co-design, we clarified that this project was a starting point. Not everything could or should be changed in one go. Within stakeholder event 2, we asked participants to use the following criteria to assess and select ideas to take forward:

1. Perceived benefit of achieving the programme aims;
2. Chronology – high-priority ideas might require other changes first;
3. Scope – ideas not in the scope of the project brief were deferred for later projects;
4. Feasibility within the current system.

Of the broad areas above, Information (all three categories) and Investigation training resources were taken forward and developed further. Online chat/advice information and Support Café were partially developed for reasons we explain below.

There was a broad consensus from all co-design partners that unless all stakeholders (investigators, staff being investigated, patients/families and organisations) were better informed, all other areas of development would be compromised. This rationale prioritised both information and training.

Informal peer-to-peer support was a priority area for co-design partners, embodied within the Support Café and Online chat/advice information concepts. This second category also encompassed independent professional advice. However, two considerations made us pause this area of development. First, there are existing support and advice facilities. Second, we recognised that the support and advice needs for patients and families may be partially resolved by development of the new information resources. Yet, we could not anticipate which needs would be resolved.

With these two points in mind, the co-design workshops mapped the support and advice needs more fully but focused on feeding as much of these concepts into the development of the physical and digital information resources, and into the new investigation process. The co-design process, documented on Miro, equipped co-design partners to understand these parameters and make an informed choice on the filtering of ideas at this stage.

Step 6: Stakeholder event 2

In September 2021, stakeholder event 2, the outputs (still in unfinalised design form) were presented to the co-design community for critical review and comments.

First draft of guidance development

A period of intensive content design was then undertaken. First, the core research team compiled content for the new materials, bringing together the co-designed ideas with the evidence, policy requirements and technical specifications such as the correct terminology. This content was designed by the design team (RP, CR) into prototypes and shared for discussion with the research team, and other key stakeholders, in particular members of PFAG and SAG. This became an iterative cycle of content and design development, gathering feedback, and making changes. Due to the existing support materials and approaches already in place for HSIB maternity investigations, we developed content specific for this setting. One researcher (SMcH) undertook a mapping session with HSIB to understand their current approach relative to our proposed approach. The gap identified was that families were not 'active participants' in HSIB's current approach. To meet this gap, we developed a Family Reflective Booklet, and investigator training to support using this within their current approach.

All draft materials were ratified with the steering group, and PFAG before approval for stage 4 testing. These supported a new process for guiding the involvement of patients and families through patient safety incident investigations. For acute and mental healthcare settings, this comprised (1) an Investigator Guidance Booklet, (2) investigator training material and content, (3) an Investigation Record (for investigators to use for each investigation) and (4) two Patient Safety Incident Investigation Information guides: one for patients or family members and another for staff. For the national independent maternity investigations, this comprised a new Investigation Reflection booklet and investigator briefing. All materials developed at this stage can be found in the 'Background Evidence' tab on the Learn Together Website: https://learn-together.org.uk/.

Discussion

This chapter presented the first part of a two-stage co-design process that was completed following the stage 4 evaluation (see *Chapter 7*). Many of our stakeholders, members of the research team and design team, family members and staff shared reflections indicating they found the process powerful, enlightening, emotional, transformational and hopeful. It was a sensitive topic, related to issues of deep, historical harm and trauma, sometimes compounded as repeated poor investigations left staff unsupported, investigators with insufficient resources, and families with senses of injustice, being duped, dismissed, and even lied to by the very system (NHS) entrusted with not just the care for the health and well-being of themselves and their family but with their lives. Even within the bounds of this programme, it had been a long journey for everyone, for some across decades, often with a sense of activism and 'struggle' with a political dimension.

All this took place in the context of social distancing. Our previous in-person co-design experiences suddenly seemed challenging to apply. With such a personal topic, it felt odd working in impersonal ways. The art of co-design is about building trust, empathy and respect between co-design partners even when they have very different, even opposing views, and creating an environment not where people are empowered by us, but where people realise their own power, take their own seat and speak their own truth. It is also about keeping an eye on the goal of achieving some tangible change – of making a difference.

There was much about this process that was emergent and responsive. Yet, through a combination of factors including the (com)passion, tolerance and commitment of the whole co-design team, and permission and freedom within the research team to try new approaches to delivering co-design, we progressed positively through a rewarding process. We now share key reflections we believe contributed to this success.

Co-designing during COVID-19

Initially, the pandemic changed everything we knew about co-design. We were honest with co-design partners that this was new territory for us, that we were learning, and likely to make mistakes. In some ways this assisted; it was a vulnerability we shared openly and perhaps helped to set a tone of honesty for all partners.

We were aware of the value of digital design tools for remote co-design, but also the potential for digital exclusion. From a design perspective, it is also harder to 'create' something together online. From the outset we wanted to maintain an analogue channel to reduce possible exclusion and to sustain a link with physical materiality – with 'stuff'. Alongside the postal channel, we maintained Miro as a continuously open digital channel. It included familiarisation and skill-building activities, accompanied by optional drop-in training sessions. It offered a space for people to tell us about themselves and why they had come to the project.

Earlier co-design experiments during the pandemic had shown it was harder to progress as quickly in online interactions. To 'gain more time', we used postal interactions before online events as a way of doing some of the work beforehand. This was particularly important for the initial postal activity, as this would set the expectations for the rest of the process. This is where the Rebuilding Investigations Kit stemmed from. Unintentionally, this proved to be a pivotal 'interaction' in our co-design process. Co-design partners who had completed the activity, began using social media to share images, thoughts and reflections. This led to early relationship building and dialogue between partners sooner than we anticipated.

Relationships in the context of co-design

Within co-design and co-production literature, the importance of developing and sustaining good relationships is deemed foundational, but often framed through notions of trust and respect, with relationships left as an implicit but unreferenced concept.[57] Despite these continuing references, there are few academic models or frameworks exploring *how* to build and sustain good relationships within co-produced research. The exception to this is the recently published Metz *et al.*[57] article proposing a theoretical model for building trusting relationships.

Understandably, relationships seemed particularly important in this programme due to the experiences and trauma many co-design partners had faced. Relationships between the research team and some co-design partners had developed over the course of the programme or earlier in developing the proposal. Some partners already knew each other, or of each other. Yet, bringing all stakeholders together was an entirely new endeavour. The components of step 1 of the co-design process helped to ease all partners into a 'design' frame of mind, emphasising optimism, creativity and empathy for other perspectives. The uniqueness of the Rebuilding Investigations kit created a common, even 'shared' experience despite everyone doing it alone. The first stakeholder event offered an opportunity to put faces to names and continue the relationship building.

Relationship building was a continual process, across all channels and interactions. The smallest of gestures and phrases accumulated to reinforce that all partners were equal and valued. In other co-design work, we frequently see researchers justifying their decisions to separate patient groups from healthcare professionals, sometimes justified ethically, or on the basis that power differentials might mean people cannot speak freely. We have demonstrated that groups and individuals with very different perspectives and power differences can be brought together in a process that levels those hierarchies and provides people the platform to speak their truth to each other.

The use of narratives in co-design

Narratives and storytelling have long been used within design as mechanisms for exploring experience. Shaw and Nickpour[58] break down the historical use of narratives in design and propose a framework for 'Design as an agent of narratives'. As our programme predated this, we used a narrative artefact (the Rebuilding Investigations Kit) in several different ways. We suggest that it might broaden the scope or value of narratives in co-design work and require a corresponding update to their proposed framework – although in what ways remains unclear at this stage.

In the first instance, narrative served to introduced research evidence into the co-design group less didactically and more interactively. The Rebuilding Investigations Kit purposefully included a degree of narrative uncertainty. The reader had to make choices in the story – it was an interactive narrative. In this position, they were forced to use narrative coherence where they apply a narrative interpretation that best fit the available facts. Secondly, our kit explored the narrative from the perspectives of different actors, sometimes referred to as multi-perspectivity or poly-perspectivity. This opened a wider worldview for the reader, aiming to build understanding, even empathy for different perspectives. It took on the form of sociological storytelling as opposed to psychological storytelling, where it is not about one character and their journey to achieve something. Rather it is about a system with various actors. From a design

perspective, the power of this narrative approach is that it can be used to speculate better outcomes, and the design process becomes framed as a form of narrative agency; co-design partners change the narrative to achieve these better outcomes.

Chapter summary

In this chapter, we described our development of a new process for involving patients and families in patient safety incident investigations. Importantly, we see design as an ongoing phenomenon – *these materials are our current iteration*. We applied a co-design approach to development of the guidance and processes for this highly sensitive subject, conducted in the context of COVID-19. We learnt several valuable lessons about doing co-design.

Chapter 7 Implementing and evaluating the co-designed processes

Chapter outline

This chapter presents the methods and findings from stage 4 of the study which involved implementing and evaluating the co-designed processes. This research presented in this chapter addresses the following research questions:

RQ7: Are co-designed processes for involving patients and families in incident investigations feasible and acceptable to patients, families, healthcare staff and investigators?

RQ8: How do co-designed processes influence incident investigations in terms of depth of learning, recommendations, action plans, and decisions to litigate?

Methods

Overview

This study received favourable research ethical approval in October 2021 (REC ref: 21/WA/0287) and draws upon data collected from five sites during a 15-month ethnographic study, selected to reflect variability in size, speciality and patient socioeconomic profile. Sites included four NHS Trusts – two mental health care (SITEMHA, SITEMHB) and two acute (SITEACA, SITEACB) – and an independent investigatory body (SITEIND). Prior to fieldwork, we trained 49 investigators to use the new co-designed processes across sites. We then worked with 16 of those investigators to appraise them over the course of 15 months, running from January 2022 to March 2023. During this period, we followed 29 investigations longitudinally in which the co-designed processes were adopted: 6 at SITEIND, 12 in a mental healthcare setting (10 at SITEMHA, 2 at SITEMHB) and 11 in an acute setting (7 at SITEACA, 4 at SITEACB). In relation to these investigations, we conducted 127 remote qualitative interviews at touchpoints of the investigation with key stakeholders (94 with investigators, 20 with patients/families and 13 with healthcare staff). Ninety-two of these were recorded semistructured interviews which were supported by a topic guide. Separate topic guides were developed for patients, families, staff and investigators, but all questions centred on experiences of the investigation, experiences of involvement and experiences of the guidance. Interviews were held via telephone, Zoom or Teams. The average interview length was 43 minutes. Thirty-five of these were ethnographic-style exploratory discussions held via telephone, Zoom or Teams, as well as significant and detailed e-mail discussions which were unstructured, based on researcher and participant interests relevant to the ongoing investigations and research questions. Interview format was selected based on participant preference and in accordance with local COVID-19 guidance. Participants were also given the option to keep a reflective diary where interviews were not feasible; however, this was not necessary in practice. We also remotely observed 44.5 hours of activity using an ethnographic approach. Observed activity included investigator training sessions, planning meetings regarding the use of the new co-designed processes, and site meetings discussing local systems and processes surrounding ongoing investigations. Workshops were also held during fieldwork which involved discussing and deepening our understanding of emerging issues, as well as developing solutions to overcome them.

Investigator training and setup activities

Each site was asked to identify an initial cohort of investigators to be trained locally, as well as responsively training investigators where necessary. In total, 49 investigators were trained to use the new co-designed processes (17 at SITEIND, 10 at SITEMHA, 6 at SITEMHB, 9 at SITEACA, 7 at SITEACB). Training involved a 2-hour virtual session to familiarise investigators with the new co-designed processes, the underpinning evidence, and to provide opportunity to discuss and compare how they might work within local organisational contexts and develop a community of practice. Training at each of the four NHS Trusts ran similarly; however, content was tailored at SITEIND to suit a national context, and took account of the ongoing work to involve patients/relatives in national maternity investigations. NHS

England's Head of Patient Safety Policy and Strategy Training provided a letter of endorsement to Trusts and relevant governing bodies, such as local Integrated Care Boards (ICB) or the CQC. Members of the research team also presented information about the study and training to the senior leadership teams at SITEACA and SITEMHA, and the approach was presented on behalf of the research team by the site key contact to SITEIND leadership. Sites were provided with a welcome pack which included printed copies of the guidance, branded post-it notes and pens, a site-specific flow chart of the research process, and copies of recruitment material.

Overcoming emergent issues with sites

Post-training, the research team circulated a weekly e-mail to key contacts (e.g. trained investigators and managers) at each site to update on recruitment progress and offer to meet with sites on an as-an-when basis to overcome any emergent, site-specific issues. A formal check-in meeting was also arranged with trained investigators and management from each site mid-way through fieldwork. Additional follow-up meetings were held with two SITEMHA and SITEIND sites who were struggling to recruit due to issues including staff turnover, limited eligible investigations, eligible investigations assigned to untrained investigators, and investigations being particularly sensitive in nature. During these meetings, solutions to overcome these struggles were discussed, implemented and evaluated, including working more closely with trained investigators, training additional investigators and seeking to follow investigations with lower levels of harm. The research team also delivered a total of seven workshops during fieldwork focused on emergent issues. First, all trained investigators were invited to a workshop held in the early stages of fieldwork, focused on discussing the opportunities and challenges associated with sharing a draft copy of the report with patients and families. Investigators had varied experience of sharing draft reports across settings, and between investigators, and so a community of practice felt necessary. Second, all trained investigators were invited to one of two workshops held mid-way through field work which focused on recruitment, as well as discussing and deepening understanding of three emergent issues: sharing the draft report, adopting a more joined up approach, and understanding the additional complexities in a mental health setting. This workshop was delivered twice to maximise the possibility of investigators being able to attend.

Third, four separate workshops were held towards the end of fieldwork and prior to formal data analysis to deepen understanding of specific issues, as well as develop solutions to overcome them. The workshop topics were generated through ongoing conversations between the research team and the design team in the closing 6 months of the ethnography. The topics chosen for the workshops were those that we needed further discussion on, in terms of how the iteration and design of the final developed Learn Together guidance and materials might address them. These were perhaps best described as the 'wicked' problems that had arisen through the ethnography. To these workshops we invited a range of key stakeholders, most from the previous co-design community, but also groups of users from the ethnographic study, and others (e.g. academics and policy-makers) who we felt could illuminate and inform the discussion from a variety of perspectives. At these events, we first presented the learning from the ethnography and invited co-design partners to propose changes to the process and resources. Workshops focused on (1) revising the co-designed guidance and processes, (2) sharing the draft report, (3) involving patients and families in a mental health setting, and (4) involving families in independent maternity investigations. Relevant representation from all stakeholder groups was invited to three of these workshops, as well as members of the wider co-design community. The fourth workshop was delivered as part of the independent investigatory body annual conference and involved preparation meetings with the family engagement team beforehand.

Focused ethnographic approach

A focused ethnographic approach[59] was used to address our research questions based on our judgement of the nature of the problem being studied, and its circumstances. We believed it to be the most appropriate way to develop our programme theory and understand and explore the phenomena of interest in a context-dependent way. As noted by Flyvberg,[60] case study-based research can be useful for developing theory, and later testable hypotheses, but also, with strategic case selection, can allow for testing of developed theory. We followed a methodological approach previously used by two co-applicants (JW, CM) for ethnography of patient safety investigations.[61,62] Ethnographic research is usually concerned with developing a rich descriptive account of social activities, including the meanings, beliefs and customs of social groups, and explaining these in the context of broader social, cultural and political institutions.[63] There are many styles of ethnographic research (realist, critical, institutional),[64] and this research adopts a focused, pragmatic ethnographic approach concerned with investigating how new interventions to support and facilitate

patient and family involvement in incident investigations are enacted and experienced in different sociocultural and organisational contexts.

Fieldwork involved 127 interviews and 44.5 hours of non-participant observations of investigation processes, to understand how patients and families were engaged and involved in investigations, including how procedures were explained, the opportunities for communication and shared decision-making, the influence of status and power differences, and the unwritten rules that seem to shape social order. Observed activity included investigator training sessions, planning meetings regarding the use of the new co-designed processes, and site meetings discussing local systems and processes surrounding ongoing investigations. All observations were recorded in either manual or digital field notes journals compiled by each researcher.

Sampling

The sampling of each investigation and relevant stakeholders related to each investigation (patients, relatives and staff) was determined together with investigators, based on what they felt was relevant and appropriate.

Investigation sampling

A key contact at each site notified the research team once a new investigation with the potential for patient or family involvement and no ongoing police involvement was due to start. Together, the key contact and researcher then sensitively collaborated to determine if the investigation was appropriate to follow. This was not left to random sampling. Rather, it was an iterative process of leaning on the investigator's expertise, considering the practicalities and sensitivities of the case, and using 'information-orientated selection'.[60] This helped to gain variation in our sample based on pre-defined criteria developed in collaboration with the steering group, which looked to identify investigations that served as (1) extreme/deviant cases, (2) maximum variation cases and (3) critical cases based on the following variables: healthcare setting, healthcare service, assigned investigator and level of harm.[60] This type of sampling is designed to 'maximize the utility of information from small samples and single cases … [with] cases selected on the basis of expectations about their information content'.[60] Where an investigation was deemed appropriate to follow, the assigned investigator was consented and trained where necessary. The investigator then provided the stakeholders they deemed relevant and appropriate to contact (patients, relatives and/or healthcare staff) with the co-designed guidance, and an initial 'briefing interview' was arranged with the investigator. During this interview, the researcher discussed the investigation and agreed how to proceed in relation to chain referential sampling key stakeholders, including patients, relatives and healthcare staff relevant to each investigation. Where possible and appropriate, the investigator invited each relevant stakeholder who had been provided with the guidance to take part in the research. This also included non-clinical staff who were indirectly involved in the investigation, to share their perception of the acceptability and feasibility of the new resources within local context.

From the point that an investigation was agreed to be appropriate to 'follow', a researcher gathered data from the investigator's perspective via semistructured and unstructured interviews. Any consenting stakeholders relevant to each investigation (patients, relatives and/or healthcare staff) were also interviewed about their experience of the investigation process and the developed co-designed processes. In total, 74 investigations were raised with us to discuss. Of those, 29 investigations were followed (see detailed recruitment summary in *Table 4*). The reasons for not following investigations included: the investigation being assigned to an untrained investigator who did not consent to being trained, the investigation having limited potential for patient/family involvement or ongoing police involvement, and delays meaning the investigation fell outside of the data-collection period. In relation to those 29 investigations followed, we conducted 127 interviews. For 20 of those investigations, we interviewed the investigator only. For eight of those investigations, we interviewed the investigator and the patient/family. For one investigation, we interviewed the investigator, patient/family and clinical healthcare staff. The 11 interviews with non-clinical staff were not specific to a single investigation, but rather related to all investigations within the organisational context of that site.

Investigators

Investigators were identified via the site key contact as part of an original cohort, or on an as-and-when basis if untrained investigators were later assigned an eligible investigation. Consent to participate was obtained from all investigators ahead of their training and before any of their investigations were followed. Forty-nine investigators were trained. Thirty-three investigators took part in the training only, and 16 investigators were trained and went on to use

TABLE 4 Recruitment summary

	SITEACA	SITEACB	SITEMHA	SITEMHB	SITEIND	Total
No. of trained investigators	7	6	3	7	13	36
No. of investigations flagged	22	10	8	18	16	74
No. of investigations followed	7	4	2	10	6	29
No. of investigators worked with	3	1	2	3	7	16
Total no. of people consenting to take part	14	11	5	11	20	61
No. of patients/families	3	2	0	2	5	12
No. of staff (non-clinical, clinical)	4 (2, 2)	3 (3, 0)	2 (2, 0)	2 (2, 0)	2 (2, 0)	13 (11, 2)
No. of interviews	38	23	7	19	40	127

the co-designed processes in at least one investigation they led on, and that we followed. The latter were interviewed longitudinally at touchpoints of their investigation(s) and provided the guidance to relevant healthcare staff, patients and/or relatives. A total of 94 interviews were conducted with investigators.

Patients and relatives

Following an initial interview with the investigator assigned to the eligible investigation, one field researcher and the designated investigator sensitively and collaboratively chose the most appropriate time to contact the patient and/or relative(s) to take part in the study. Given the multiple practical and emotional challenges that might be experienced by those affected by, and involved in, patient safety incidents, we did not require consent to proceed to follow the investigation. Rather, we employed an 'open-door' consent approach to involvement in the research which allowed for patients and/or relatives joining the study at a time that felt right for them throughout the course of the investigation, changing their mind about taking part or not taking part at all. As well as providing an information flyer and a detailed information sheet (in easy read where necessary), the investigator and/or researcher explained the study in detail and answered any questions. Of the 29 investigations followed, only 9 investigations managed to recruit patient and/or relatives given the recognised emotional sensitivities associated with experiencing patient safety events. Of these 9 investigations, we recruited 12 representatives (2 patients, 10 relatives). Relatives were parents, children, grandchildren, siblings, spouses or cousins. The 12 patients/family members were interviewed a total of 20 times. The method focused on qualitative depth of understanding, rather than numerical breadth or statistical representativeness. Given the explicit focus on the assessment of feasibility, exploring cases of non-engagement was as important as cases of successful engagement, and so the data were included within the analysis. The research team also followed a distress protocol due to the sensitive nature of the research topic, and the proximity of the interview to the serious incident being investigated.[65] This involved researchers offering to contact participants within a 48-hour window to check-in, and drawing from a continuously developed pool of resources, to signpost patients and relatives to appropriate sources of support where necessary.

Healthcare staff

Clinical healthcare staff involved in the patient safety incidents being investigated were recruited in the same way as patients and families described above. Non-clinical healthcare staff who were stakeholders in the systems and processes surrounding investigations were approached by the site key contact and/or researchers identified via chain referential sampling. Twelve clinical staff were provided with the guidance and invited to take part in the research and two of them consented to taking part in a total of two interviews. Eleven non-clinical staff were approached and 9 of them consented to taking part in a total of 11 interviews.

Analysis

Interview data, field notes and reflexive diary notes were transcribed by researchers, in-house transcribers and outsourced to TypingWorks. Data were then qualitatively analysed using an inductive approach, guided by the research questions, yet remaining open to relevant emerging issues. Two field researchers (LR, DH) led the analysis, with

weekly support from wider research group and monthly support from the expert qualitative co-applicants (LS, JW). These 'data sessions' ran prior, during and after the data-collection period, to discuss initial impressions, and deepen understandings. A half-day workshop with the whole team was also held to elucidate analytical ideas and ensure they were grounded in the data.

An adapted version of pen portrait methodology[66] was used to collate complementary data sources for the purpose of completeness, and to support analysis. Pen portraits are an analytic technique which aims to integrate multiple sources, and often large volumes, of qualitative data into a concentrated account, focusing on a given topic.[66] Data were first organised according to investigation, nested within wider contextual data relating to each study site which was collated within a working document. Notes of initial impressions were made, and researchers explored the similarities and differences within and between sites via open and thematic coding. This helped to develop descriptive accounts of the common and distinct processes of investigation, the expectations and experiences of stakeholders in these processes, and the types of learning and recommendation developed. Interesting foci, both specific to the research questions and those capturing novel ideas, were integrated to form the basis of a pen portrait, one per investigation. Each pen portrait was further developed via an iterative process of revisiting the data and research questions and populating the pen portrait with significant data excerpts until a consensus was reached. Using the agreed template, a pen portrait was then fully developed for each followed investigation, synthesising data relating to that investigation from each perspective sought. The representation of data sources was not necessarily equal, and all sources were not necessarily represented, but included dependent on data quality and significance to the foci identified.

We conducted a multicase analysis adopting a reflexive thematic analysis approach,[67] recognising the importance of considering linked typical and atypical cases and drawing higher-level conclusions to understand complex phenomena.[68] We used the case reports as the unit of analysis, as well as the wider contextual information case reports for each site and revisited the raw data where necessary. This helped to gain a holistic view and achieve immersion within the data. Descriptive comments were made based on commonalities and differences between cases, and initial impressions of higher-level themes and significant extracts were highlighted. Broad candidate themes were identified on a semantic level using an inductive, bottom–up approach based on significant and common features, issues and concepts and refined via the data sessions. According to broad candidate themes, significant extracts helped to further find patterns of meaning as well as define and evidence each theme, until a consensus was reached. At each stage of analysis, decisions were discussed between researchers and original sources were revisited to ensure they were grounded in the data. Conflicting accounts were taken note of, and where necessary, captured in the analysis. Analysis paid particular attention to the research questions while keeping unpredicted, but relevant themes.

Findings, Part 1: Organisational contextual summaries

The organisational contextual summaries related to each of the five sites are summarised in *Table 5*. Sites were selected to reflect variability in of size, speciality and patient socioeconomic profile, as well as pragmatic decisions based on locality to the research team. The contextual summaries reflect the organisational contexts during and at the end of fieldwork, but do not reflect any changes that have been made since. The summaries were produced in collaboration with key contacts at each of the sites as part of a sense-making exercise.

Findings, Part 2: The acceptability and feasibility of the co-designed processes

In this section, we explore research question 7 – 'Are co-designed processes for involving patients and families in incident investigations feasible and acceptable to patients, families, healthcare staff and investigators?'. We do this by highlighting the commonalities and differences within and between sites, based on followed investigations relating to suicide (9), therapeutic cooling at birth (4), retained surgical item (3), unexpected death (2), attempted suicide (1), neonatal death (1), neonatal cardiac arrest (1), stillbirth (1), displaced pacemaker wire (1), death following fall (1), wrong patient procedure (1), missed maternal tear (1), missed diagnosis (1), infection at cannula site (1) and self-harm (1).

TABLE 5 Organisational contextual summaries

	SITEACA	SITEACB	SITEMHA	SITEMHB	SITEIND
Organisation summary					
Healthcare setting	Acute	Acute	Mental health	Mental health	Maternity – National
No. of patients	Approximately 500,000	Approximately 800,000	Approximately 580,000	Approximately 980,000	Approximately 700 families per year (based on 2021–2 figures)
No. of sites	6	8	2 (largely community care)	50	307 (all maternity units in England)
Socioeconomic profile	One of the most deprived areas of England	One of the most affluent areas of England	One of the most deprived areas of England	A mixture of affluent and deprived areas	National reach across all of England
Investigation process					
How is an incident declared?	The clinical services unit (CSU) team and Quality and Patient Safety Facilitators review all cases deemed to have resulted in moderate harm submitted to Datix, with clinical input sought for any that are considered potentially serious. The cases are then presented at the safety events group, where it is decided whether the incident meets the criteria for an incident investigation.	Clinical governance facilitators review all cases submitted to Datix and consider which need further investigation. Those that do are discussed the quality and safety meeting, where it is decided whether the incident meets the criteria for an incident investigation.	The patient safety team review cases submitted to Datix or notified by the coroner where it is decided whether the incident meets the criteria for an incident investigation.	The patient safety team review cases submitted to Datix and consider which ones need further investigation. Those involving death are reviewed by a patient safety manger and discussed at the learning from incidents and mortality meeting. Here the team decide if the incident meets the criteria for an incident investigation.	Maternity incidents that meet criteria are referred by each Trust in England. The NHS Trust remains responsible for the local 72-hour review. In order for the investigation to proceed, the Trust must gain consent from the family to pass on their contact details.
How is the investigator assigned?	Depending on the circumstances, either a clinician within the same CSU where the incident took place or a member of the patient safety team is assigned to carry out the investigation.	The governance facilitator contacts one of the six care groups in which the incident took place and asks a clinical member of staff to investigate. Where that is not possible, the investigation is assigned to a regular bank staff investigator.	Clinical teams involved in the incident are asked to do an initial review as well as the investigation being assigned to a member of the patient safety team to carry out the investigation.	The investigation is allocated an investigation lead from the patient safety team, as well as a clinical lead chosen on the basis of their specialist knowledge.	Investigators tend to be assigned investigations within their region based on current case load, unless variability in demand means that investigations are assigned elsewhere. Each investigation has both a lead and a support maternity investigator.

continued

TABLE 5 Organisational contextual summaries (*continued*)

	SITEACA	SITEACB	SITEMHA	SITEMHB	SITEIND
Who conducted the investigations	We worked with investigators who had varying levels of experience, training and caseloads. Incidents that were deemed complex or resulted in severe harm or death tended to be investigated by those with more experience, whereas historical cases and those resulting in less significant harm were investigated by those who were new to the role. All investigators' roles sat alongside another governance or clinical role. Some maternity staff conducted regular investigations.	We worked predominantly with a bank investigator, whose role was purely to investigate. This individual conducted most of the Trust investigations, was experienced in patient safety, had completed training and had a background in nursing. Other investigators had current senior clinical roles, with limited time in their job plans to investigate.	We worked with investigators who were employed at the Trust, as well as bank investigators who were used regularly and investigating was their only role. Investigators had varied backgrounds in patient safety, complaints, audit and nursing. Investigations tended to be assigned based on caseload.	We worked with investigators who were employed at the Trust, as well as bank investigators who were used regularly and investigating was their only role. Bank investigators included retired members of staff who investigated on a part time basis. Investigators had varied backgrounds in patient safety, national investigations and nursing.	We worked with independent investigators whose role was purely to investigate. Investigators were supported with central resource and training focused on family involvement and the process of investigating. Investigations were assigned based on region and caseload and worked in pairs. Investigators had varied background in midwifery, nursing, academia, safety science, governance, patient safety, risk management and inclusion.
How are patients/relatives approached?	The investigator makes initial contact with the patients/relatives to explain the investigation process and ask how they would like to be involved, usually via telephone.	The investigator makes initial contact with the patients/relatives to explain the investigation process and ask how they would like to be involved, usually via telephone.	The investigator liaises with the involved clinical teams to determine what, if any, contact has already been made (e.g. condolences in cases of death) with the patients/relatives before explaining the investigation process, usually via letter and provide contact details if they wish to be involved. In order to do this, the investigator may need to seek next of kin contact information via the coroner.	The care team makes initial contact with the patients/relatives, and introduces the investigator where possible. Otherwise, the investigator makes initial contact to explain the investigation process and ask how they would like to be involved via the method that feels the most appropriate including letter, phone call and family meetings. In order to do this, the investigator may need to seek next of kin contact information via the coroner.	The investigator and investigation support makes initial contact with the family, usually via telephone, to arrange an in-person meeting in the family home where possible, to listen to the family perspective of what happened and to explain the investigation process.
How are patients/relatives involved?	The investigator provides updates as regularly as agreed.	The investigator provides updates as regularly as agreed.	The investigator asks those who make contact with them, how they would like to be involved.	The patients/relatives are offered to contribute to setting the terms of reference and the investigator provides updates as regularly as agreed.	The investigator provides updates as regularly as agreed, guided by a 10-step process.

	SITEACA	SITEACB	SITEMHA	SITEMHB	SITEIND
What is the process for sharing a draft report?	This is not formally part of the investigation process.	The draft report is checked for accuracy by the clinical team. Permission is then sought from a subset of the serious incident group to repeat the process with the patients/relatives if they wish to receive it. Feedback is considered and changes are made where necessary.	The draft report is shared with the clinical team. Patients/relatives are notified that the report is ready to share and asked if they would like to receive a copy, usually via letter.	The draft report is signed off by the quality assurance group. The draft report is then shared with the patients/relatives if they wish to receive it, via the method that feels the most appropriate.	The draft report is reviewed at a report panel attended by internal and/or external clinical subject matter advisors. Once agreed, it is sent to the Trust to check for factual accuracy and any subsequent amendments are made. The same process is then repeated with the family.
How is the investigation closed?	The Associate Director of Quality provides final sign off of the report.	The investigator presents the report to the serious incident group) for final sign off. A copy is sent to the patients/relatives by post. Liaison is then handed back to the care group.	The final report is provided to the coroners where necessary.	The Trust incident review group provides final sign off of the report. The report is provided to the coroners where necessary.	The final report is shared with the family, the Trust, NHS Resolution and any other involved or relevant organisations. A tripartite meeting is also offered in which representation from the Trust, independent investigatory body and the family are invited. If the meeting is accepted, the Trust is then responsible for arranging the meeting.

Overall, there was an overt appetite for the meaningful involvement of patients and families in investigations across sites, with a general consensus that it felt like the morally right thing to do, as well as a sense that guidance and support to do this well was lacking. Because of this, the co-designed processes were generally supported by investigators as well as their wider teams, and deemed acceptable and feasible across settings. The timely NHS England policy transition from the SIF to the PSIRF was an important external enabler that also meant that relevant conversations were being held internally at different levels of each organisation, as well as wider national conversations, leading to various re-structuring efforts and adaptations of processes. However, these efforts were nested within wider organisational contexts, which differed within and between settings. Despite similarities, we found that some of the underlying constraints of involving patients and families were different, or more pronounced: between setting, when different organisational models were adopted, depending on the nature of the incident being investigated, the resource and capacity of the teams, and also due to the various disciplinary backgrounds, levels of experience and capacity of the individual investigator. Sites also had different histories of involving patients and families in investigations, which influenced current attitudes and beliefs. Some of the nuance associated with these factors, determining the acceptability and feasibility of the approach in particular circumstances, is explored according to three key stages of the investigation (1. Inviting engagement and involvement; 2. Gathering information; 3. Sharing the draft report).

1. Inviting engagement and involvement

The co-designed processes encouraged investigators to engage with patients and families, and invite them to become involved early in the investigation, where possible, in a way that was sensitive to their individual circumstances. Experiences relating to this stage of the investigation are detailed below, including complexities that were apparent in national and acute care settings, but often appeared more common and complex in mental health care. This was thought to be largely due to the nature of incidents being investigated, which were predominantly suspected death by suicide among other moderate to severe harm incidents.

‘Pre-investigation’: Sourcing the appropriate next of kin details

One of the first major challenges of implementing the guidance for investigators focused on finding the appropriate person or people to invite to be involved, which sometimes felt like an informal investigation in and of itself. This was especially so in cases of death or suspected suicide, which formed a significant proportion of investigations in mental health care. Investigators were often required to liaise with different services, care teams and the coroner’s office to piece together potentially incomplete, outdated and/or conflicting information. Some felt uncomfortable making forced and difficult decisions based on limited knowledge.

> *We predominantly have deaths as our main serious incidents, just due to the nature of kind of, you know, mental health trusts.*
>
> *Patient Safety Manager, SITEMHA*

However, we also found that investigations had sometimes progressed without inviting involvement, or there were significant delays in anticipation of it. For example, the most appropriate next of kin was also often difficult to pinpoint for a variety of reasons, including confidentiality tensions where the service user made explicit requests to not involve the listed next of kin in their care or where family were unaware that the individual was receiving care. Some members of staff described feeling a sense of obligation to protect their patients and service users. This meant that any potential benefits of the guidance were deferred or could not be seen until it was arguably too late.

> *You have to tread carefully because you don’t know what is going on in people’s lives. Divorce, estrangement, how much does the person who has died want them involved? We feel a responsibility for the person who has died. We’re protective of them. It can be an ethical minefield. We sometimes have different next of kin information to the coroner – what do we do then? The coroners’ office is overwhelmed with backlog and responses aren’t always quick. Family dynamics are quite often difficult and relationships are strained.*
>
> *Verbatim field notes, Patient Safety Manager, SITEMHB*

Investigators were required to navigate multifaceted family dynamics, including fractious relationships and other complexities, such as histories of abuse and/or violence, which sometimes contributed to the reasons services users had needed to receive care.

> *No next of kin had been formally documented relating to an investigation of suicide. However, it had been noted that there were difficult family dynamics. After multiple conversations, it was suggested to the investigator that a parent would be an appropriate next of kin, but the investigator later became aware that the service user was estranged from them following allegations of abuse. There was also mention of a foster parent, and it appeared that the service user had been previously removed from their parents, however this was unclear. Their parents were with them in hospital where they died. The investigator was unsure about the relationship of the service user with parents or foster parents prior to death. A potential partner, or ex-partner, also arrived to visit the service user, unaware that they had died. Parents suggested this individual should not attend the funeral as they were a risk. A complaint had been raised in relation to the incident by a relative, which was later followed up by a parent. The service user was also receiving ongoing palliative care support from a charity which they seemed to have more contact with than the family. The investigator was unsure who it was appropriate to address the duty of candour letter to, as well as provide the guidance and invite to be involved, and it felt like it was a decision they were unable to make with the available information.*
>
> *Field notes, SITEMHA*

Additional complexities included family self-blame or shame, cultural or religious reasons to not recognise or acknowledge suicide, long histories of mental health issues in the family, and chaotic family lifestyles.

> *A family would be really reluctant for people to find out that a member of their family took their own life during Ramadan. Culturally, this is not socially acceptable and so the family would not want it spoken about in court because this could lead to newspapers finding out. Trying to engage with a family in these circumstances would be very difficult.*
>
> *Investigator, SITEMHB – verbatim field notes*

Other issues that were more equally apparent across mental health and acute care settings included commonly missing or outdated next of kin information on NHS Trust systems, elderly or otherwise vulnerable next of kin, and multiple people wanting to be the main point of contact on behalf of the family, as well as difficulties in determining the status of relationship prior to death.

> *I haven't made any contact with the next of kin for that reason – it's documented as a friend … she was in hospital for a couple of weeks and she fell at some point which was when she sustained a fractured neck of femur and the next of kin, when he was contacted, didn't know that she was even in hospital, so I'm not feeling it's a very close next of kin and therefore we've made the decision not to contact him about the investigation.*
>
> *Investigator, SITEACA*

Many of these issues were circumvented in a national investigatory body context, as NHS Trusts provided contact information once families consented to their case being investigated. Typically, where possible, parent(s) were also the obvious stakeholder to involve in maternity related investigations, in addition to other close relatives.

Juggling the ethical dilemma of involving versus re-traumatising

Investigators sometimes felt responsible for juggling the ethical dilemma of inviting involvement, but also not wanting to overburden or re-traumatise those who did not want to, or did not feel able to be involved, which often needed to be inferred.

> *We kind of had partner, mum and sister, who were all really vocal, wanted to be involved, and that's okay, but none of them spoke to each other, didn't have a good relationship … mum was saying don't share it with my daughter, daughter was saying don't share it with my mum, and then we had partner on the other hand, who was a service user and really struggling and she went onto hurt herself after speaking to me. So then mum and sister were saying don't share it with her anymore, she's not okay, she's saying I want it … the mental health side of things … there's some really difficult dynamics to try and manage … when somebody's struggling with their mental health it does fracture relationships, and those kind of dynamics in families. It's not isolated just to mental health incidents, I'm sure. But I do think it is amplified.*
>
> *Investigator, SITEMHA*

Both mental healthcare trusts had a history of an 'opt-in' approach to involvement. In practice, this meant that a single letter was sent providing follow-up contact information and in cases of no follow-up, it was assumed that families had

made an informed choice to not be involved. Instead, in some instances, investigators suggested that it meant that the invitation had not been received by those who did want to be involved, they were unable to comprehend the invitation to be involved at a difficult time in their lives, they did not trust that the organisation would listen to their views if they did become involved, or they did not want to be involved temporarily to allow for grieving and recuperation. Interestingly, one of the two mental health Trusts transitioned to an 'opt-out' approach and saw an increase in involvement. This choice was prompted by families asking to be involved on receiving the investigation report, often via the coroner or upon request from a legal representative. Some felt that finding out information for the first time via an external source indicated that the organisation did not care, nor wanted to learn from what had happened. The responsibility of juggling this ethical dilemma was a significant part of the role during some investigations.

Within the context of national investigations, positionality differed, coming from the standpoint of an independent investigatory body. While the risk of re-traumatising families was a concern, the relative luxury of gaining the confidence of families was perhaps afforded, in comparison to investigators employed by the Trust where the harm event occurred. With the cloak of independence, greater resources and time, independent investigators were instead, sometimes perceived as a 'saviour' for the family.

> *Investigators often come from healthcare, they have got that very emotional nature and they're compassionate, they're considerate, they walk the mile in those person's shoes. It has a big effect on them and how they want to communicate with the families and that can be beneficial but it can also be very negative for both parties because families can become very reliant on the investigator and the investigator can also become reliant on the families, yeah, because they see themselves as being a saviour.*
>
> *Family Engagement, SITEIND*

Dispersed approach

Having unclear organisational processes, roles and responsibilities surrounding inviting engagement and involvement also meant that in some cases, there were avoidable delays in providing the guidance, negatively experienced by patients and families. Some of the issues sites encountered included: being unsure who was responsible for stocking and storing copies of the guidance, central administrative staff working remotely or being on leave causing delays, disagreement about how and when the guidance should be introduced, and a lack of clarity about who was 'eligible' to receive it. Without the underpinning information the guidance provided, other forms of communication could be perceived meaningless, and the purpose of an investigation remained elusive.

> *Following the incident, the patient received a letter from the Trust apologising for what happened, confirming that an investigation was being launched and outlining estimated timelines. However, no other information was provided at this stage. Due to delays assigning the investigation and disrupted processes, the patient was left feeling confused about what was going to happen next. Prompted by the research team a few weeks into the investigation, the assigned investigator sought to send a copy of the guidance. As a bank investigator working remotely, they were unable to determine where the Trust copies of guides were kept. Instead, they asked a member of the administrative team to print a copy and send it via post, as well as providing a digital copy by email. The patient received the guide six weeks post-incident. The patient suggested that information would have been useful if it was provided sooner.*
>
> *Field notes, SITEACB*

> *So that in-between, for me, is not really good communication. You don't really know what's going on, you don't know what the next steps are, so that for me was like the biggest thing.*
>
> *Patient, SITEACB*

Additional operational issues included difficulties obtaining contact information and investigators, whose role was designed to provide a single point of contact for patients and families, changing post-introduction. While these issues could be perceived relatively minor with simple solutions, they did sometimes have harmful consequences to patients and their families, who were left to make sense of the reasons why.

> *We've still got a little bit of learning to do in terms of making sure that we're consistently sending out the information at the right time. And again, that often is because initially we don't have the contact details and then sometimes it can kind of slip off the radar a little bit. So, you know, it's just making sure that we're tight on our processes and I think we've still got a little bit of work to do around that.*
>
> *Patient Safety Manager, SITEMHA*

> *I've had contact. She did send an email … and she did look into me accessing [my sisters] medical records … She was helpful but that is the only time I've actually heard from them … Now, I don't know if that's just a normal thing because I suppose they can't just keep ringing you up or e-mailing … you don't want to just keep ringing up and asking, do you? I would prefer her to ring me and say this is where we're at now and this is what we've found out so far … we've just had Mother's Day and I know it's a trivial thing but Mum got two cards instead of three … it makes it more painful … the waiting and the not knowing … It can feel a little bit like it's easy to not involve people after any progress, hoping that they'll not make a fuss or question. And I'm sure that's probably not the intention but it does feel like that.*
>
> *Relative, SITEMHA*

Most operational issues were able to be resolved over time across sites, meaning that the approach helped to systematise the processes of inviting engagement and involvement. Within a national context, these issues were largely offset by having a clear and standardised 10-step process, which guided families on what would happen procedurally, and where their engagement would be invited. Without referring back, families did not necessarily know what each step entailed, but it provided a useful shared reference point for families and investigators, to hang ongoing involvement and engagement from, as well as providing initial reassurance that the procedure would be thorough.

> *They sent us something by email … a 10-step thing of like all the main processes that they kind of go through to make the report that will eventually appear … it's felt like quite a robust process … it did seem very comprehensive.*
>
> *Relative, SITEIND*

> *We all know that families that are distressed don't remember everything they're told or don't look at everything that's written, so to have a one page visual where I can say to you, you know 'when I spoke to you 2 weeks ago I told you this is what we were doing, on that diagram we're now at step 5, step 5's going to take a couple of weeks and then I'll ring you Monday week when I'm hoping we're moving towards step 6 and step 6 is when I can do this'.*
>
> *Family Engagement, SITEIND*

By appraising the co-designed processes in real time, we were also able to identify discrepancies between what harmed patients and families told us that they would have wanted in hindsight which informed the approach via co-design (detailed in *Chapter 6*), and what people actually wanted in the moment when they were distressed, grieving, receiving ongoing treatment, had new babies to care for and/or were generally leading busy lives. The guidance was often used by patients and families but not necessarily as intended. Despite good intentions of engaging with every detail, this was often not possible due to the demands of life at what was often a very difficult time, and the paper-based format meant that it was not always readily available when they needed it, or did not cohere with their usual way of recording information.

> *We usually record things kind of digitally, so we might have liked a Word document or something rather than doing it on paper … What I would probably do, is want to fill it all in digitally but then once it was done print it … so that I did have kind of the ease of filling it in digitally, but then I have like an actual physical thing as well.*
>
> *Relative, SITEIND*

Some felt that the initial phase of the investigation was 'information overload', and others suggested that they would benefit from more regular prompts to access relevant information at the time it would be useful for them, and to have a supplementary digital platform. These challenges were perhaps symbolic of a wider issue of a lacking joined-up approach.

> *If there was something to kind of explain it more … a web page … a basic overview of what this process entails … it was still a couple of weeks before I was contacted after that letter so there was still a few weeks where you're in limbo. I do think something like that would have definitely helped.*
>
> *Patient, SITEACB*

In a national setting, these issues were largely circumvented by an initial meeting between the family and the assigned investigators, often face to face and in the family home. This proved hugely important for setting the tone of the investigation, in which the role of investigators was to actively listen to the family perspective about the issues they chose to raise, allowing them to feel heard. Often, at least some element of what families described during this meeting fell outside of the terms of reference for the investigation, but it might have been the first time following a traumatic event, that those experiences had been validated. We argue that giving space for this, while not necessarily being able to address the issues raised, contributed to a dignified, family-centred approach.

> *[The family meeting] is not expecting them to walk into the very place where something tragic may have happened … it's putting the families as a credible part of the investigation, not an afterthought, not a, you know, attitude of 'there, there, there, there, I'll speak to you because I've got to do a duty of candour' … it's actually valuing that they've got a really important part to play … I know that comes with time and resource pressures but I think it's a fundamental part of doing it with any form of meaning really. It's crucial.*
>
> *Family Engagement, SITEIND*

2. Gathering information

The co-designed guidance aimed to support investigators, while working to gather information from various sources, in preparation for writing the investigation report. Some experienced investigators who felt familiar with the guidance content referred to the investigation guide as an 'aide-memoire' and engaged sporadically to make sure they had not missed anything important, while others followed step by step, or sought to engage with the content in greater detail to prompt a larger cultural change within the team. Experiences and challenges associated with this stage of the investigation are detailed below.

Fluctuating involvement

While investigators gathered information, the involvement of patients and families across settings was rarely consistent, including those who were most enthusiastically involved initially. Some patients and relatives openly spoke about the reasons that their involvement would fluctuate upfront, such as needing to preserve their emotional energy, or managing other simultaneous processes, such as litigation, complaints, or inquests, as well as life demands. Others decided to step back when they felt that the investigation had served its purpose, or no longer met their needs.

> *If I feel like I'm flogging a dead horse I'm not going to chase it. Because for me, none of this is about anything other than I have been robbed of my best friend and my wife, and my daughter, whose 4 years-old, has been robbed of her mum. And you know, this isn't pointing fingers at anyone individually, this is the system itself. The whole crisis team, it's just shambolic for me, it's just, that is what I'm trying to get some form of justice for, it's not for anything else and I will not chase it. If someone says to me, you're not going to be able to achieve anything from this, then I will say, fine and I'll listen to them. You know, I'm not going to chase something that's not there.*
>
> *Relative, SITEMHA*

However, in many cases, investigators were left to make sense of the reasons that involvement may have fluctuated, and decide how to proceed based upon those assumptions.

> *The family were initially very engaged. They are both nurses and work within the hospital in which they lost their baby. I felt we had a really good rapport the first few times we spoke and we still had the same rapport so I don't, I think, I know that she was, she's waiting for counselling and she feels that the wait has been too long and she could have benefited from it earlier but that's just the waiting list of the Trust so I don't, so I think everything's fine. I think she maybe just disengaged because it was just quite difficult and also nothing was really happening.*
>
> *Investigator, SITEIND*

Without knowing the reasoning, some investigators referred to feeling discouraged by unrequited attempts to engage.

> *I feel quite disheartened by this particular case, with that lack of involvement when I've tried my hardest to keep her involved.*
>
> *Investigator, SITEACB*

Conversely, during the gathering information stage of the investigation, patients and families who were keen to be involved sometimes felt left in the dark. Investigators had to navigate various challenges, including hearing multiple perspectives which were often at odds, making judgements about the weighting of perspectives, and determining what should be included or omitted from the report. This was made particularly difficult when it was deemed impossible to reconcile a coherent narrative of what happened and workloads were high, sometimes leading to reduced engagement.

> *I haven't contacted them yet because if I'm honest, I've been putting it off because we've had a clinical lead get involved and he absolutely feels that categorically, you know, this dressing has not been retained during surgery, but I know that the lady's husband's view is that it has … I'm avoiding that difficult conversation to be honest. I'm thinking about inviting them in but getting the consultant anaesthetist that's investigating with me to meet with them together and then we can feedback what we know and we can go from there really.*
>
> *Investigator, SITEACA*

This was made more challenging when investigators were on leave, investigators changed roles, staff turnover was high, and investigators caseloads were moved between the team. These issues appeared to undermine what the guidance was aiming to achieve.

> *A pack came in the post which was sent from [the first investigator assigned], actually, and that was just really so that you could write things down as the investigation progressed. But when you have no contact, there's nothing to write down.*
>
> *Relative, SITEMHA*

Within the national context, initially setting the tone relationally with families was experienced positively. However, expectations were sometimes then heightened, and so perversely, investigators had a more elevated position from which to fall. While investigators were gathering information, families were not necessarily involved in the ongoing processes, which could be jarring. For some, updates about the process were enough; however, one family described this switch from a relational focus to a procedural focus, as 'procedural breadcrumbs'.

> *The reason why I developed [the 10-step process] was because the beginning of the process can be really busy for families, the end of the process can be really busy, but in the middle it can look as though they're forgotten. They're not, but in the middle the report writing, the quality assurance, the clinical panels are all happening.*
>
> *Family Engagement, SITEIND*

From an investigator perspective, this period was also challenging in some circumstances when families were asking for more than they felt ready or able to share with confidence, while also feeling an ethical obligation to not unnecessarily withhold information.

> *My new family know that there's opportunities and they're saying, have you learnt what these opportunities are yet? That kind of thing, and basically until you've finished your investigation and until you've been through all your panels and it's been agreed that yeah, this is what we're saying, you don't want to give anything out to a family too soon that might change as the panels go on … but it's how much do you tell them because you don't want any surprises at the end, you don't want them to wait longer than they need to.*
>
> *Investigator, SITEIND*

Navigating the 'grey area'

Unlike in local investigations – where once an incident was declared, relationships aimed to be built between families and representation from the Trust – in an independent investigation, this process was disrupted and there were multiple

points of contact. The absence of formal policy to support navigating this disruption sometimes created uncertainty for everyone involved.

> *I don't know if the input from the Trust is going to ultimately long-term help or hinder me, I don't know, I don't know if we'll say the same thing or if we're going to say different things.*
>
> *Investigator, SITEIND*

In part, this was because it was not uncommon for families to continue engaging with the Trust for ongoing treatment, perhaps coming into contact with staff who cared for them under formal, and informal circumstances. While independent investigators could control how they worked with families within an investigation to some extent, this was only part of what families experienced. A sense of what was right and wrong in these circumstances was not necessarily clear cut, and risked placing investigators, healthcare staff and families in uncomfortable, and ethically compromised situations, without the appropriate support to navigate the 'grey area'.

> *There is no legislation … what is there to stop a Trust looking into it, in their own way, to improve things? … In a way it's right for them to do it, it's right for them to gather information and do some learning … Trusts might have identified a lot of these things themselves and put those remedial actions in, all to the benefit of patients … by understanding in their own way what's happened, it's necessary for that duty of candour, the explanation to the family, those initial meetings between clinicians and the family. So should they just wait for [the independent investigatory body]? No, I don't think they should and I think that it would be wrong for them to do so but whether that's a personal opinion or whether it's the right opinion, I don't know.*
>
> *Family Engagement, SITEIND*

3. Sharing the draft report

The co-designed guidance encouraged investigators to share a draft copy of the investigation report with patients and families, prior to finalising, to gather their feedback. Neither acute Trust had prior experience of this; however both mental health Trusts had done this sporadically, and SITEIND shared draft reports with families routinely. Experiences relating to this stage of the investigation are explored below.

Symbolic of something more fundamental

We argue that this stage of the investigation could be considered the fulcrum around which all other process operate, as the act of sharing the draft report arguably signifies the underlying organisational values and ethos of patient and family involvement. Generally, investigators, as well as other non-clinical staff, agreed that it felt like a morally good thing to do in theory, and were also aware that it was becoming a formal expectation set out in PSIRF which was being rolled out nationally. The changing policy landscape meant that things were changing locally at each site, and the guidance helped patient and family involvement to remain in the forefront of the minds of investigators, and in turn senior leadership and other decision-makers. However, deeply rooted concerns, worries and practical questions surrounded sharing draft reports. By observing initial conversations, as well as the planning for, and enactment of this activity, huge gaps between 'work as imagined' and 'work as done' were evident. This stage was often the thing 'to give' when investigators felt under pressure and faced time and resource constraints, resulting in patients and families being given limited time, space and support to engage with, and feedback on the draft report.

> *It was the first time we'd sent the family a copy of the draft before approval and I had asked their feedback. Now they hadn't had particularly long to feedback, they just had a week, ideally two weeks, but time only allowed one week.*
>
> *Investigator, SITEACB*

In these circumstances, some investigators described feeling forced to offer a compromised version of involvement, which was perceived to be unfair for some families.

> *We felt, because it took such a long time for the report to be done, that for us only to then be given a week to respond to it, with a bank holiday included, it didn't seem very fair … It kind of felt pressurised because I know that [our investigator] has to then have the final report done by [date]. So it feels a bit late for us to now ask questions, for her to go back and find*

> *the answers to those, when it's all got to be completed within seven days now. I suppose there isn't the opportunity for those questions to be answered and then them come back to us again before it's fully completed.*
>
> *Patient, SITEACA*

There was also disagreement surrounding what constituted a 'draft' report, requiring different levels of sign off within and between organisations, before it was deemed acceptable to share with the patient or family. Staff struggled with balancing the concerns of sharing a draft report too soon, only for it to change once it had gone through various layers of governance procedure, and others fearing it appeared tokenistic, to share a draft report only once it had been given final organisational sign off.

> *I think the idea of sharing those draft reports, to get the comments, is good. I think it's also done in the right way by giving it to the Trust first and again, that can be controversial but I think it's right because when you present it to the family, you want to have it as complete as possible with the least errors as possible, otherwise all you're doing is changing and changing and changing again. That undermines confidence in the organisation, it undermines confidence in the investigators and the actual family are being put through more stress than they need to.*
>
> *Family Engagement, SITEIND*

Navigating systemic barriers alone

The emotional labour undertaken by investigators throughout the course of an investigation was evident across settings. In some ways, the co-designed processes made this more challenging, as it was encouraging a further shift that the organisational infrastructure and culture were not necessarily, or wholly ready for. Generally, the act of sharing a draft report with patients and families was not well supported organisationally. Because of this, in addition to investigators often being placed in the difficult position of having ongoing contact with patients and families who had varied experiences of care, and being the first port of call for their questions and frustrations, they also had to navigate systemic barriers to do what felt like the 'right thing'. Processes not being set up to facilitate this relatively new way of working contributed to an additional upfront workload, and investigators reflected on navigating the system to prepare for, share, and deal with any resulting feedback and questions. A big part of this was the burden of having to win the hearts and minds of middle management, and convincing the wider team that this stage of the process was something of value, as well as dealing with the apprehensions of what the outcome of doing so might be. This stage of the investigation, therefore, seemed to illuminate the loneliness felt by individual investigators. Views also varied as to whether the additional work required felt worthwhile. In some cases, investigators were disheartened at investing additional time and resource, only for the patient or family to not engage. Others referred to being 'burned' by negative experiences, and it sometimes feeling like a thankless task when people nobody was happy with the report at the end of it.

> *I spent a lot of time I suppose, taking the draft report to a committee, for that committee to then have to read it to give me permission to send it out. Other people then having to password protect it, then emailing it out and then hearing nothing … that served no purpose in the end … It hasn't changed the content of the investigation, but it's created more work for me and others.*
>
> *Investigator, SITEACB*

In other cases, sharing the draft report led to unintended consequences, or generated additional questions or concerns that did not necessarily fit within the terms of reference or were deemed insignificant to the clinical outcome or opportunities for organisational learning, but were important to the patient or family.

> *There were also a whole range of other concerns that were brought up by the family … one saying they hadn't felt supported by the Trust and they were very let down, they were very disappointed and that came as perhaps a bit of a surprise because on the one hand they're saying they're very supported by me … the family wouldn't actually say what it is they wanted, they just felt let down, so it was quite difficult to actually really understand why they felt that way.*
>
> *Investigator, SITEACB*

To make this stage of the process more easily manageable, some were keen to boundary the elements that patients and families could feedback on. At the independent investigatory body, this process was referred to as a 'factual accuracy

check', in which families were invited to reflect on their account, but not provide feedback on the clinical findings. Views varied about how effective this approach was, with some having previous experience of families presenting legitimate clinical challenge, leading to changes in the report.

> *It's not factual accuracy, actually, usually they challenge opinion or our analysis, which we say is not challengeable, but sometimes it is. Sometimes we get the wrong information from our clinical advisors and we have to change our analysis, that's happened … but that's just the fallibility of, you know, knowledge, I suppose, isn't it … It's just another opinion, after all. Our advisors are current, they're in practice and they're high up in their game, but there's nothing to say that their word is absolutely final … There are some experts, I suppose, that people rely on, but sometimes it is about opinion.*
>
> *Investigator, SITEIND*

Despite an increase in workload for individual investigators at this stage of the investigation, engaging with patients and families did appear to have the potential to reduce workload downstream. From the perspective of patients and families, this was a significant point in the investigation process with the potential to either restore faith in the organisation, or shatter the trusting relationship that may have been built with the investigator. Some explicitly described that their decision to litigate was based on how the organisation wrote their report and dealt with any subsequent questions, suggesting that a higher upfront workload for investigators may avoid this workload needing to be absorbed elsewhere in the system, for example, formal complaints, legal teams.

> *The granddaughter of the patient who died had collated questions, together with her mum and wider family to send to the investigation. She suggested that she would wait and see how they were responded to, to inform what she would do next – nothing, or take legal action.*
>
> *Field notes, SITEACA*

In a national context, these issues were present, but to a lesser extent as a longer history of sharing draft reports with families had led to a better established, and standardised process in which families were formally allocated time to read and feedback on the report, despite timings being relatively short and feedback often being limited to their account of events. National independent investigators were also solely employed to investigate with the support of a central family engagement team, as well as clinical advice and a regional and national support network of colleagues. Without investigators working within a system which supports them to do this properly, we argue that there is a risk of compounded harm for everyone, including patients and families, but also investigators.

Findings, Part 3: Depth of learning, recommendations, action plans and decisions to litigate

In this section, we explore RQ 8 – 'How do co-designed processes influence incident investigations in terms of depth of learning, recommendations, action plans, and decisions to litigate?'

Learning as a competing priority

Priorities surrounding processes that followed patient safety incidents included learning; however, learning was rarely the only motivator. For patients and their families, while the idea of organisational learning helped to give meaning to their harm, it was not necessarily their key priority. Often, their key priority was to seek answers to their questions relating to theirs, or their loved ones care, and to gain the necessary support in relation to that to rebuild their trust in the health service, as well as the wider implications on their lives. As described, the draft report was a significant point in the investigation process with the potential to either restore faith in the organisation or shatter their trusting relationship that may have been built with the investigator. Importantly, how the investigation 'felt' was critical to the decision to litigate. Patients and families often hoped to be treated with compassion and reported needing an account of what happened which reflected their experience, and sensitively indicated that the event was significant and with consequence. For some, minor inaccuracies with little medical consequence and insensitivities or expressions of indifference went on to have huge emotional consequence for the patient and family in terms of shattering their trust, and ultimately informed the decision to escalate.

> *He hasn't smoked cigarettes for like the last nine years so it just felt like it wasn't right to call him a smoker … I feel like [the report] painted a picture of him as being a confused old man that fell all of the time, which wasn't the case.*
>
> *Relative, SITEACA*

From an investigator perspective, the prioritisation of organisational learning sometimes brought into question morality, with ambiguity felt for where alliances laid which was at time in conflict for individuals, and within and between teams. For example, in cases of death, some investigators considered their alliances to lie with protecting and respecting the person who had died, and for others, their alliances remained with their employer, and the ultimate goal of organisational learning. This complexity was illuminated in a team meeting of investigators.

> *The investigations team reflected on ethical tensions associated with involving next of kin where there had been histories of abuse. All agreed that navigating the ethics and morality surrounding this was challenging. Some felt that they must respect the assumed and/or explicit wishes of the service user who had died, whilst others argued that if the purpose of an investigation is to learn – then they are obliged to involve the next of kin to speak to that aim, regardless of the complex history.*
>
> *Field notes, SITEMHA*

Additional layers of tension were apparent in a national context, where investigators had to walk the tightrope of independence. It was sometimes unclear what it really meant to be independent – was it independence from the organisations in which harm events occurred, or was it independence from everyone involved, including families? Viewpoints seemingly varied, but if it was the latter, then arguably, investment in engaging with families should be proportionate to investment in engaging with staff and collaborating with Trusts. Without that, independent investigatory bodies may no longer be considered truly independent, but rather, a pseudo-advocacy service for harmed families.

> *I think that acting as a conduit between the family and the Trust and the Trust and the family, should be what the role of the investigator is … what can happen all too easily is the Trust see the investigator being part of the family and that's where the skill of the investigator has to come in and show that they are impartial.*
>
> *Family Engagement, SITEIND*

Because of this, the problems local level investigators face in building meaningful relationships with families may lie elsewhere within independent investigations. Instead, similar challenges may be seen with building meaningful relationships with staff and Trusts. In the absence of collaboration, investigators reflected on the varying support systems offered by Trusts ranging from encouraging staff to view being part of an independent investigation as a positive opportunity through to fear-based discouragement.

> *The staff can be swayed in whichever way, depending on how the governance department is set up to present us … 'have somebody in there with you to support you, and you don't have to be recorded, say you don't want to be recorded' – we know that in some Trusts their governance departments, or people in it, have actually said that to people, we pick that up, because you interview people and none of them want to be recorded, and you think, well why, why do none of them want to be, it's a bit suspicious, you know what I mean.*
>
> *Investigator, SITEIND*

To overcome these issues, there is perhaps a need for proportionate investment, as well as formal agreements regarding collective responsibilities, and collaboration to achieve shared goals between local-level, and independent investigation efforts.

Learning de-coupled from investigation processes

Generally, the issuing of the final report was considered the end of the investigations' team responsibilities and marked the point at which patient and family engagement tended to draw to a close. While some patients and families had disengaged with the investigation prior to this, others felt that this was just the beginning for them. This was particularly true for those who felt like their needs had not been met nor their questions answered and pursued alternative routes

to meeting those needs such as raising formal complaints or pursuing litigation. Others were also involved in separate but related processes such as coroners' inquests, resulting in further delays and complication.

> *I did think that there would be an inquest but then it sort of, it just prolongs everything, doesn't it? And it's the waiting. I accept that it's not easy to glean all the information … but it is awful, just being in limbo … I feel that [my sister], perhaps will not have justice, as it won't change things … we're all sort of on tenterhooks waiting as to when it might be and it could be ages yet.*
>
> *Relative, SITEMHA*

The guidance usefully signposted patients and families to potential sources of support, but was designed to supplement, rather than replace, any existing support provided. Nonetheless, confusion was evident about whose responsibility this was. This illuminated a perhaps deeper dilemma of the siloed approach to learning, in which investigation reports were handed over to care teams with any impact of such remaining elusive, not only for investigators, but importantly to patients and their families. Across sites, efforts were not directed towards closing the learning loop, or meaningfully involving stakeholders in such work. In attempt to overcome of some these issues, efforts were being made to develop closer working relationships with senior representation from the concerned care teams. For example, SITEMHB had begun regular 'findings meetings' in which clinical managers attended to discuss the proposed recommendations and advise if they felt reasonable and feasible in practice. Similar activities were being set up at SITEMHA. The core goal was to ensure that the appropriate investigations were being conducted, and that the recommendations presented in the final report were actionable and accounted for local context, as well as tried and failed interventions, and that progress could be better communicated with patients and families. A further interesting change was to replace 'action plans' with 'management responses', in which senior staff indicated if recommendations had been addressed, were part of an ongoing project, actions needed to be developed, or they were not achievable.

> *Because of the nature of the death under the current framework, it would require us to do a review even though we feel that there's probably not much of an opportunity for learning … for some cases we spend time doing an investigation that doesn't really deliver anything other than saying everything was okay. Now, we're linking that learning and improvement kind of mind-set so that we don't keep repeating the same investigations time and time again, so that we can tell families this is the improvement we're doing, this is where we're at.*
>
> *Patient Safety Manager, SITEMHA*

Routinely enabling patients and families to feedback on the draft report also mean that clinical teams were hearing more from their perspective, despite it not always falling within the terms of reference and becoming a formal part of the report or learning.

> *We had quite a good discussion about that concern and I have since fed that back to the clinical teams – no action required on it, but they've heard what the patient had to say.*
>
> *Investigator, SITEACB*

Gaps created by independence

In cases of national independent investigations, one of the strengths of independence was not being constrained by the context, limited resources or other issues that might influence recommendation processes within Trusts. However, divorcing context from recommendations may have meant that they were less likely to be effectively implemented. Unlike Trust investigators who were employed by the organisation they were trying to intervene within, the very nature of being independent placed investigators at arm's length. This made it more difficult to ensure that recommendations were realistic, meaningful and could contribute to organisational learning. We argue that this may create further problems for the rebuilding of the trust between families and services, if families feel that services cannot, or will not make changes to reduce the likelihood of what happened to them, happening to someone else. It may also set unattainable goals for staff, which risks disenfranchising Trusts.

> *How can we learn effectively unless people have got that, 1) ability to take part in it, 2) confidence to take part in it and 3) knowing that if they don't take part in it we're missing a piece of that jigsaw and that we're reliant on that and therefore they're going to get a slap on the wrist somehow.*
>
> *Family Engagement, SITEIND*

The scale of the incident and potential for learning

For patients and families who were involved in particularly complex investigations – such as those spanning long histories, involving multiple care providers and external agents or resulting in death, people were often raising more fundamental issues with care. Adding further nuance were suspected suicides completed in the community, and where service users had limited interaction with the organisation responsible for investigating. This meant that the often limited terms of reference regarding the scale and scope of the investigation did not cohere with the families' experience, what they felt needed to be investigated and what they would like to see improved as a result. This sometimes resulted in an additional layer of frustration for families who sensed that their involvement was futile. The co-designed processes prompted involving families sooner, setting clear expectations and having flexible terms of reference, which was perceived to help, but for some the investigation system felt like it was against the very thing that they wanted the investigation to achieve. A further barrier posed to learning was when investigations involved staff who have moved on from their role, or agency staff who were difficult to get hold of and whose involvement was expected to happy in their own time.

> *There might be a bit of a delay actually, which I ought to let [the family] know about, because one of the staff members is an agency midwife so she's not been contactable through the Trust.*
>
> *Investigator, SITEIND*

Revisions to the guidance

Based on these findings, four separate workshops were held towards the end of fieldwork and prior to formal data analysis to deepen understanding of specific issues, as well as develop solutions to overcome them. Three were delivered by the Lab4Living co-design team, together with the research team and one formed part of an annual conference delivered by the national independent investigatory body. At each workshop, learning from the ethnography was presented, discussed and attendees were invited to propose changes to the process and guidance. Workshop topics were generated through ongoing conversations between the research team, representation from study sites and the design team. Workshops focused on: (1) revising the co-designed guidance and processes, (2) sharing the draft report, (3) involving patients and families in a mental healthcare setting and (4) involving families in independent maternity investigations. Relevant representation from all stakeholder groups were invited to the first three workshops, as well as members of the wider co-design community who we felt could illuminate and inform the discussion from a variety of perspectives. *Figure 8* summarises the proposed revisions following these three workshops. These were later discussed as part of two full-day workshops between the research team (JOH, LR, JM, DH), and used to inform revisions to the guidance, as well as the development of a new supplementary website, imagery and video content.

FIGURE 8 Management of ideas (format and content) from workshops 1–3.

The fourth workshop was attended by over 150 maternity investigators, as well as senior management and the family engagement team. Collectively, attendees identified a series of key recommendations to take forward for consideration as the investigatory body transitioned with a new name and focus.

Final co-designed materials and processes

The final co-designed materials centre around a new process – termed the 'Five-Stage Process' – which is summarised in *Figure 9*. The primary idea for the Five-Stage Process centres on the interactions between the investigation team and patients or relatives within a patient safety incident investigation. The main adaptations, prompted by the ethnography findings, the suggestions from three workshops with key stakeholders and two workshops with the research team centred on when and how patients and families were engaged in the investigation process.

Throughout the Five-Stage Process are details relating to the tone of engagement or interaction, the messages communicated and involvement in specific investigations activities. This was based on a recognition that the needs of patients and families varied widely, and frequently changed as investigations progressed.

These details are not something that can be summarised here as 'one idea'. They are distributed throughout the design responses to our concepts, in small details. We use the notion of a cumulation of benefits to convey the idea that many small, but pervasive touches of respectful, compassionate and sensitive interaction are what build the necessary relational foundations. Conversely, the absence of these positive touches is what cumulatively build negative perceptions and result in compounded harm. We want to stress this point – it is not good enough to merely be 'neutral'. Many organisational responses may not be disrespectful and can be based on good practice or good intentions, yet can still lack compassion or sensitivity and build negative perceptions. Put simply, our reorientation of the final versions of the guidance, was driven by the principle that harmed patients and families want human responses to harm, not organisational responses.

Stage 1: Understanding you and your needs

Patients and families need time and space to talk about what has happened, in their own words. This is an important step on the road to recovery and helps them begin to make sense of what happened. This stage seeks to understand them and their needs following the incident.

Stage 2: Agreeing how you work together

Investigators work with patients and families to develop a shared understanding of how the investigation will progress, what the investigation will look at and how they will work together based on the 10 common principles derived earlier in this work.

Stage 3: Giving and getting information

Investigators will gather information from relevant sources, including the patient and family, who have a unique and valuable perspective on what happened and may have information others do not have access to. This step includes regular updates (in a manner agreed in stage 2), even if there is no specific news, and being transparent about any delays.

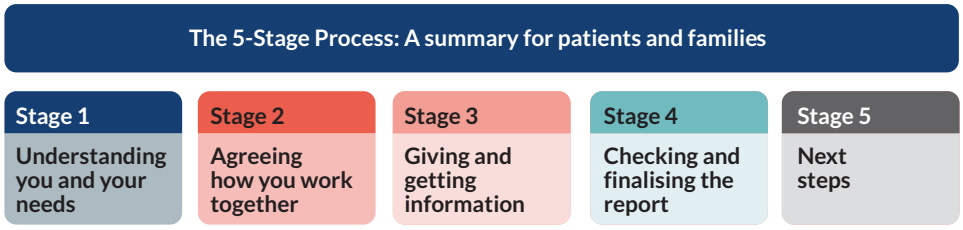

FIGURE 9 Summary of the 'Five-Stage Process'.

Stage 4: Checking and finalising the report

Key findings should be discussed with patients and families before passing on the draft report, sensitively preparing them for any information that might be unexpected or any points of disagreement. Reading the draft report for the first time can be very difficult for patients and families even after such discussions, and they should be prepared for this. Patients and families should be invited to feedback on the draft about the accuracy of their account of the incident and other important details, raise any additional questions or challenge other content.

Stage 5: Next steps

Close the investigation in ways that dignify and reflect the potential impact on those involved. A copy of the final report should be provided and check whether they have any further questions or needs for support. If you are unable to meet their needs, you should advise them on where to access the appropriate support.

The new guidance and materials are hosted on a bespoke website (https://learn-together.org.uk/), designed iteratively with a web development company, in conjunction with the PFAG. The website has a range of digital media assets explaining the new process, providing supporting information resources, outlining the process of research and development and providing video perspectives of people who have been involved in the programme.

Discussion

To our knowledge, this study represents the first attempt to implement and evaluate guidance to support the meaningful involvement of patients and families in real time, longitudinally, and gather stakeholders' views across multiple care settings. This makes a valuable contribution to the literature, as well as highlighting the importance of evaluating and refining co-designed materials in practice. We found that people are philosophically signed up to the idea of meaningful patient and family involvement, and generally agree that it can add a unique and valuable perspective to investigations that would be otherwise missing. The co-designed processes supported systematisation of involvement, as well as encouraging the rebuilding of therapeutic relationships, with a key enabler being the rollout of the PSIRF. Nonetheless, the findings highlight a need for more formal recognition and support for the complex challenges different stakeholders face as they navigate the system both procedurally, and as a human being experiencing emotion.

At an organisational level, this approach may require both subtle, and larger-scale changes to infrastructure, and the wider context they exist within. Equally, culturally entrenched attitudes beyond the individual investigators, or investigations team, need to be aligned and in support of this work, in order for it to stand up against other organisation priorities when falling under time and resource constraints. For example, these activities must be formally recognised as skilled 'work', and people cannot simply do this on the side of a demanding role because they are clinical – at least not well, or in a way that does not compound harm for people.

Additionally, the draft report stage of the investigation is perhaps symbolic of something much more fundamental, having the power to restore trust and enable voice, or when not handled well, the potential to shatter trust and lead to outcomes including formal complaints and litigation. With the appropriate organisational support, as well as adequate time and resource, sensitively supporting all stakeholders through this stage of the investigation may provide a golden opportunity for organisations to meaningfully engage with patients and families in a way that enables them to feel heard and reduces escalation. Without those changes, we may be trying to fit an approach that centres people, into organisations which centre processes – which can be likened to trying to fit a square peg into a round hole. This may result in patient and family involvement becoming the thing to give when organisations and individual investigators come under pressure, indicating that it is not a priority. It is perhaps too early to tell from our data, if the ongoing rollout of PSIRF poses opportunity, or further challenge, in the meaningful involvement of patients and families following patient safety incidents.

We now reflect on what the findings mean in relation to the current evidence, before reflecting on the need for future research and the process of iterating the guidance. The findings support research which suggests that patients and their

families can share credible information regarding the safety of their care.[15] However, what came across overwhelmingly in our evidence was the need for harmed patients and families to heal. This furthers calls made by the Parliamentary and Health Service Ombudsman in a recent report[69] for accountability for a robust and compassionate response to harm, which supports learning for systems and healing for families. It also aligns with recent work in NHS Scotland, suggesting that when meaningful involvement is done well, it can help with reconciliation following a traumatic event and help restore their faith in the healthcare system.[53] Our co-designed processes were able to go some way to meeting those needs; however, we recognise that further systemic changes are needed to truly support patients and families to heal. There remains a paucity of research to suggest that moving towards restorative approaches to harm, such as those being taken in New Zealand,[28] are feasible within the current English healthcare system.

What is clear is that there is no one perfect organisational model to meet the needs of patients and families. Rather, each comes with a set of benefits and challenges which must be balanced, and considered in light of local organisational context. Rather than the role of individuals fulfilling the duty of patient and family engagement, these decisions should be grounded in the ability to meet their needs, as well as the needs of other key stakeholders. Regardless of the organisational model opted for, the responsibility of patient and family engagement should also be recognised as part of a professional and skilled role, with protected time and space, underpinned by relevant training and support. What our evidence was unable to evaluate was the increasingly established patient and family liaison officer role, which require further research to evaluate its effectiveness.

A further issue is the sparsity of approaches which are truly equitable and inclusive. This means that safety inequities are twofold. For example, people with learning disabilities are more likely to be affected by patient safety incidents,[70] yet systemic safety inequities may mean that they are least likely to be able to engage in an organisational response.[71] To avoid exacerbating existing healthcare inequities, it is crucial that engagement and involvement is accessible and inclusive to all, with organisations adapting processes where possible, rather than simply expecting people to adapt. One example of where this has been attempted is the HSIB Family Inclusivity Toolkit which focuses on three key areas – communication, health and well-being, and social and community needs of families – to assist investigators to provide tailored support.

One limitation of this study is that while patient and family involvement was the core focus and intention of the funded programme, we developed co-designed guidance and processes for staff we were unable to fully evaluate as only two clinical staff members consented to participate. Further research would be needed to evaluate and refine this guidance to support clinical healthcare staff involved in incident investigations.

Revisiting our programme theory (see *Chapter 5*) in light of the ethnographic evidence, we reconsider the 'who' (i.e. who needs to be involved). Our centring of the investigator as the 'fulcrum' of involvement remains. However, we now recognise the loneliness felt by these individuals faced with an emotionally demanding role, as well as navigating systemic issues alone. Because of this, we emphasise the importance of not only the investigator, but also middle management, senior leadership and the wider system and outside agents who all play a significant role in enabling or making it difficult for these people to do what feels like the 'right thing', and meaningfully involve patients and families following patient safety incidents.

Finally, reflecting on the process of refining the guidance, a pivotal moment in the co-design process. Up to the second sharing event, the guidance had been developed following the chronology of an investigation. This assumed that time would be the most common reference (with some minor variations) across different investigations. However, on critical examination our co-design partners concluded this would not work for patients and families. We realised that a loud message we had not be paying attention to fully was that patients and families are not always ready to engage in an investigation process whether due to emotional state, or practical constraints of everyday life, and that the entire concept of 'time' itself can be experienced in a fundamentally different way for people who recently experienced trauma. After a rapid design 'crit' with partners, we shifted the focus from investigation process touchpoints to relational engagement touchpoints. This accepted that the 'start' point for patients or families might happen after an investigation has started. And that their level of engagement may vary at different stages of the investigation. The important point was that if they wanted to be more engaged at any point, it should be possible. And that regardless of

when they wanted to engage in the process, the same relational 'touch points' would apply. This understanding now sits at the heart of the new investigation process and support resources.

Chapter summary

This chapter has presented the evaluation and refinement of the co-designed guidance. The next chapter explores the specific issue of investigations following suicide.

Chapter 8 Exploring meaningful involvement in, and learning from, investigations following suicide

Chapter outline

In Autumn 2022, the research team were awarded further funding to address additional research questions related to the wider programme, but which were specific to mental healthcare settings. This chapter presents the findings from this substudy. The conclusions of the study are integrated into the general discussion and recommendations in *Chapter 9*.

Changes to protocol

There were two changes to the protocol. First, we decided not to proceed with data collection at the mental healthcare sites already involved in the wider programme. This was principally due to the intensity of the work being conducted within the stage 4 ethnography, and our existing challenges with recruitment of participants at one site. We were also aware of the potential for limiting the generalisability of our conclusions based on the regional focus. Second, we amended our method of data collection for people who had been bereaved by suicide, from interviews to a qualitative survey design. This change was undertaken following discussion with our family representative, who also supported the design of the survey. Having reflected on the experience of conducting interviews within the wider programme, and the additional emotional burden this placed on all involved, proceeding with a focused set of questions within a survey allowed us to explore the issues in the most direct and least intrusive way.

Background

The National Statistics definition of suicide includes '… all deaths from intentional self-harm for persons aged 10 years and over and deaths caused by injury or poisoning where the intent was undetermined for those aged 15 years'.[72] Most unexplained deaths or suspected suicides that occur where the deceased is (or has recently been) under the care of a NHS organisation are reported as serious incidents. Under both the previous (SIF) and current incident response policy (PSIRF), patient safety incident investigations (incident investigations) are conducted for the purposes of learning to prevent recurrence. However, between 2015 and 2019, the number of deaths by suicide reported by Clinical Commissioning Groups in England had risen by over 1000, to 14,788.[73] This highlights an important, yet relatively underexplored issue – what is the possibility for learning in investigations following suicide that has the potential to reduce incidence?

Improving learning following suicide

Suicide is complex but to some extent preventable. Incident investigations are one of the main ways that management of risk is explored in mental health care. They are also posited as the primary route through which organisations should learn about the circumstances leading up to, or surrounding suicides, and thus how to prevent recurrence. However, there are currently no known UK-based studies exploring the specific learning from NHS Trust-level investigations into death by suicide and how that can contribute to organisational strategies to prevent incidence.

Involvement in investigations following suicide

Both the previous and current incident response policies encouraged healthcare organisations to involve and support families bereaved by suicide, throughout the investigation process. In particular, there is a recognition in the PSIRF that families need to be compassionately engaged in investigations, in a way that 'prioritises and respects the needs of people who have been affected by a patient safety incident' [National Health Service England (NHSE), 2022; p. 4].[25]

There is also a recognition that involving families in investigations 'substantially improves our understanding of what happened, and potentially how to prevent a similar incident in future' (NHSE, 2022; p. 5).[25] Given that death by suicide is most often an individual action in response to numerous complex factors,[74] without involvement of those who might

provide insight not just about what happened but why, any investigation is unlikely to fully meet its espoused aims of organisational learning. In addition, interpersonal problems and social/familial isolation are known risk factors for death by suicide.[75] Involvement of families may therefore be potentially more problematic where they were estranged, had dysfunctional relationship dynamics or where they were unaware of the complex factors that led to the victim dying by suicide. Limitation of involvement only to next of kin (or nearest relative) might also preclude involvement of individuals who might have been closer to the victim, and who could therefore potentially provide more relevant information about the circumstances of their death. However, despite the both moral and logical arguments for involving families and other non-clinical staff following suicide, there are currently no known UK-based studies exploring this issue, and specifically the question of who should be involved, and how involvement can lead to more effective learning.

The present study

The proposed research aims to address these evidence gaps, with the following research questions:

1. Do stakeholders involved in investigations following death by suicide believe they contribute to organisational learning, and risk management and suicide prevention strategies?
2. How do we define meaningful involvement in investigations to prompt learning following death by suicide?

Method

Design

We conducted a qualitative study combining two methods of data collection: (1) semistructured interviews and (2) a qualitative free-text survey.

Interviews

We undertook interviews with people who had experience of suicide investigations, across the following groups: healthcare staff, investigators who have been involved in the process of incident investigation following a death by suicide, organisational managers, policy-makers, risk managers and those working within coronial services. These interviews explored their views on the utility of investigations following death by suicide for their espoused purposes, their experiences of involving families in investigations following suicide, and more generally how we might define involvement and who that should encompass. The interviews were semistructured, with an emphasis placed on exploring what was important to the participants themselves. Topic guides were developed, based in part on the findings of stages 2 and 3 of the wider programme (interview study and co-design), and agreed by the research team. The guide was piloted prior to the first interview with a non-executive director known to the research team, and some alterations made in response. All interviews were conducted virtually, either online or via the telephone, at a time and date most convenient to the participant. All meetings were recorded and transcribed verbatim. Purposive sampling was used to achieve a representative sample across the four key stakeholder groups: healthcare staff, people with experience investigating incidents, policy-makers and managers. Two mechanisms were employed: (1) advertising the study via the social media site Twitter and (2) approaching policy-makers involved in suicide investigation policy. We also employed snowball sampling through getting recommendations for potential interview participants from those we had already interviewed. Given that suicide can happen while receiving care across all healthcare settings (acute, mental health and primary care), we did not restrict our sampling to mental health care.

We planned to recruit up to 15 participants, although the exact number of participants interviewed would depend on achieving both coding, and meaning, saturation. That is, we would cease interviewing when we feel that we have 'understood enough' as well as having 'heard enough'.[37] This was achieved by the fieldworkers meeting regularly to discuss data collection and emergent ideas.

Survey

A fully qualitative survey design[76] was chosen as it allowed us develop our understanding of the nuances of the experiences and needs of families following death by suicide, and their involvement in the range of processes that follow. Further, given the relative low frequency of suicide within populations served by individual mental healthcare organisations, it allowed us to reach an appropriately representative sample that supported wider generalisation of the study findings.

The survey development was informed by the interview topic guide, from the findings of stage 2 interview study (where participants had been affected by suicide), and from our research questions. The questions were designed to replicate an interview format and iterated through discussion within the research team and our family representative (PP). Given the sensitive nature of the topic, we wanted to give participants the space to write about the person who died and how they died but indicated that this section would not be used directly in our analysis. This decision was based on families we had spoken to in our original interviews who had been positive about being given the time and space to talk about the person who died. We developed the survey to accommodate the experiences of anyone bereaved by suicide, including families, friends and colleagues.

A flyer-inviting participation was distributed via a number of routes, including social media, the Samaritans, the CQC, the National Suicide Prevention Alliance and the West Yorkshire Suicide Prevention Action Network. The flyer contained background information about the study, how to access the survey and researcher contact details. Participants could be anyone bereaved by suicide (as a relative, carer, friend, colleague), or members of the public who may have been the last person to see someone alive/who may have witnessed a suicide. All potential participants were recruited either by responding to the study flyer, or through direct e-mail contact for those participants who were known to the research team through involvement in the wider Learn Together study. We monitored the balance of different groups of participants recruited to the study, and if necessary, targeted particular groups.

A copy of the survey questions can be found in *Appendix 5*.

Patient and public involvement

In this study, we worked with Penny Phillips, who had been involved in the wider programme of research and supporting the co-design process. Penny was bereaved following the suicide of her daughter, Anna. Penny was an important source of advice and guidance in supporting the design and conduct of the study and writing of this chapter.

Analysis

The data were analysed using reflexive thematic analysis.[67] Our approach was principally inductive – meaning was created with reference to the two broad research questions, remaining open to novel ideas. The two data sources (interviews and qualitative survey responses) were integrated and analysed together as a single data set.[77] Our analysis followed the six-phase process, beginning with one researcher (JOH) familiarising themselves with the data and developing a preliminary coding framework. A second researcher (GL) took the same approach with a sample of four interview transcripts and four qualitative survey responses. A coding framework was then agreed between JOH and GL through consensus discussion. One researcher (JOH) subsequently applied the agreed framework to code all data and generated the initial themes. As guided by the six-phase process, these first phases were recursive, with constant moving between the data and the constructed themes. Once the initial themes were identified, they were shared and discussed with the second researcher (GL), and further refined to ensure the themes were cohesive, and represented patterns of shared meaning and a 'central concept'.[67] The first draft of the final stage of analysis – writing – was conducted by one researcher (JOH) and then discussed with two co-authors (GL and PP), followed by final iterations. The background and positionality of those conducting the analysis need to be acknowledged within this analytical approach. JOH is the principal investigator of this programme of work, with a background in psychology, safety science and the experiences of harmed patients. GL is a health services researcher and co-applicant, with a background in psychology. PP is a family representative with lived experience of bereavement and investigations following the suicide of her daughter Anna. All of us brought these experiences and backgrounds into the analysis.

Ethical considerations and approval

Ethical approval was obtained from the University of Leeds (ref: PSYC-807). All participants received an information sheet outlining the study, what would happen, and what their data would be used for. Given the sensitive nature of the interview and survey topic, a distress protocol was agreed, ensuring that participants in both the interview and survey had options available to discuss with researchers, any potential distress arising from participation, and be signposted to appropriate sources of support. All interview participants provided informed consent prior to interview. Following University of Leeds guidance, completion of the survey was taken to be confirmation of consent. This was made clear to participants in the information sheet, and at the beginning and end of the survey.

Findings

Sample

Recruitment material was sent to 20 participants who had expressed an interest. Fourteen interviews were conducted via MS Teams and one by telephone. Interviews lasted on average 59 minutes. *Table 6* provides summary characteristics of interview participants.

Eighteen people affected by suicide responded to our survey. *Table 7* provides summary characteristics of survey respondents.

Summary of findings

Seven themes were generated from the analysis: (1) what are investigations achieving?; (2) is suicide different?; (3) reflecting services or shaping services?; (4) precarious foundations; (5) a fine balancing act; (6) conflating involvement with postvention; and (7) how might it be different?

Theme 1: What are investigations achieving?

The purpose of investigations following suicide, and the degree to which they are achieving that purpose, was contested. Some interview participants were clear that investigations following suicide were principally for learning and improvement, and for supporting the family to understand what happened during what can clearly be a very difficult time. However, for many interview participants there was confusion over what the actual purpose of investigations is.

> *I guess the biggest problem is, are we really sure what the purpose is?*
>
> *IP6*

Other interview participants, however, were less confused about the purpose, identifying that the problem lies in the multiplicity of reasons for investigations, some understood explicitly and others implicitly by those conducting or experiencing them.

TABLE 6 Interview participant summary characteristics

Participant	Gender	Role	Region
IP1	F	Policy/current clinical staff	National
IP2	F	Policy	National
IP3	F	Policy/former patient safety management	National
IP4	M	Patient safety management/former clinical staff	South-East
IP5	F	Policy/former clinical staff	National
IP6	F	Senior manager	North-East
IP7	M	Clinical staff	North-East
IP8	F	Manager	North-East
IP9	M	Patient safety management/former clinical staff	South-East
IP10	F	Clinical manager	South-West
IP11	F	Coroner	North-East
IP12	M	Patient safety management	South-West
IP13	F	Clinical staff	South-East
IP14	F	Patient safety management	North-East

TABLE 7 Survey respondent summary characteristics

Participant	Age	Gender	Self-reported ethnicity	Relationship to person(s) who died by suicide
SR1	27	F	White British	Daughter
SR2	46	F	White other	Sister
SR3	64	F	White British	Aunt
SR4	56	F	White	Mother
SR5	74	M	White British	Father
SR6	61	F	White British	Mother
SR7	70	F	Jewish	Mother-in-law
SR8	52	F	Mixed	Friend
SR9	77	F	White British/other	Parent
SR10	35	F	White British	Daughter
SR11	57	F	White British	Daughter
SR12	66	F	White British	Spouse
SR13	57	F	White Irish	Sister
SR14	65	M	White British	Father
SR15	61	F	White British	Mother
SR16	39	F	White British	Sister
SR17	72	F	Scottish British	Multiple family members
SR18	48	M	White British	Husband

> *Oh, so I'm going to be really controversial here, I have a personal view and a professional view. My professional view is: 'to understand if there is anything that the organisation could have done to mitigate the risk or to mitigate something happening'. My personal view is: 'arse-covering'.*
>
> *IP9*

> *So I think … officially, this is about learning lessons and thinking about how we can do things better … Unofficially, the feeling that I get about it … it feels a bit like it's a chance for the trust to say we didn't do anything wrong.*
>
> *IP13*

While the existence of multiple purposes was discussed by most interview participants, there was a palpable view that current processes for investigating suicide were not, at least fully achieving their espoused purpose, and in some cases, resulted in unintended negative consequences for those involved. Some of these unintended consequences are further explored below in Theme 3.

> *I think probably the controversy is that I don't think they actually change anything [yeah]. I think they take a lot of time, they, um, potentially cause a lot of upset in different systems with actually very little gain.*
>
> *IP1*

Where survey respondents had indicated an investigation had been conducted, few reported that they felt they had been effective in finding out what happened, why it happened, and what the NHS might have done differently. Further, the multiplicity of purposes, and the extent to which they are explicitly articulated or implicitly known, seems to partly explain the perception, reported by both interview participants and survey respondents, that investigations should identify things to change or do differently, if they are to meet their purpose.

> *On the first two points (what and why) the investigation was effective. I am not sure the Trust has admitted exactly what they should have done differently.*
>
> *SR16*

> *IP13: It's like … We must produce a learning outcome and if that means that we have to focus on the minutiae of how many minutes it was to make a phone call to refer to another team that just … If I'm honest, I'm not sure who that helps.*
>
> *INTERVIEWER: So do you feel like there's a pressure to produce learning outcomes?*
>
> *IP13: Oh God, yeah, 100%.*

There was a sense that to be valid, the investigation must identify specific issues that could be changed to prevent the likelihood of future recurrence. This 'performative learning' was reported by several interview participants, who described internal pressure from their organisation, as well as external pressure from commissioners and regulators, to identify 'things' to change, that could then be evidenced to have changed.

> *[R]ather than actually look to try to solve problems, they'll be influenced by external factors like reputation, ICB reputation, CQC and all that type of thing. So they'll try and squeeze action plans out … where … realistically there may well have been nothing that could have been done differently.*
>
> *IP4*

However, there was concern that such 'performative learning' would not actually make the desired impact upon future outcomes, and that in reality, learning from investigations following suicide rarely revealed such 'causal' factors.

> *There is learning that's identified; but something that would materially have made a difference to prevent somebody's death by suicide? It's not often that I've seen reviews or done reviews where I've gone, my goodness, absolutely, if we had done X, it would have prevented Y.*
>
> *IP12*

Theme 2: Is suicide different?

Interview participants diverged in their views about the uniqueness of investigations following suicide. For some, they were no different from any other type of investigation, especially where the focus is explicitly on learning and improvement. However, for most of those interviewed, there was a recognition of several complexities that present challenges for the investigation of suicide.

The first issue highlighted was that care within mental healthcare settings is often significantly less prescribed, and more variable. This makes the usual approach to investigations – which often focuses on the extent to which policy and procedures were followed – more challenging.

> *The one thing I think is quite different … is acute doesn't always get it right, but you've normally got a source for what ought to have happened, you know, quite a defined set of practices. And you don't have much excuse for not being able to find it … So, you actually have you know, fairly authoritative gold standards to use in your investigation. Um we're miles away from that in mental health so often.*
>
> *IP6*

This variability is exacerbated in the context of suicides happening in the community, where service users engage with services less frequently, sometimes irregularly, and where continuity of care is less likely.

> *In community setting much more difficult to see where something has gone wrong because there's so much more … the patient is involved in their own journey and what they are doing.*
>
> *IP4*

> *I just don't really understand how we have got to … an expectation that we can really monitor someone 24/7 in the community when we might only be seeing them monthly.*
>
> *IP1*

Some participants described this as having less 'control' over the likelihood of suicide, making the assessment of preventability – a core aspect of patient safety investigations – almost impossible.

> *I've worked, prehospital, mental health and then specialist acute, and the mental health site, I've never worked anywhere where there was just so much, like, you are out of control of a patient's destiny … Because there is so little control, you know, if you can only control what you can control, [IN INVESTIGATIONS] you go, 'Well, did we do everything right?' and then everything else is for the Coroner to work out.*
>
> *IP9*

Where suicide occurs in or around an inpatient mental healthcare setting, or an acute healthcare setting (often in emergency medicine), it was felt that this variability is much reduced, and investigating a suicide in these settings was less idiosyncratic. However, the lower frequency of suicide in such settings, along with the belief that suicide is more preventable, means that the impacts on healthcare staff were felt to be perhaps more pronounced.

The final difference discussed by interview participants was the challenge presented by the distribution of care and input provided to service users, across multiple health and social care providers, as well outside agencies, such as the police and the charitable sector. There was a sense that if investigations are actually to learn and improve, asking only what each individual service had 'done right or wrong' was problematic. Put simply, the sum of these individual investigations would not provide an answer to how the person was being supported, or could have been supported better, across these multiple inputs.

> *So what I … haven't seen in my career so far is that … we don't learn from each other. We see each other as … well in A&E we do it like this and in mental health, we do it like that. I also think that we don't in terms of the recommendations, the actions that come out of, even they are created in silo, again because they're not shared and because they're not cross pollinated, they're also then not cross delivered.*
>
> *IP3*

The limitations of such siloed approaches to investigations are perhaps nowhere better exemplified that an investigation following suicide in, or following a visit to, emergency medicine. In such circumstances, an investigation may be undertaken by the acute healthcare organisation, or the mental healthcare organisation, or both. This can feel confusing for families and exacerbate their distress.

Theme 3: Reflecting services or shaping services?

The theoretical intent of investigation processes is to explore and document the circumstances surrounding a patient safety incident, and the degree to which it may have been preventable. This suggests that investigations simply reflect what happened (and sometimes, what usually happens) in a service. However, this assumption was challenged by some interview participants, who described impacts of investigations that suggest that they not only reflect how a service has been functioning, but also shape how it will function in the future. Of course, a 'good' investigation, with demonstrable learning and a sound action plan, should impact the future functioning of a service positively. However, interview participants described that the process of suicide investigations, rather than the learning outcomes, can have a range of unintended, and often negative, impacts on service functioning.

First, investigation processes were viewed by some as creating unrealistic expectations of the degree of control of future suicides. As mentioned in the previous section, there was a sense that suicide, and in particular community-based suicide, is incredibly difficult to predict, outside of general factors, such as socioeconomic deprivation, loss of work or housing, for example. This perpetuates what some participants believed to be a misconception, that much of what might prevent suicide is not within the 'organisational gift'. Further, this pressure often ends up manifesting in defensive practice, and the reduction of liberty for service users deemed at risk of suicide.

> *[Nurses have] been forced down a risk management route because of defensive practice and because of what comes out of the coroner. Because of expectations around XYZ rather than actually thinking, how can I help this person to live their best life? You're just thinking about how can I make sure they're still alive tomorrow and next Monday.*
>
> *IP1*

Multiple interview participants also described profound and enduring impacts on healthcare staff in the event of a service user suicide. Some of this appears to result from the experience of losing someone that has been under your care. However, without identification of, and support for this distress, clinical judgement may be affected over time, as well as the ability to positively 'hold risk' for other service users.

> *[W]hen some when patients I've been involved with have died, I want to section everybody. I'm like … everybody has to come into hospital.*
>
> *IP13*

Some of the distress is also clearly linked to the conduct of investigations, which can compound the distress staff can feel following a suicide, and can have profound effects on them, and ultimately the service and the profession, if not managed well.

> *Investigations I think, push you over the edge, to be honest. I've talk to lots of nurses that have been subjected … they never come back to work and certainly with inquests, where they really do feel that they are being scapegoated, blamed … and that's not what they came into nursing for. So I think [suicides] shape you, but I would say it's more likely to be an investigation that tips you over the edge, or not, depending on how its conducted, because not all investigations are awful. But certainly it's not just the investigation it's the coroners and I don't know if you can look at one without the other in some ways.*
>
> *IP1*

This profound sense of loss, and the accompanying distress, was termed by one participant, as 'grief'; a grief exacerbated by the expectation that a professional should not feel emotion about people they care for, and should be able to dispassionately proceed through the process of an investigation.

> *I don't even think we recognise that staff grieve. Think that they are seen as a professional body. That's, you know, we could have somebody that's being the care coordinator of somebody for 3 years … knows the family, has met the children, has listened to their inner most worries. And then they die unexpectedly, or they die by a suicide. And you know then we are knocking on the door; saying you know, can you write the report? Because the coroner is going to want you to go and speak, and you just think, where's the, where's their grief counselling's? It is a grief.*
>
> *IP14*

Taken collectively, this suggests that the conduct of an investigation may not achieve its espoused aims of learning and improvement, if staff involved in the investigation are not treated as humans, with emotional responses that drive current and future behaviour, and ultimately, service outcomes.

Theme 4: Precarious foundations

This theme concerns the precarity of the foundations upon which investigations are conducted, and the impact this has on their perceived effectiveness. There was a sense from across both interview participants and survey respondents that the response to patient safety incidents, the wider needs arising from them, and the validity and credibility of investigation processes were not supported with adequate infrastructure.

> *So the best that you get is people with kind hearts and goodwill who try their best … with what they've got, which every now and again you'll get kind of a golden nugget of … something that worked really well … but it's not consistent and it's not reliable because that infrastructure is just not there.*
>
> *IP3*

> *[Y]ou don't get any training on the SI investigation. They're like, right, part of your job, crack on.*
>
> *IP13*

Indeed, conducting and learning from investigations was generally seen as a thing to be done, not a skill to nurture, or an infrastructure to develop. The perceived lack of skill and understanding required to support investigations to achieve their espoused aims, was felt to be replicated across all levels of organisations. However, the impact of this lack of skill at more senior, decision-making levels of organisations was felt to be particularly problematic, causing anxiety for those both conducting investigations, as well as those involved in them.

> *[T]he sheer nature of it's just baffling that you have these people who make the decisions on the reports of people that have probably got no sort of understanding of what it's like working in the services.*
>
> *IP7*

> *I think it's … a lack of transparency not knowing who's involved in in these, these [senior level] meetings because even with my report, which I've finished … and it got sent off to someone … to whom? And then some questions come back and you really don't know who's looking at it and … what their background is … so I think more transparency and I think more of an acknowledgement from the trust … that we're humans and trying to do our best … that we don't always get it exactly right.*
>
> *IP13*

The precarious foundations were particularly evident for survey respondents, who described how their experience of loss following suicide was often met with no support from healthcare providers, or other agencies.

> *[T]here was no support of any kind offered to me after the death.*
>
> *IP15*

Across survey respondents, there was a sense of abandonment by services, at a time when they were at their most vulnerable and needing of support and guidance. While this is often the case for patients and families following patient safety incidents, following suicide – and particularly where families have not been involved generally in their care up to the event – navigating this period can be even more complex. Some families reported having to fight to get basic information from services to allow them to deal with administrative issues; others were left to seek help themselves, either privately or through charitable agencies.

> *After his death I had huge problems accessing any information from CMH or Social Services. His finances were administered by them before his death but they said their involvement ceased when he died. I had to get my local County Councillor involved in order to get information about his benefits, bank accounts etc so that I could deal with his affairs.*
>
> *SR1*

> *I contacted a charity … after his death. Although supportive during my initial phone conversation, it was several weeks before I heard from them again about counselling sessions. I needed help more quickly as I was grieving and in shock, but still had young children to care for. Therefore, I needed to pay for private therapy. Not everybody has this option.*
>
> *SR6*

It was clear that postvention services were almost non-existent, an issue that is described in more detail in Theme 6. However, the impact of this legacy of abandonment on the process and effectiveness of investigations was to increase mistrust, reduce the likelihood of involvement in learning and improvement, as well as force families to seek redress through complaints processes at local or national levels.

Theme 5: A fine balancing act

It was clear that investigations following suicide are very complex to navigate, due to understandably heightened emotions of those involved, the enduring 'scars' sometimes felt by families from the history of care, and the differences in the perceived control of – particularly community services – over the act of suicide itself. Of the 18 survey respondents, 11 indicated that there had been a local Trust-based investigation, of which seven reported some involvement. This involvement varied, however, with most respondents only providing some information at a single point, or having a meeting with Trust staff at the beginning of the investigation with no further involvement. Four respondents described how they would have liked to have been more involved, with a feeling that they could have contributed important information. Only 3 of the 11 respondents who reported there had been an investigation, relayed neutral or positive feelings about the investigation process and outcome, with all others reporting having at best, mixed feelings, and at worst, being *'very angry'* (SR10).

Meaningful involvement of families in the investigation was generally described by interview participants as being given the opportunity to share their experience of the care, and the events surrounding the suicide, and being treated with empathy and compassion. There was agreement that families may have important information for the investigation, that can support learning. There was also a recognition that there were often complications around involvement, where families had not been aware of, or an active part in the mental health care for the person who had died by suicide. In some instances, families were actively not involved in the care preceding the event, which presented complexities following the suicide, with investigators trying to simultaneously 'fill in the gaps' for families about the history of care, as well as gathering information that would support learning.

Involvement in investigations was often serving two purposes – to gather information from families, but also, to provide information for families, to try and help them make some sense of what happened. However, there was also a recognition that if investigations are for learning and improvement, families might not be the only source of information that should be sought.

> *[I]f they had a close friend that they spent a lot of time with, then then absolutely I'd want them involved because I'd want to say to them, did you notice anything? Was there an obvious … sign? … We lose a lot of that soft intelligence.*
>
> *IP9*

Managing these multiple purposes of an investigation, and with the particular complexities of suicide, seems to feel like a fine balancing act for investigators, which, for both families involved and those working within healthcare organisations, is not often felt to have been successfully achieved.

> *[I]n my experience, it's never been a very positive process for families.*
>
> *IP3*

Theme 6: Conflating involvement with postvention

It was evident that a suicide has profound, compound effects, felt by those who loved them, were related to them, or had cared for them. Being involved in an investigation following a suicide – or least getting some understanding from an investigation about what happened – seemed to be necessary but not sufficient to support families to begin to process their loss and reconstruct themselves and their lives. One relative described this succinctly, sharing how despite being involved in what they felt was a thorough investigation, it was not a source of succour.

> *It does not offer me any comfort that 'a number of care and service delivery problems were identified' and that the investigation 'has also identified actions that can be taken to prevent a reoccurrence of this nature'. There can't be a reoccurrence because [MY SPOUSE] is dead.*
>
> *SR15*

There was also a recognition across both interview participants and survey respondents that investigations do not, and perhaps cannot meet the need of families. Two issues were identified – the sense that families may sometimes simply want to connect with, and hear from, those who had cared for their loved one who died, and the need for some recognition of accountability for their loss. These together highlight the tension often felt between those commissioning and conducting investigations for learning and improvement, and those who are involved in them, needing to make sense of their loss, and begin to repair themselves and their lives.

> *[Families] want the opportunity to speak to people who have looked after or not looked after their person. I don't think that's the purpose of the investigation, I think that should be a separate piece of work in itself which is about supporting people to come to terms with their grief and that's quite different and I think at the minute the investigation is trying to do all things and it gets itself in a spin.*
>
> *IP1*

> *I should have liked to ask why the Trust behaved in the way it did towards our daughter … I was not interested in apportioning blame but I was interested in holding people to account, which I consider to be different.*
>
> *SR16*

As touched on in Theme 3, staff caring for people who die by suicide can experience their own version of trauma. In some cases, this trauma, as well as the experience of the investigation, can change the course or length of clinical careers. Supporting staff affected by the suicide of people they have cared for was identified as an important but often missing part of the formal and informal processes that follow a suicide. Undertaking such postvention support for staff can help to reduce the potential negative impacts on them, and then in turn the service.

> *I can think of people where it's informed their practice for the better, where they're found being involved in an investigation and attending an inquest so powerful that it's changed the way that they approach things … On the flip side … we have staff that have ended the nursing careers because they found it so traumatic … At times I'm almost like a counsellor, where I have to speak to somebody every day just to make sure that they are keeping a balance, and what I'm always trying to tell them is … that they're healthcare professionals and this is the last piece of care that we're providing to that person. That's how important it is.*
>
> *IP14*

The effects on the families and friends of people who die by suicide can be significant and lasting. There was a sense that current investigations are overstating the meaning of the involvement of families to be more than a simple 'compassionate engagement of a key informant', and that dedicated postvention services were needed to support people through their grief, separate from the organisational need to learn and improve. Similarly, if investigations are to gain from the perspectives of all stakeholders, including healthcare staff, organisations need to invest in postvention services for staff, if they are to retain them following a suicide, and ensure that they feel able to contribute fully and honestly to the learning and improvement processes that follow.

Theme 7: How might it be different?

This theme concerns the hopes, possibilities, and challenges for the future of investigations following suicide. Perhaps unsurprisingly, the narratives for people affected by suicide, and those within organisations, were not entirely convergent. There was a strong sense from the survey respondents that while both investigations and coronial services avoid the question of 'why' something happened, and fail to address accountability more purposively, many families would be left feeling unable to fully move forward.

> *… as far as [I'm] concerned, we're asking how and not why, you know, so again that's tricky with that familial expectation.*
>
> *IP11 (Coroner)*

> *Useful and detailed for why and what happened. No discussion about what might have been done differently.*
>
> *SR6*

Further, the use of investigation reports from the Trust, rather than coronial services conducting their own investigations, as well as their perceived lack of power to effect change in services were frequently cited as frustrations for families.

> *The investigation was not at all effective, due to the report being submitted as evidence to the coroner prior to inquest it was quite clear it was a vehicle used to cover up their failings.*
>
> *SR10*

> *A Prevention of Future Deaths report was issued. It covered our concerns. But there is nothing that ensures the actions required have been taken and the same Crisis Line has been associated with two subsequent coroners reports.*
>
> *SR12*

This tension between the organisational and coronial view of the purpose of processes that follow suicides, and the views of people bereaved by suicide, in some ways appears to be at best, an uneasy truce, and at worst, irreconcilable.

Some interview participants did, however, feel that there were ways to improve investigations, that they believed might help reconcile these two, or at least reduce the distance between them. The first suggestion, mentioned in Theme 6, was to decouple investigation from postvention activity. There was a feeling from some interview participants, that shorter, more urgent, team-based reviews of what happened – perhaps after-action reviews, or 72-hour reviews

– would achieve better learning for the organisation, using fewer resources, and would be proportionate considering that most suicides, organisationally speaking, do not highlight new sources of risk. This, coupled with immediate, well-resourced support for families and staff affected by the suicide would, in their minds, deal better with the two main espoused purposes of investigations following suicide.

> *So I think there [should] be a shared agreement with all mental health trusts that if there was [a suicide] and … a patient's family wanted mental health support, they could … jump the queue.*
>
> *IP9*

Building on this, it was suggested that more traditional investigations could be triggered by shorter reviews, if circumstances warranted a more in-depth look. This was particularly true for supporting the timely identification of new sources of risk, either regionally or nationally.

> *Should we actually be concentrating on the rare and unusual? Should we be concentrating on, you know, your 80-20 rule? You know you pick up those little rare and unusual, [because] actually most investigations are telling me what the NHS has told you or what your past local investigations have.*
>
> *IP6*

There was a clear desire for increased capacity for, and competence in, investigations and patient safety more generally, to support both learning (and service improvement) following suicide, as well as families and staff affected. Further, there was a sense that underpinning all of this, was a need for greater honesty across all parts of the process. Participants spoke of moving away from cultures of blame, which were thought to subvert learning, and increase pressure on staff following suicides. One interview participant described a vision for staff 'retreats' where certain events or circumstances are unpicked as a whole team, in a psychologically safe environment.

> *I suppose what I'm talking about is, is everyone feeling part of the process. Cause they are. They all get to meet and air their views and you know, put names to faces.*
>
> *IP7*

Interview participants diverged on whether the current move to the new PSIRF would support improvements in, and from, the processes that follow suicide. Some felt that the problems that plague these processes and disrupt organisational learning and improvement would not be any different under the new policy. However, the majority of interview participants were more positive about the opportunities afforded by the policy change, particularly the focus on different types of team-based reviews and thematic reviews. One participant noted that the focus of PSIRF on identification and exploration of lower-level harms, might afford the opportunity to move away from just outcome based investigations, to those which might improve the treatment and care for people that might be at risk of dying by suicide in the future.

> *I think PSIRF is working us towards looking at the lower-level self-harms. Because what we find in serious incidences [is] … that person will have a history of and escalation of incidents … that that you think, actually, had we investigated at that point, would we have done anything different around [their] care?*
>
> *P14*

Finally, given the focus of the new policy on learning and improvement, and the greater powers divested to individual organisations to make decisions about what gets investigated and how, the needs of families to understand not just 'what and how' a suicide happened, but also 'why' and 'who or what' is 'accountable' for their loss will likely remain sources of tension.

Discussion

To our knowledge, this study represents the first UK-based study to examine the views of those working across the multiple levels of healthcare design and delivery, and those bereaved by suicide, about the perceived utility of

investigations to achieve their espoused purposes. Further, it adds to the wider programme of work by exploring the nuances of involvement of families and other non-healthcare staff, in investigations following suicide.

We found a confusion about what the purpose of investigations was, and that the explicit reasons – for learning and improvement, and supporting the family understand what happened – were different from the implicit reasons – minimising reputational damage, and potentially seeking individual staff to 'blame'. There was a general view that suicide as a 'safety event' was different to other types of safety events, including the greater variability in treatment and care standards, the degree of control over the event (especially in community settings), and the fact that care is often distributed across provider setting and time. Investigations were also found to not just reflect how a service is functioning, but also shape it into the future, through creating risk aversive behaviours, compliance-based improvements, and treatment of staff leading to turnover. Capacity and competence to undertake investigations and other support following suicide was a concern for both staff and families. We found that most families reported a negative experience of investigations, and in some cases, inquests. Meaningful involvement of families tended to follow that described within the wider programme, although there was recognition that sometimes familial dynamics might make this more complex. If services want to learn and improve their care, in some instances involvement should be widened from next of kin or nearest relative. An important finding was that involvement in the learning of investigations should be decoupled from postvention support, for families, but also for healthcare staff. It was clear, however, that even with this decoupling, the needs of families – particularly for some sense of accountability – might always be at odds with the organisational position that investigations are for learning and improvement. Some suggestions for changes to the approach of investigations following suicide were proposed that might address some, if not all, of these issues.

While there has hitherto been limited research exploring the specific issues for investigations following suicide, this study adds to a small, but growing literature. Our findings are consistent with an important recent review on investigations following suicide,[78] which concluded that there are significant weaknesses in approaches internationally. These weaknesses include a failure to include perspectives of patients and families; a focus on organisational issues rather than understanding the individual factors in suicidality; limited time frames for analysis; lack of cross-provider investigations; the focus on individual staff behaviours at the expense of systems factors; and the lack of competence and capacity for investigations. However, while their review drew on a broad literature across investigations of suicide, and broader investigative methods and methodologies, they found that 'the literature on investigations of suicide as incidents of patient harm is sparse'.[78]

This study also builds on this growing body of work, in two main ways. First, we have taken a multi-perspective lens on the utility of suicide investigations, through exploring the views of people both investigating and experiencing them. It is clear that in keeping with previous literature,[78–80] investigations following suicide may benefit from improved methods that expand on simply looking at whether services have met prescribed standards, to methods that promote a broader consideration of how people (particularly those being treated within community settings) can be successfully supported within a framing of 'positive risk'.[81,82] Indeed, our findings strongly suggest that for community suicides at least, investigations are currently revealing very little learning, and potentially negatively impacting individuals and services.

Second, this study provides evidence specific to the English NHS that can be used to inform policy and practice. In particular, the juxtaposition of perspectives has highlighted that even with compassionate, meaningful involvement, the needs of organisations to learn and improve may diverge with the needs of families to understand why something happened, and have individuals or organisations held accountable for their loss. It is unclear from our analysis, whether these needs, for some families, can be reconciled with organisational needs.

Chapter summary

This chapter has explored the specific issues for investigations following suicide, including their effectiveness in meeting the aims of learning and improvement, and the complexities of involving those affected by suicide. While we have illuminated a number of important issues, further research is needed into what might improve the process of investigations following suicide, and in particular, how to reconcile the multiple, sometimes apparently incompatible needs of organisations, staff and families. The findings have relevance to the wider programme of work and will be incorporated into the recommendations section in *Chapter 9*.

Chapter 9 General discussion, recommendations and contributions to theory, methodology, policy and practice

Chapter outline

This chapter summarises findings across the research programme and describes and explores our most significant contributions to research, theory and methodology. It also presents a summary of the current impact, and our plans for supporting the legacy of this work, as well as exploring the strengths and limitations of the research and recommendations for future research, policy and practice. Finally, we describe and reflect on the important role of patient and public engagement and involvement (PPIE) in the programme, and issues relating to equality, diversity and inclusion (EDI).

Summary of findings

Our exploration of the current evidence, and policies supporting patient and family involvement in incident investigations, suggests that it is valued by all stakeholders but not effectively facilitated or supported by local policy. This is problematic, given that our review specifically identified that staff found involvement easier when guided by systematic, flexible processes. We found that if patients and families felt involved, they were less likely to pursue litigation, further underlining the logic of supporting this important activity.

Our interview study found that involvement was complex, with patients and families often starting with cautious hope, only to feel disempowered and disengaged further into the process due to lack of information or the difficulties navigating a largely opaque process, or indeed, perceived exclusion from investigations. The harms associated with the incident, and the process of the investigation, ripple out and affect people's lives. To reduce these harms, the investigator was identified as key.

Our synthesis of the scoping review, documentary analysis and interview study generated 10 principles foundational for meaningful involvement, which if not met can result in *compounded harm* – that is, harm arising from the processes that follow the initial incident. Our developed programme theory for our guidance proposed that organisational learning was not the only desired outcome of incident investigations. For patients and their families there was a second purpose, relating to their need to be restored or 'repaired'. In a new approach, the key role would be the investigator, who should be trained and supported to balance the organisational needs with those of patients and families. The new approach needs to be flexible and person-centred, and provide navigational support, which recognises the relational nature of involvement in investigations and the importance of transparency.

With our co-design community we developed four guidance booklets which were accompanied by a short training session for investigators. Various options were explored, but priority was given to information-based guidance to support navigation through investigations. These guides were ratified prior to exploring their use in practice in stage 4.

Our ethnographic exploration of the use of the guidance in practice found that people are philosophically signed up to the idea of meaningful patient and family involvement, and generally agree that it can add a unique and valuable perspective to investigations that would be otherwise missing. The co-designed processes supported the systematising of this work, as well as encouraging the rebuilding of therapeutic relationships, but requires skilled personnel, with the time, capacity and competence to undertake this important relational work. However, at an organisational level, we found that this approach requires both subtle and larger-scale changes to infrastructure, and the wider context they are governed by. In particular, the sharing of a draft report was found to be a critical window of opportunity for enacting

the fundamental principles of meaningful involvement, one that shaped as much by the flexibility of the wider system, as the approach taken by individual investigators.

Our final study explored the utility of investigations following suicide from multiple perspectives, and the complexities surrounding involvement of families and those affected. Investigations had both explicit and implicit purposes, which caused confusion, and perhaps limited the effectiveness of achieving the espoused purpose of learning and improvement, and supporting families. There was a general view that suicide as a 'safety event' was different to other types, due to greater variability in treatment and care standards, the ability to control risk, and distribution of care across settings and time. What constitutes meaningful involvement was both similar to that in the wider programme but different, in part due to the fact that people who die by suicide may have a long history of receiving care, and the sometimes complex familial dynamics. Investigations need to decouple learning from the provision of postvention support. However, even once decoupled, we suggest that the needs of families might always be at odds with the organisational driver of learning and improvement as the principal aim of investigations.

Research, theoretical and methodological contributions

Each chapter has discussed specific findings in relation to current evidence. For brevity therefore, in this section we present what we consider to be our principal contributions to research, theory and methodology.

Research contributions

In the period since funding, there has been a growing literature on the experiences of harmed patients and families, and their needs across incident identification and investigation.[42,43,53,83–85] However, this programme represents the first known international research to co-design guidance to support the meaningful involvement of patients and families in incident investigations, and evaluate it in real time, longitudinally, and gathering multiple stakeholder perspectives. Further, it is the first to develop a programme theory to support this activity, and both identify and seek to enhance the role of the key actor in an investigation – the investigator. These contributions are significant, as existing examples of guidance and practical frameworks are often based on data from one perspective only,[53] or are not based on research evidence.[86] Some are simple value statements, akin to the common principles developed here, designed to encourage appropriate action but stopping short of providing practical guidance.[53] Importantly, in our scoping review of extant literature, we found no examples of real-time evaluations of any framework or guidance. However, the knowledge generated from the longitudinal evaluation, and the resultant changes to the guidance, demonstrates the crucial role of exploring use in practice. As our evidence showed, even when everyone at all levels of an organisation was morally signed up to the involvement and engagement of patients and families within incident investigations, the reality of achieving it was rather more complex. We were able to reflect this complexity within the final versions of the guidance, both enhancing future uptake and reducing the likelihood of compounded harm for patients and families.

Theoretical contributions

At the time of the award, theory to help guide the research questions and likely form of the guidance to enhance involvement and engagement was largely absent. The original proposal was based solely upon a 'grand theory' – the organisational accident model[26] – which, along with empirical evidence,[12,13] supported the broad proposition that patients and families can provide information about patient safety incidents, which if acted on, could reduce the likelihood of future incidents. In support of this proposition, we did find evidence (particularly within the ethnography – stage 4) that patients and families might support depth of learning within investigations, sometimes through broadening the scope of the investigation, their understanding of the history of care delivery, or through the inclusion of specific questions they wanted to be answered within the investigation. However, this paradoxically caused problems with investigatory processes, with the scope and remit defined up front by the organisation, and explicitly to explore the bounded patient safety incident, rather than the care journey as experienced by the patient or their family. So, while organisations, and the investigators working within them, broadly welcomed the input of patients and families to support organisational learning following patient safety incidents, what was clear that this was often the learning that the organisation defined as important. This tension, and the frustration that it caused for both investigators, patients

and their families, exemplified why this theoretical lens, and its direction of hypotheses about the role of patients and families in enhancing organisational learning, had limited explanatory power for the phenomenon we were exploring. The only additional framework we could draw on for our initial research proposal was the NHS Resolution early intervention model.[6] This posited that more timely involvement of patients and families might circumvent later complaints and/or litigation but was neither based on research evidence nor evaluated at the time of funding. Further, its focus was on reducing litigation which was not the central theme of this programme.

During the period of the programme delivery, interest in the application of restorative justice and associated approaches[28] to patient safety incidents has grown internationally. Through drawing on this emergent theoretical exploration, this programme has both benefited from, and added to, a growing literature about the potential for restorative approaches. We have explored the complexity of harm, and along with international colleagues, defined the notion of 'compounded harm'.[40] Further, we have been able to explicate and illuminate how it may be manifested for patients and families but also other stakeholders, as part of incident investigations and surrounding processes.

A final important contribution has been to apply this new theoretical lens to the design of guidance specifically aiming to reduce the harm associated with investigations, evaluate its use, and refine the theory. From this evaluation, we have come to understand that compounded harm is something that may never be fully eliminated, primarily because the organisational need for learning can often diverge with the human need for accountability, understanding and reconciliation between those affected. Nowhere is this better exemplified than in investigations following suicide within the community – organisations may see such investigations as producing little new learning, whereas those affected may be among the most motivated to understand what happened, and sometimes, get a sense of accountability.

Methodological contributions

Chapter 6 described how due to the pandemic, we had to make necessary adaptations of the planned co-design process, including several innovations that have since been shared more widely in conference presentations and workshops. However, we consider that our most significant methodological contribution for this programme is what might be described broadly as co-designing policy. We achieved this in two ways: (1) involving policy-makers in the co-design of the guidance; and (2) working with policy-makers over time to develop and refine their policy.

Involving policy-makers in co-design

The aim of this research was to design guidance that met the needs of those involved in investigations but could fit within current organisational realities and processes – in effect, 'starting where we are'. We sought to achieve this by exploring people's experiences and organisational processes retrospectively, co-designing the guidance with those affected, and then observing and evaluating its use in practice. While this process would help us to address user design issues and organisational process issues, there were still factors of the national policy context that we had to consider. These were of a subtly different nature to organisational contexts, as they included other issues, such as the political dimension. To address this, within our co-design group we included two senior policy-makers from the NHS England national patient safety policy team. Rather than us simply reporting the co-design outcomes to policy-makers, they were part of the co-design dialogue, iteration and decision-making. They engaged first hand with patients and families, healthcare staff and investigators. They understood the rationale behind the design concepts. Yet importantly, they also knew which concepts would fit within both current and future policy – and which would not. A prime example of this is the shift from using the term restorative justice to restorative approaches. While this may seem a mere semantic difference, it allowed restoration to be a founding principle of the approach, which aims to balance learning alongside supporting healing for families. The legal notions of 'justice' may have made the term restorative justice too problematic politically.

Co-designing policy

As described in *Chapter 1*, across the course of the programme, the research team developed an ongoing, productive and reciprocal relationship with members of the NHS England national patient safety policy team. This started through regular checkpoint meetings, which were arranged principally to support the research team to ensure that any developed guidance was synergistic with the incoming PSIRF policy. However, it soon became clear that the meetings were a space for mutual learning and discussion. As a result, we invited members of the team to be part of the

co-design process, which they engaged with enthusiastically, attending most of the workshops across the 6 months, and two of the three final workshops described in *Chapter 7*.

Following this, members of the research team were asked to join a small working group comprising members of the national policy team and representatives from HSIB, which was brought together to support the writing of the national policy guidance for compassionate engagement of patients and families in incident investigations. This document would be one of the four supporting documents accompanying the PSIRF. Over a period of 6 months, we worked with the group to share our evidence, and first draft of the guidance (evaluated in stage 4), and collaboratively developed the new national guidance. The common principles were adapted to form the founding principles of compassionate engagement, and the guidance adopted the same structure as the Learn Together first draft guidance. The term compounded harm was introduced, and emphasised as an important issue that engaging and involving patients and families in ways that meet their needs might help to minimise. Finally, the first draft of the Learn Together guides was signposted from the document and made available to download by any NHS organisation that wanted to adapt them.

In working together in this way, we were moving evidence into policy and practice at the point of need – during a significant national policy shift. To wait until the end of the programme would have meant the national guidance not benefiting from the evidence generated up to that point by the programme. The research team were clear with the policy team that the guidance was evidence-based, but that we did not yet have evidence of its use in practice and that we would be revising it based on our evaluation, at the end of the programme. The policy team recognised this, but also felt that even without evaluating, the guidance was based on research evidence in a way that nothing else available in the UK currently was. To resolve this tension, the guidance supporting compassionate engagement that accompanied the PSIRF was explicitly released in draft. That is, it was stated within the guidance that it was based on the current evidence from research but would be further revised following the findings from the evaluation.

Working in partnership with the policy team in this form presented enormous and exciting opportunities to shape policy and practice, in ways that we could never had anticipated at the beginning of the study. However, it also meant working in a fundamentally different way to the usual knowledge mobilisation approaches, where implementation and policy engagement follow publication of evidence. The policy team themselves stated that this was not how they normally worked, and that this was a 'leap of faith' by both sides. The revised version of the national guidance is currently being developed, based on the full findings from this programme, with a view to being released in 2024.

The 'co-design of policy' is a novel approach for patient safety research in England, and represents an emergent, important methodological contribution. There is considerable interest in this approach, exemplified by the research team, members of the patient safety policy team, and patient and family representatives jointly delivering a 75-minute workshop at the International Forum on Quality and Safety in Healthcare in London, in April 2024. However, further research is needed to understand the strengths and limitations of this fluid approach to adoption of evidence into policy and practice.

Impact and legacy

Impact

This programme has had a range of impacts, across academia, policy and practice, summarised in *Figure 10*. In terms of academic impact, the programme has resulted in four peer-reviewed articles to date, with 10 more being planned. We are leading on a book chapter due to be published early 2024 and have presented at 39 conferences.

Our research has been cited in the recent report by the Parliamentary and Health Services Ombudsman,[69] and we have been invited contributors to a blog on the Patient Safety Commissioner's website.[87] It is of note that much of our academic dissemination has been delivering invited presentations to clinical, or patient safety-focused meetings, events and conferences, indicating the interest in the work from those working within health services.

In terms of impact on practice, our work has been adopted via a range of mechanisms. First, we have contributed to training and development activity, including with charities (Baby Lifeline), and practitioner networks (Patient

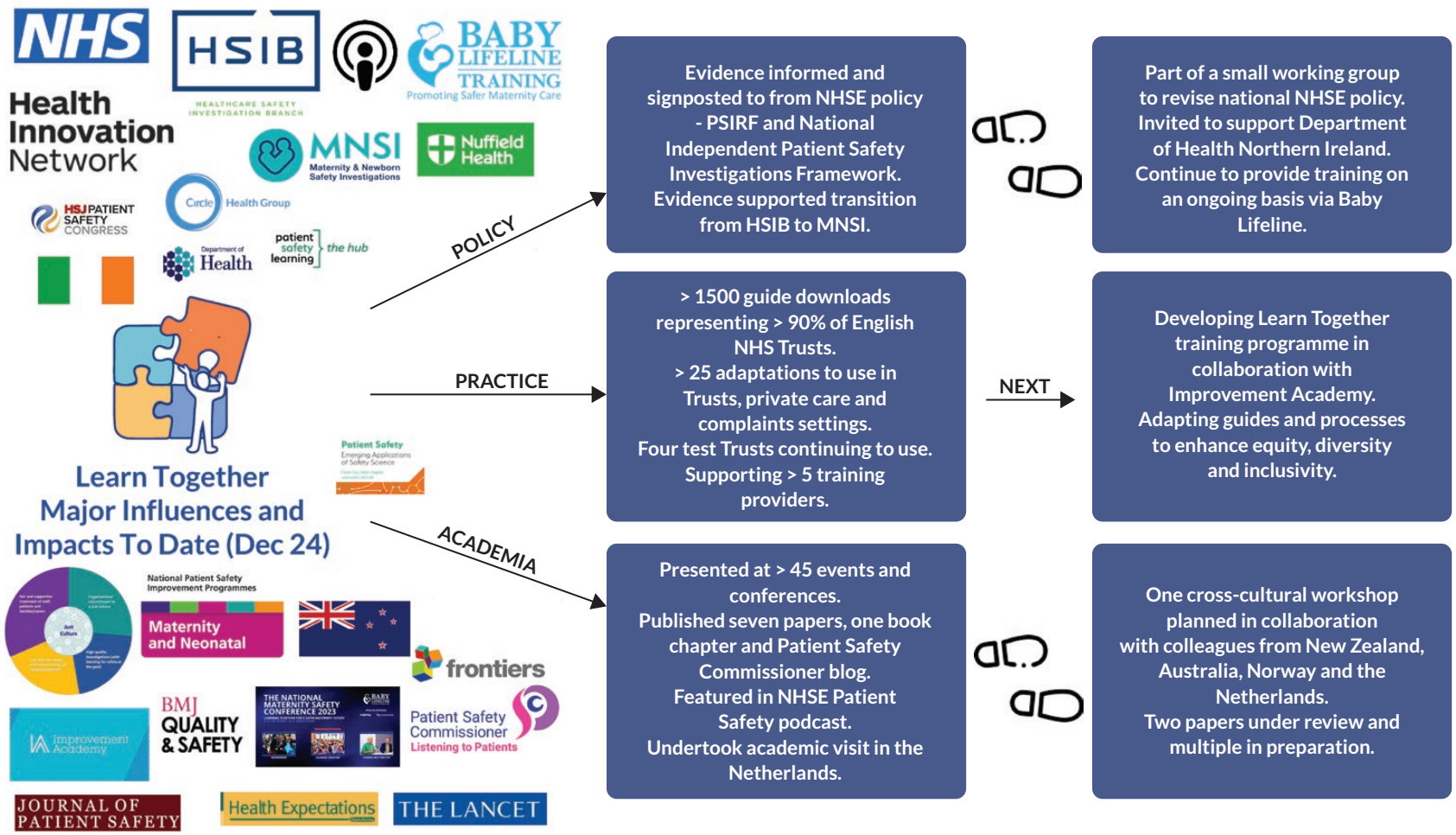

FIGURE 10 Summary diagram of the programme impacts.

Safety Manager Network). Our principal impact on practice, however, has been through our guides and website being signposted from the PSIRF guidance, and made freely available to use or adapt locally. The guides have been downloaded over 1000 times, and to our knowledge, have currently been adapted for use at 20 NHS organisations, in addition to the continued use at our four case study trusts.

Policy impact has been perhaps our most significant impact, having directly inputted into the current version of the engagement and involvement guidance that accompanies the PSIRF[25] and contributing to the small working group aiming to refine it in 2024. As part of the transition from HSIB to the Maternity and Newborn Safety Investigations programme, our findings contributed to the further refinement of family engagement processes for this new body. Finally, we have had interest in our work from several international policy-makers and are currently working with both the Department of Health within Northern Ireland and the Health Service Executive in Ireland, in relation to changes to their policies for engagement and involvement.

Legacy

Given the interest in and impact of the programme to date, we are keen to continue to support it going forward. We are currently working with the Improvement Academy (a regional improvement body in the Yorkshire and Humber region) to develop a training programme based on the collective evidence from the programme. Towards the end of the programme, we sent a survey to all those who had downloaded the guidance, asking them to provide feedback about what future adaptations and changes they think would be of benefit to support uptake, with particular reference to issues of EDI. Based on the findings of this survey, we are developing plans to support cultural adaptations to the guides, to ensure their wider use among underserved, vulnerable or minoritised groups (see also *Equality, diversity and inclusion*).

Limitations

Each chapter has discussed specific limitations, so here we only describe those relevant to the whole programme. First, this work commenced just ahead of the pandemic, and as such we had to adapt some of the study design to accommodate social restrictions and the move to remote working, to manage the ongoing delivery of the programme. This may have influenced the representativeness of the sample in the interview study (stage 2A), with most patient and family participants recruited via social media forums, who may have been motivated to participate because of particularly poor experiences. However, given that similar issues and experiences were documented within the stage 4 ethnography, we can be more reassured that the sampling for the interview study was not unrepresentative.

Second, as is usual in qualitative studies, all participants self-selected into the studies across the programme. This may have impacted our findings, as we may have over-represented people with either particularly negative or positive experiences. However, given that within the ethnography (stage 4) we were sampling people experiencing the process in real time (and so were yet to form an opinion about their experiences), this limitation is perhaps less significant.

Finally, throughout the course of this programme, we have found it difficult to connect with and hear from people from ethnic minorities and those more disadvantaged socioeconomically. While within each study we made efforts to sample in line with hospital populations, and in particular, discussed this with investigators at a number of points across the ethnography (stage 4), we were ultimately not successful in achieving a sample fully representative of patient demographics. This is an important issue, as evidence is growing that people from underserved communities can be more likely to experience a safety event or poor-quality care.[70,88–91] It is possible that the methods we used did not help our efforts to achieve adequate representation within the sample. Despite going to great lengths with our co-design process, it is by its nature a very involved process that might preclude people with less time or resources, or who would not normally feel able – or welcome – to contribute to formal research. We suggest that future research would be better to focus on this topic specifically, and use methods that seek to work with communities to understand their collective experiences following healthcare harm. Without knowing who the group of non-engaged patients and families are, and how their experiences differ from those documented in our programme, it is currently difficult to speculate the impact that this has had on our findings. Therefore, we recognise the lack of diversity within our sample as the most significant limitation of our current work, and we reflect this in our recommendations for future research.

Patient and public involvement and engagement

Patient and public involvement and engagement in the research proposal

Patient and family involvement in the study began prior to funding when two of the co-applicants (JOH, RL) attended an inaugural meeting of the scientific advisory group of the then HSIB and met with a family representative whose shared experience shaped future HSIB priorities in relation to patient and family involvement in investigations. This person subsequently became our lay co-applicant and helped shape the original application. During the application stage, the research team also consulted with two lay leaders and two patient safety panels who fundamentally agreed on the importance of the study.

Finally, as part of the application, four patient and family representatives agreed to be the founding members of the PFAG, two of whom are authors of this report (DH, JH). Discussions with these founding PFAG members were instrumental in shaping the study focus and design. Indeed, the decision to use remote (virtual) methods for convening the PFAG was shaped through these early conversations, as they felt that people affected by incidents might come from anywhere across England and may well have physical or psychological disabilities resulting from their harm, and so asking them to attend meetings locally would potentially limit involvement. This approach was felt to be quite unusual at the time of the application (although it has become the norm during the pandemic) and was directly influenced by PFAG members.

On commencement of the study, the PFAG was expanded. This process was led by the PFAG themselves, with the research team providing administrative support. The recruitment materials (distributed via Twitter) outlined how additional members needed to meet one or more of the following criteria: had experienced a serious incident in a NHS healthcare setting as a patient; had experienced a serious incident, either as a patient or family member, in a mental healthcare setting; were from a minoritised ethnic group; or had a positive experience of an incident investigation process. Expressions of interest were reviewed by the team and by existing members of the PFAG, with the aim of ensuring diversity in experience and avoiding conflicts of interest with other studies. We did not ask members to self-identify in terms of gender or ethnicity (see *Equality, diversity and inclusion*). However, we may suppose with caution that the final PFAG membership comprised two men and seven women and that all were White British.

Patient and public involvement and engagement in the research programme

This programme has been supported from conception of the idea, through to analysis and dissemination, by a dedicated, engaged and passionate PFAG. The role of this group was varied and meaningful. The range of roles they have had is detailed in *Table 8*, but can perhaps be summarised as being the 'north star' of the research team, helping

TABLE 8 Summary of PPIE activity

Stage	Main activities
1. Scoping reviews and documentary analysis	Ways of working agreed; contributed to the development of the scoping review protocol
2. Interview study and development of principles and programme theory	Assisted in the development of an ethics application; co-produced materials to support the co-design phase of the project
3. Co-design of processes and guidance	Attending workshops and contributing to co-design process
4. Testing of processes and guidance	Informing development of recruitment flyers. Exploring and offering suggestions about the challenges of engagement during a Serious Incident Investigation (SII) and use of the guide during testing. Advising on changes to protocol to support recruitment and data collection
5. Iteration of guidance and digital platform	Training in qualitative analysis to support and contribute to a secondary analysis of the stage 2 data exploring types of compounded harm for a future publication. Attending workshops informing iterations to the Learn Together guides and development of recommendations. Taking part in films for the Learn Together website. Writing sections of the Learn Together guides.
End stages of the study	Reviewing and writing sections of the Learn Together monograph.

us to come back always to why, and for whom, this research is being done. In addition to providing a consistent, supportive foundation for the research, they also challenged our thinking at critical points, and we can specifically point to changes that were made because of their input – for example, the impact of legal teams, as well as early indications that organisational learning should not be the only outcome of interest. Their activities included sharing their own experiences, advising on the development of protocols and recruitment materials, collaborating in data, co-designing and iterating the intervention materials, and providing reflections on challenges within the research process. A very important role, which we had not imagined when setting up the study, was how this group came to provide support for each other and members of the research team. This group transcended traditional, prescribed forms of PPIE and became a true collaboration between those with research experience and those with lived experience. We genuinely believe that without their involvement, the Learn Together Programme would not have been as successful or impactful as it has.

Patient and public involvement and engagement reflections

At various stages of the programme, PFAG members were invited to share their views on their involvement. Overwhelmingly, the group found the experience positive, feeling less isolated and working together to move forward psychologically. The group's bravery in sharing their experiences and the ways in which they engaged with the study both humbled and sensitised the research team to the humanness of a serious incident, which ensured that they were deeply committed to a desire to create system change around patient and family involvement balanced with methodologically sound research processes that were trustworthy and defendable. The symbiotic relationship that developed across the PFAG, the research and the policy-makers is without doubt a key reason for the impacts seen from this study.

In addition to working with the PFAG directly, the research team were aware of the wider public interest in the research. The team employed Twitter (now X) to keep the public informed; however, this was not always a positive experience. Strong emotions were expressed and sometimes the purpose of research engagement was misunderstood partly driven by use of academic titles such as 'Dr' and use of NHS e-mails which engendered a misperception that the research had a conflict of interest. The team met to discuss these challenges and adapted their approaches by ensuring that external communications reinforced independence and avoided medical titles.

Equality, diversity and inclusion

On recruiting members to the PFAG we did seek to purposively recruit representation from patients and families from minoritised ethnic backgrounds. However, as they were collaborators not research participants, we did not ask individuals to self-identify and we did not gather data on protected characteristics. Across the programme we have become increasingly aware of how certain population groups (individually and intersectionally), such as minoritised ethnic groups, people with disabilities, people from poorer backgrounds, and people experiencing mental ill health may also experience safety inequities.[71,92–94] Within our PFAG we recognise that these experiences were not necessarily expressed, and so we know that we did not represent many of these underserved groups. One of the members of the group whose family relative had experience of care in a mental health trust and subsequently an incident investigation showed us how system and organisational-level processes can differ in the presence of at least one protected characteristic. Consequently, we undertook further work exploring this particular area in one of the final co-design workshops (see *Chapter 7*).

We suggest that the same common principles and 'Five-Stage Process' for patient and family engagement and involvement in incident investigations are important for all population groups, but that wider system and organisational-level challenges may directly influence how and whether patients and families engage. As a consequence, we recommend adapting the Learn Together resources to ensure they are equitable. We have begun this process by undertaking a survey with downloaders of the Learn Together guides to explore their views on adapting the materials for this process. The findings from this survey have been shared with an EDI Working Group within the NIHR Yorkshire and Humber Patient Safety Research Collaboration, whose advice has informed work to be undertaken within an upcoming safety equity internship.

Recommendations

At the final stakeholder event (held May 2023), we shared eight draft recommendations for policy and practice, and invited attendees to rank them in order of importance. Here, we list the four most important recommendations as jointly agreed by the research team and co-design community.

Policy and practice

1. Policy and procedures need to formally recognise that there are multiple purposes for responding to a safety incident and that organisational learning is only one of these purposes.
2. The relational work of involving patients, families and staff is important, but complex, and needs to be resourced, valued and recognised within policy and processes.
3. When embedding processes for involving and engaging patients and families in incident investigations and responses, organisations need to first seek to understand how this is currently done and seek to adapt current organisational infrastructure to support them.
4. Organisations should undertake ongoing monitoring of processes for involving and engaging patients and families, which centre their experiences, as well as objective outcomes, such as subsequent complaints and litigation.

Further research

In addition, we propose the following recommendations for further research.

5. Research should explore how current approaches to involving and engaging patients and families in incident responses might be different for people from minoritised and underserved groups, and what adaptations might be required.
6. Research should explore the possibilities for 'harm-centred' rather than 'incident-centred' responses to safety, and how this might address the seemingly intractable divergences in the needs of patients, families and organisations.

Conclusion

Incident investigations are complex, relational processes, which have the potential to either repair or compound the harms from patient safety incidents. Our co-designed processes were found to be both feasible and acceptable with stakeholders. While we found variability in their use – both at individual and organisational levels – where patients and families were engaged, the guidance did support more systematic involvement of patients and families in incident investigations. Based on the ethnography findings, our revised guidance, and in particular the Five-Stage Process, is designed to centre the needs of patients and families to be heard, and their experiences dignified, before moving to address organisational needs for learning and improvement. This may reduce the significant and long-lasting effects of compounded harm for patients and families. However, we did identify a number of important divergences in the needs of the different stakeholders involved in investigations, often relating to their purpose and focus. Navigating this complexity requires skilled, well-supported investigators, who work with an organisational infrastructure flexible enough to allow them to individualise their approach.

Additional information

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

All necessary ethical approvals were received. Stage 2A: July 2020 (Health and Care Research Wales REC ref. 20/EE/0133). Stage 4: October 2021 (Health and Care Research Wales REC ref. 21/WA/0287). The study on involvement and learning from investigations following suicide: February 2023 (University of Leeds PSYC-807).

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Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/KJHT3375.

Primary conflicts of interest: Justin Waring was a HS&DR Researcher-Led Board member. Gemma Louch was a member of the NIHR Research for Patient Benefit (RfPB), Yorkshire and Northeast Regional Advisory Committee May 2021–May 2023. Carl Macrae was employed as Associate Director of Research and Evaluation at HSIB from June 2017 to January 2019, which encompassed the period when the proposal for this research was being planned and developed but was prior to the start date of the project. John Baker is NIHR DCAF Panel Chair, and a Non-Executive Director at Leeds and York NHS Partnership Foundation Trust. Rebecca Lawton is the Director of the NIHR YHPSRC which ran concurrently with the NIHR HS&DR funding that supported this manuscript. The objectives of the YHPSRC are to build capacity in patient safety research. Thus, the Learn Together project was hosted within the YHPSRC which offered a thriving research community in which to deliver the programme of work. However, the YHPSRC did not support the Learn Together project financially. Sarah Seddon and Jane O'Hara are part of the advisory group for the charity Harmed Patients Alliance, for which they receive no payment. Sarah Seddon is a Specialist Clinical Pharmacist and trains students, doctors, nurses and pharmacists as part of this paid role. Sarah Seddon delivers annual training to medical students on 'Managing Adverse Events', unpaid, and is a paid Maternity and Neonatal Independent Senior Advocate, working 2 days per week. Joanne Hughes undertakes paid training on Engagement and Involvement guidance for PSIRF (MedLed, and Consequence UK) and is Co-Founder Harmed Patients Alliance. Joanne Hughes, Debra Hazeldine, Sarah Seddon and Penny Phillips all received payments for their involvement in the programme as part of the Patient and Family Advisory Group.

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Appendix 1 Scoping review short report

Background: Alike all safety-critical industries, health care is an inherently hazardous environment. However, there has been recent recognition that serious incident investigations have the potential to compound harm. For instance, staff report working within defensive blame cultures alongside patients and families feeling unheard and demoralised. To help tackle these issues, there have been calls to make serious incident investigations fair for all. One key area of focus has been the inclusion of patients and families. Therefore, the objectives of this review were to understand the current involvement of patients and families in serious incident investigations and to understand the experiences, benefits and challenges of involvement from the perspectives of key stakeholders.

Methods: The protocol was developed in collaboration with the study steering group. Authors performed a search of three databases: Medline, PsycInfo and CINAHL. Original studies in which patients and/or families were involved in investigations following a serious incident in health care were eligible for inclusion. Included studies were searched via Connected Papers for additional articles. Data extraction of eligible articles is complete and drafting of preliminary findings is underway.

Results: 27 of 13,679 papers were included in the review. The majority focused on involvement in serious incident investigations generally; however, others explored suicidality, child death and stillbirth specifically. Settings included acute hospital care, mental health care, maternity services, paediatric ICU and cancer care. Varied perspectives were sought, including those of patients and families, healthcare professionals, senior healthcare staff, legal teams, policy-makers and coroners. Interventions supporting patient and family involvement included: the disclosure, apology and offer model, the improving post-event analysis and communication together tool, open disclosure, and communication resolution programmes. However, interventions tended to predominantly focus on involvement at the stage of incident disclosure, with less focus on involvement throughout investigations in their entirety.

The included research suggested that most patients and families valued being involved; however, investigations were complex social events requiring staff sensitivity to a multitude of factors to avoid compounding harm. These included initial active listening with empathy for trauma, fostering a sense of trust and transparency, realistic timelines being made clear, and effective non-adversarial communication being established. Additionally, it was important that staff were sensitive to language, particularly surrounding timely and sincere apology, and approaches were inclusive to both medical and emotional components of care. Patients and families had wide-ranging needs including desires to: gain information, tell their story, provide feedback, access emotional support and achieve closure. Additionally, some noted the importance of being offered advocate and legal support where necessary. However, most preferred to be asked about their specific needs rather than them be assumed.

Most staff perceived that patient and family involvement could improve investigation quality, promote an open culture and help to ensure the safety of future care. Serious incident disclosure was largely viewed as a moral and professional duty; however, this was made more difficult when: multidisciplinary team input was absent, workload and staff turnover were high and investigations did not integrate with wider patient safety improvement efforts. Staff also highlighted various needs including: access to adequate training to help prepare for, deliver and follow-up on investigations, and needing to feel supported centrally, organisationally and by immediate management and co-workers. Many found that formal protocols and supporting structures helped staff to gain clarity, but some also noted the need to make considerations for litigation.

Implications: This review provides new knowledge and practical insights for policy-makers, healthcare organisations, staff, and patients and families on how to incorporate patient and family involvement. This includes suggested action points to ensure that involvement is meaningful for both learning and healing from the perspective of key stakeholders.

Appendix 2 Patient and family interviews short report

Stage in the process	Initial impressions
1. Problem identification	*Patient/family role in escalation* Some had to actively fight for the known problem to be formally recognised by the organisation and were real drivers in resolving complexities and pushing that forward – sometimes over a period of months and years. Nuances of this included the complexities of getting to the bottom of what had happened and feeling unable to stand up to the organisation when in disagreement, sometimes taking toll on people's mental health, for example, some reported knowing something was wrong before they had been told. Many reported feelings of not being listened to by clinicians or their attempts at escalation being misreported or absent altogether in resulting investigations, for example, knowing their own body, or knowing their family member, better than clinical staff would, and the feeling that these concerns were overlooked in place of more clinical/procedural detail. Others were unaware that there was a problem in the first instance and did not have any role in the problem identification process. *Accountability* Where patients/family members reported a more positive experience, it seemed to be due to timely acknowledgement of 'error' by the treating clinicians at the time of the event itself. Separate to disclosure of the serious incident grading, there was more understanding of the 'everyone makes mistakes' concept where they felt there was accountability for actions. More sympathy for staff and the difficulties of these conversations following error. Negative experience of the process often stemmed from feelings of lack of accountability at the stage of problem identification, and a lack of communication. Patients/families sometimes felt worried that errors had not been identified earlier which led to lack of trust in the organisation.
2. Disclosure	*Disentangling experiences of care and investigation* It was difficult for some to disentangle their experiences of care with the incident and investigation itself, particularly when those experiences were negative, with some having a long history of issues, for example, formal complaints, informal communications with staff raising issues. Some went into the investigation process with cynicism and preconceptions that the service was not a supportive environment; therefore, the investigation would not be. Others were hopeful viewed the investigation as a valuable opportunity to finally being listened to and aiming to get answers to longstanding questions that they had been searching for throughout their care experience. Those with more positive experiences of care were perhaps better able to separate the investigation as a standalone process and felt more hopeful about the investigation in terms of meeting needs. *Disclosure by complaint* Patients/families had to be (and have the understanding to be) proactive in pushing for complaints procedure information, although sometimes misreported in investigations that the Trust had offered this procedural information at the point of problem identification/discharge. Some patients/families viewed this regrading as a secondary 'error' by clinicians and a way of placating them. Often caused feelings of anger or distrust in the system even before the investigation had started. However, some patients/families felt strongly about not going down the formal complaints route even following disclosure of a serious incident and were pleasantly surprised that the Trust had a process of investigation that was internally triggered without a complaint being made. *Duty of candour versus disclosure* Confusion between the two from perspective of patient/family. Duty of candour does not mean disclosure of a SI grading leading to an investigation as the thresholds are different. Some found it difficult to distinguish between duty of candour and disclosure of a SI (and investigation), and many reported not knowing that an investigation was taking place. Confusion about the language of disclosure, and about what disclosure meant. Was this an invitation to engage, or just one-way delivery of information?

Stage in the process	Initial impressions
	Mechanism of disclosure: Who and how People were most commonly informed of the serious incident via letter and/or as part of an in-person or telephone conversation. There was particular confusion about when the disclosure happened, but also the person who had contacted them to 'do' the disclosure, especially when this had been on the telephone. People did seem to feel that telephone was the better option generally, although some viewed this as more intrusive where there was no letter of information alongside. Generally, people seemed better satisfied when there was an option for two-way conversation, rather than a confusing and unannounced letter arriving at the doorstep. However, problems were identified with all channels of communication. Issues with letters included people being unsure what they were supposed to do with the information they were given, there being no invitation for questions or their input, people feeling less able to respond due to the impersonal nature, the letter being generic and un-empathic, and one participant was upset that the disclosure letter of a baby death was inappropriately addressed to only to the mother and not the father. Issues with phone calls seemed to centre on the timing, but also on confusion about whether the call was an invitation to engage in the investigation or simply a call to inform and disclose. Issues with in-person disclosure included a lack of answers to their questions, people getting a sense that staff were disrespectfully trying to suss if they would be perusing legal action and one participant was upset that staff had disclosed the issue to her mum before herself. *Range of feelings invoked by disclosure* – *Relief:* Some found the disclosure process brought relief and catharsis, validating their experiences and finally allowing them to feel believed, for example, participant who had been fighting over a period of years to get her nerve damage formally recognised, but had begun to question herself. – *Shock:* On the other hand, disclosure came as a huge shock for some, as the meeting was initially perceived to be just another routine clinical interaction, but ended with them being told life-changing news. One participant person felt unprepared, and that had he have known how serious the meeting would have been, he would have taken his wife with him for both support and to help absorb the information he was being given. He had a vague recollection of being told that his cancer should have been picked up sooner and things should have happened that did not, but he was in too much shock to comprehend that a serious incident was being disclosed – 'in one ear and out the other'. – *Anger:* Some held resentment regarding the delay in disclosure, with a perception that staff had known about the problem earlier without communicating it to them, as they were too afraid to say. Some also felt that the initial disclosure meeting set the adversarial tone, and it felt as though all usual standards of care were disregarded, for example, lacking compassion. Staff had put up the defensive barriers and disputed things being said by patients and families, rather than actively and openly listening to their trauma. For example, participant found this particularly shocking and insensitive in a mental health context, where their expected therapeutic model should mean that this was standard practice. On meeting with the ward manager on the day of her mothers' death, condolences were not offered but instead, felt that staff were trying to place blame on the grieving family. – *Appreciation:* Some expressed appreciation for being supported throughout the disclosure process, for example, having a professional in the room to keep notes of what was being said for the patient and family to read through and consider once they got home and had the headspace to consider it. Another participant was also grateful that a staff member had come in on her day off to talk her through what had gone wrong. – *Fear:* For some, disclosure heightened a sense of fear and rumination, for example, participant had not realised the incident was serious initially, but considered that it must be if it is being investigated which played on her mind and made her consider if the health service could be trusted or not. Disrupts perceptions of an infallible NHS. – *Confusion:* While people knew something had gone wrong, 'serious incident' and/or 'investigation' was not always mentioned to them, and even where it was, people did not always know what this meant – misconception that disclosure meant clarity for patients and families, instead it left lots of people confused.
3. Investigation	*Initial expectations setting about the investigation process* Patients and families largely had no experience of serious incidents and/or investigations, and felt they needed their hand holding throughout the process with expectations made clear from the outset (i.e. to be told in simple terms; this is what an investigation is, this is what we do, this is what you do, this is what you might expect, this is what the investigation cannot do, here are all the other processes you might be involved in and how they are similar/different to an investigation, etc.) In the absence of transparency, many felt that they were *muddling through a convoluted, nonsensical web of processes* which set them up for compounded harm, despite best efforts and energy being expended, that is, patients and families could provide very little 'process' detail during interviews. Patients/family members commonly expressed the need for their questions to be answered during the investigation process, and often reported feeling that this had not happened. They felt the investigation terms were set by the organisation, and that having no chance to input meant that they had no chance to ask questions. On occasions even those who were initially engaged by the organisation and were given the opportunity to input into the investigation and terms of reference, often felt that this engagement was disingenuous when they subsequently received the report which they felt was representative of the organisational needs but not their own. *Involvement did not equal expectations being met*.

Stage in the process	Initial impressions
	Patients and family members often reported feeling that they were starting from a position of powerlessness due to their lack of understanding of the SII process, the national guidelines and the different timescales that had to be met. This was especially true if the coroner's court became involved, or where the incident went to inquest, but was also highlighted when discussing litigation. Many felt their distress was compounded when they were told that time limits had passed for the incident to be investigated through certain routes and felt that organisations held more power in their better understanding of these timelines, and there being no route by which patients or family members could access this information. Some felt that it was the role of the organisation to educate them about the investigation process, and the different routes down which the investigation might proceed, especially where this could involve external organisations, although others felt that this was the role of a more national body/that this should be nationally available information that is independent of NHS Trusts, especially where they lack trust in the organisation. For one participant, this was offset by having a Macmillan Nurse present at meetings and a Cancer Lead who personally took charge as a single point of contact. She fully explained the missed opportunities from the Trust, what they should have done differently, her role, and what she planned to do next. She actively sought involvement and information from the patient and took that into consideration in the investigation. *Discriminatory process* Many felt that patient and family involvement was discretionary from the organisational perspective, determined on a case-by-case basis by an individual lead. In the absence of standardisation, some had to elbow their way in, which took great strength and determination within the context of a challenging time in their life. People noted how the system discriminated against those who became understandably beaten down by the investigation process and had limited knowledge, power, strength, systems intelligence, social capital, etc. to draw upon, leaving a feeling of injustice, for example, one participant mentioned iterating a detailed 30-page document of relevant information which took time, effort, and determination from the family, which was then ignored. Others felt that they were made *disingenuous promises*, and that the organisation manufactured a false sense of security, seemingly providing a supportive, helpful, and welcome meeting initially. Here, people were 'promised the world', which never materialised, and some described how it was painful to have been asked to be involved and then that be shut down and dismissed – an invitation to be involved is not enough. In hindsight some, did not feel that the emotional strength and reserve required to be involved in the investigation process was not worth the outcome, and they were left feeling more vulnerable than they had before the investigation. Others felt naïve, and that they did not realise that their vulnerability was being exploited until it was too late, for example, things said in the initial meeting later used against them or blaming their harm/upset for false recollection. *Whose needs are being served? Meeting organisational needs but causing patient and family distress* Where it seemed to work best from the patient/family perspective, was where the investigation seemingly catered to the needs of the organisation, staff and patients and families and patient and families had been invited to be involved – even where they had decided not to engage, and especially where they had, the offer and opportunity particularly of being invited to meet the investigator and/or other stakeholders in the process was considered positive. For instance, some mentioned the value in having the opportunity to meet with staff directly, considered therapeutic for all. Some went into those meetings 'all guns blazing', but once faced with honesty, compassion and apology, and with an opportunity to ask each other questions, a mutual ground was formed and helped with healing. However, where it seemed that the investigation was working purely to *organisational agendas*, it tended to work less well, and was viewed as *missing humanity* and being a *missed opportunity*, for example, 'difficult to comprehend that as human beings, the investigation could be approached in that way'. *Accountability for error for error was integral early on – the power of sorry*. But where apology was delayed/non apology given, it was insulting. Some were felt that sorry was not necessary and was too easy to say – accountability and honesty more important than apology as a 'way out'. Sorry seen to shift balance of power back to organisation. While this was the general consensus, one participant has a different experience who was satisfied that the investigation processes were to serve organisational needs and was happy to oblige in providing information where it was needed, but was confident that clever people were doing their job and the organisation was learning – implicit trust that it was in safe hands and it was not his responsibility. The impersonal nature of the investigation was simply reflective of the investigation being triggered by the organisation. They saw this as a positive step that the organisation wanted to understand what had gone wrong, and were happy to provide information, if necessary, but did not feel the need to be involved any more than necessary.

Stage in the process	Initial impressions
	Working to organisational deadlines Where timelines were made clear, people expressed more satisfaction and less distress. Where they were not, people were unsure how to approach communications. Most patients/families initially sat back in fear of unnecessarily burdening busy staff/politeness but hoping that someone was picking up the investigation and running with it to an unknown timeline – in the meantime (sometimes months waiting for a response), some blamed themselves. This was despite a *desperation for information* – it was something to cling on to, gave the day some purpose, even if it was just an update to say that nothing new has happened but they will be back in touch. It was perceived as an administrative and impersonal extra thing to do for staff, yet life changing for some patients and families – 'we were just names on a piece of paper'. Many perceived that they were put through unnecessary trauma of having lengthy waits for valuable information that came available due to organisational deadlines, and not the needs of the family. Some thought that this was strategic, hoping that the investigation process would become so long and awful that people would simply give up. For one participant, at times the fight became too much, and she was happy to let them win and go with their version of events for her own peace and mental health. With hindsight, some wished they would have been on their case more from the beginning to have their voices heard. Others spoke about *insensitivity of timing*, for example, one participant mentioned getting a phone call the day before her baby's funeral and scheduling a call the day after the funeral, but the call was not made at the agreed time. And only been given an hour meeting to discuss an unexpected baby death. This level of positivity was not felt to the same level where written statements were gathered. Some patients/family members felt particularly positive about the time limit set for the investigation process as they felt that this meant the organisation would not be able to drag out the process or be allowed to 'lose interest'. Patients/families felt, particularly following a bereavement, that arbitrary timelines set by the organisation did not meet their needs particularly during the grieving process. They also felt that being given a single opportunity for engagement in the investigation was not sufficient when the emotional impact of the incident was often so raw, and that this was an opportunity for organisations to tick an involvement box, rather than showing genuine interest in engaging patients/families. Some reported receiving letters or phone calls around the time of the funeral or significant dates, which they felt represented an impersonal or dehumanising position taken by the organisation. This was also true where patients were still receiving treatment. *Organisations being disingenuousness/defensive* While people felt that they were trying hard to be reasonable, measured and understanding of the Trust after harm, many felt they were not given the same respect in return. Issues included letters being back-dated, conveniently incomplete information, careful wording to omit blame, avoiding accountability for error, changing answers depending on where the conversation was going, withholding details, a lack of transparency, factually incorrect details, hallow promises, collusion, finding out things had happened after the fact, etc. For example, 'when I got a letter of response, I have often said that it was the worst day of my life'. The perception that investigations were *internal affairs* was an additional nuance perceived to deny any real scrutiny. With a HSIB investigation, the family welcomed the receipt of a draft report with the opportunity to comment, meet and discuss, etc. but felt that staff had more power to steer and mislead the investigation in the drafting process, bam-boozle them with clinical language and remove information that only the patient and family thought was important. *Litigation changing the path of the investigation* Once legal teams became involved, there was a breakdown in any informal communications directly with the Trust – the tone changed, delays, contrived language, additional layer of scrutiny, etc. Worked both ways, for example, one participant was disappointed that the legal team stripped some of the personal elements she had included in her correspondence with the Trust. Pursuing litigation was not a money grabbing exercise. Legal route was seen as a way of having experiences validated, being listened to, and getting a 'proper investigation'. Decision to pursue litigation was not taken lightly – disagreement within families and strain on relationships to go down that route. Also, additional expense that took time to be reimbursed.

Stage in the process	Initial impressions
4. Response	*Long-awaited report compounding harm and re-trauma – report reinforces divergence in expectations of Trust vs. patients and families* Report described as disheartening, disrespectful (e.g. copy and paste, typos, incorrect name), dishonest, paying lip service, tying themselves up in knots to protect the institution, lacking empathy, formal in tone and language, difficult to take in and understand, clinically focused, skirting round the edges avoiding the elephant in the room issue – also issues with *accessibility of report*. For most, reading the report was like it was talking about somebody else. It was the *first time they are finding out a lot of information*, for example, the promises to consider the information provided by patients and families were not upheld, did not acknowledge the questions they asked despite suggesting that they would – now decided that they all fall outside of terms of reference. Frustrating as the report is then *accepted as an objective truth* – feeling that the Trust can say whatever they want and there is no comeback from patients or families to that – It was common that between disclosure and receiving the investigation report through the post, patients/families had received no further contact from the Trust. *Exploitation of power dynamics*. Vulnerable/grieving patients and family feel like they are taking on an institution of professionals, for example, Headline conclusion of report was that the family had not communicated their concerns – assigning blame to the family who had been tirelessly trying to get the Trust to listen and were struggling with grieving their mum. Some felt really strongly about specific aspects of the report, for example, angered by the *recommendations for learning*, whereas others spoke about the report in a more general sense, for example, disappointed by it as a whole and unable to understand what it was actually saying – nuanced within and between participants. HSIB also went in as a 'one off', so the report could not address anything that came up later or find the underlying cause of discrepancies. Generally, patients and families appreciated that staff input was also important, but felt that more weighting was given to the staff involved in the incident and their version of what had happened, rather than the investigation considering the 'truth' of the incident from all perspectives, for example, participant perceived that where there were discrepancies between the family and staff version of what happened, the report tended to assume that staff were correct. Some patients/family members reported being happy with the investigation process outlined in the report, and felt they would have had nothing to add as they did not understand clinically what had happened to them, for example, participant noted minor errors but was satisfied with the report – he did not see it being something for him but for the organisation. *Left to pick up the pieces/motivations for further action* Once the report was published there was a sense that the organisation had done their job, and patients/families were left to pick up the pieces with their life in turmoil as a result, for example, loss of career, lifelong disability and loss of identity, ongoing care and treatment, disruption of family dynamics/other family members dealing with their own trauma, for example, divorce and challenging questions from children 'messed our whole family up', fear of revisiting health services/accessing private care in future, trying to process what happened and why, for example, self-blaming, mental health decline, etc. For some it became all-consuming, 'soul destroying' an ongoing 'outrage' of wanting to make sure that it does not happen to anyone else in the future. The investigation often ran alongside other emotionally and physically demanding things too, including those directly related to the incident which were often confused for one another, for example, inquest, coroner, legal processes, complaints processes, HSIB investigations, ongoing surgery and treatment, deterioration of health, fighting to be reimbursed for legal fees following the death of a baby while grieving, parliamentary inquiries, going through the appeals process, own investigations, registering the birth of the baby – staff congratulating even though the baby had died, liaising with experts to find answers and bring about change – universities, NHS improvement, looking back at relevant information – CQC reports, safety policy, etc. But also, other significant life events, for example, miscarriage of another baby while going through the investigation of baby death, breakdown of relationships, etc. *Sourcing support* Support offered by the Trust was not universal. Some accessed bereavement support, funeral arrangement support, introduced to charity support, offered counselling (but this compounded harm for patient as one of their opening questions to check if it was an appropriate environment to talk, the counsellor asked 'do you have any children in the house' following a baby death) – offers of support seem more common in maternity, for example, bereavement midwife went to funeral. Some built supportive relationships with others struggling in the same situation, often via social media. Some struggled to get support from loved ones due to diverse ways of dealing with it – often broke down rather than strengthened relationships. Some mentioned a tokenistic offer from the Trust to meet and answer any outstanding questions – but the organisation already knew the family had outstanding questions that they were promising to address in the report and did not.

Appendix 3 Handshake Booklet

PFI-SII
Involving Patients and Families in Serious Incident Investigations

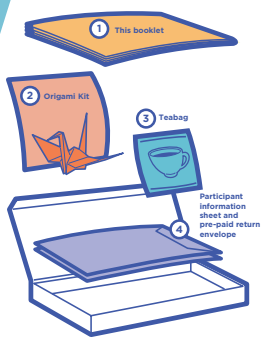
Hello, it's nice to meet you.

If you would like a member of the team to help you read or complete this document, or to answer any questions, please get in touch using the following details:

For questions on the design process and your involvement, contact Rebecca at **r.partridge@shu.ac.uk**

For questions about the wider project or to discuss any concerns, contact Lauren at **l.ramsey@leeds.ac.uk** or Siobhan at **siobhan.mchugh@bthft.nhs.uk**

What's in the Box?



1

"Hello, welcome to the start of the design phase of the Serious Incident Investigations Co-design Project. I'm Rebecca, one of the Design Researchers who will be leading this phase. You can find out more about our team on page 11.

Receiving this pack marks the beginning of this stage of the project. Please keep this booklet safe, it contains important information about the project, co-design sessions and what to expect. You can come back to it at anytime and our contact details, should you need them, are on the opposite page.

Thank you for joining us, we know how precious your time is and it's great to have you on board."

2

All the best things start with a hot drink. You'll find a teabag included in your box, so take a moment to put the kettle on and have a brew while we tell you a bit more about the project.

In this booklet.

Project Information.

It is estimated that ten thousand cases involving harm or death are reported in the NHS every year. Some of these cases are investigated as serious incidents by the NHS. **Indications suggest that greater involvement of patients and families in these investigations leads to better learning from such incidents, meaning they are less likely to occur in the future.** However, there is currently limited UK evidence to guide organisations in meaningfully involving patients and families in serious incident investigations.

What we hope to achieve.
This project aims to develop guidance to support more **meaningful involvement** of patients and families in serious incident investigations.

How we hope to achieve it.
We are working collaboratively with people who have experience of serious incident investigations (that's you) via a process called co-design. We will then test this new guidance out in live investigations.

Project Overview.

This project spans three years. The bit that you're involved in now is the second year. There are a range of activities happening across this year, as you can see on page 17.

At the end of year three we'd like to invite you back to an event to celebrate everyone's contributions and share the outcomes of the project. We'll be in touch with a date closer to the time.

We're here!

Final event

Year one

Interviews
Documentary Analysis of policies
Literature Review

In the first year the research team interviewed people who have experience of serious incident investigations. They looked at current policy documents along with published literature to understand current experiences.

Year Two

Co-Design Activities

The focus of the second year is to take the learning from year one and over a series of interactions work together to design new processes to support more meaningful involvement of patients and families in serious investigations.

See page 17 for a detailed view of what we have planned in year two.

Year Three

Trial of new processes

During the final year, the new guidance will be applied to live investigations. The team will talk to those involved in these investigations to understand their experiences. This will help us to evaluate the guidance.

Team Members.

This project draws on expertise from multiple areas. You may have already met the research team from Bradford. If not, then here are some of them who you might meet during your involvement in this project.

Whilst this team are overseeing the whole project and have conducted all the activities during the first year it is the team at Lab4Living who will be running the design phase discussed in this booklet. You'll find out more about them on the next page.

9

Jane is a Professor of Healthcare Quality & Safety. Her expertise is in patient safety and she leads this research project.

Ruth is the PFI-SII Programme Manager. Her expertise is in psychological trauma, mental health and wellbeing.

Siobhan is a Research Fellow. Her expertise is involving patients, families and staff in health service improvement and patient safety.

Lauren is a Research Fellow. Her expertise is in exploring different perspectives of patient and family involvement in patient safety.

10

Lab4Living.

Lab4Living is a collaborative community of researchers in design, healthcare and creative practices. Our work spans more than 100 research projects and has included collaborations in over 80 academic, hospital and community organisations in over fifteen countries.

Here at Lab4Living our expertise is in designing things with end users like yourselves. It's important to know that we're experts in co-design but not serious incident investigations. As far as we're concerned, if you are reading this then you are the expert. If you've never been involved in co-design before there's more information on the next page.

11

Becca is a Design Researcher. Her expertise is in the facilitation of creative methods.

Joe is a Principal Research Fellow. His expertise is knowledge mobilisation.

Chris is a Designer and Illustrator. His expertise is making knowledge accessible to everyone.

12

Co-design.

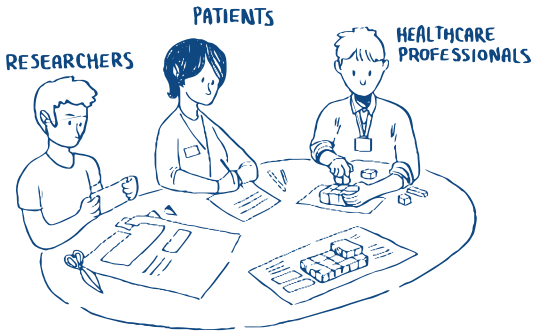
Co-design describes a design process used in research where **designers and those with experience or knowledge of the thing to be designed, work together.**

Co-design spans the whole design process from **understanding experiences, deciding design priorities, proposing solutions, and developing the desired outcome.** It doesn't dwell on the past, but looks to create new and better futures.

In co-design, designers, other researchers and co-design partners (you) share knowledge, skills and experiences. **It is creative and uses a range of methods.**

13

You will be asked to draw upon your previous experiences to create these better futures - but we won't dwell on the individual. Therefore **there may not be an opportunity for you to share your personal experience completely.**



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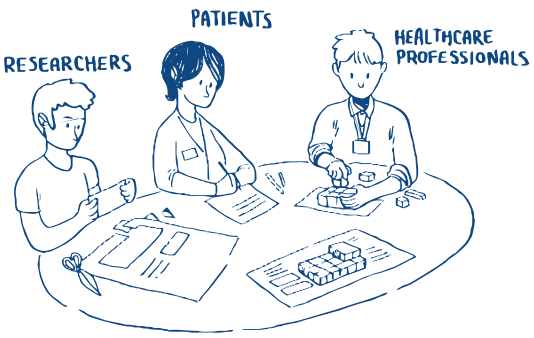
13

You will be asked to draw upon your previous experiences to create these better futures - but we won't dwell on the individual. Therefore **there may not be an opportunity for you to share your personal experience completely.**



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What to Expect.

Here's an overview of what your involvement will look like. There are around 50 people involved in the project in total, who will all meet for the stakeholder events. For the co-design sessions you'll meet in smaller groups of around 15, these are specific to a workstream; acute, mental health or national investigations.

We are asking that everyone attends all the events they have signed up for. We are trying to accommodate ways that people can maximise their project involvement. We'll ask you for more information on this in information sheet.

17

Co-Design workshop dates
Mental health: 17th May & 5th July
Acute Health: 19th May & 7th July
National Level: 21st May & 9th July

All workshops are from 1-4pm and will be held virtually using zoom. You will receive a link nearer the time.

Arriving on your doorstep w/c 12th April: An at-home activity to complete. You will be invited to reflect on an example serious incident investigation and the different perspectives throughout.

21st April: A full project event to establish common principles based on the findings from year one and reflection on the building stories kits.

Smaller workstream groups

W/c 17th May & 5th July (see box on left for workstream dates) : Using the common principles we'll consider what the new processes might look like and refine them to make sure they work for everyone.

22nd September: Final sharing event to reflect on what has been learnt, and agree the final processes and guidance

Date TBC: A full project celebration event.

18

Your Information.

Throughout this process we'll send things to you and ask you to send things back to us in return (electronic or via post). As we're all doing this research from our own homes, these are the best ways for us to share information.

The first thing to send to us is some information and your communication preferences. This helps us to get to know you a bit better and ensures we have all we need to support you.

You may have already provided some of this information to the research team, but this ensures that the Design Researchers are communicating in the way that best suits you.

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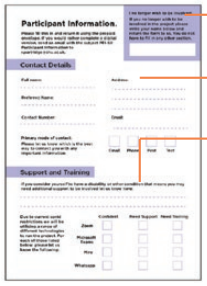

If you would rather return this information electronically please send an email with the subject heading **PFI-SII participant information** to r.partridge@shu.ac.uk. I will send you a digital version of the form.

If you no longer wish to be involved in this project, fill in this section only.

Contact Details: So we know how best to contact you.

Support & Training: To make it as easy as possible for you to be involved or you require additional support or training needs.

Information about you: So we can get to know who we're working with.

Payment: If you are not participating in your professional capacity, or are participating during your own time (on leave, days off etc.) then we are happy to pay you for your time, at rates suggested by INVOLVE. Please tick here if you want us to send information to you to claim for your time in this co-design community.

Experience: So we can understand the range of experience within the group.

20

What's Next?

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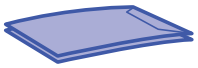
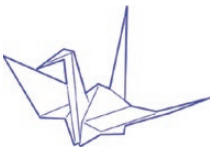


Put your Information sheet in the post. Unless you say otherwise, we'll assume you still want to be involved. **If we do not hear from you by April 19th then the design team will follow up to confirm your information and preferences.**



Have a go at your origami kit.

Keep an eye out for your investigating the investigation kit. This will arrive on or close to the 12th April. Please complete this before the first stakeholder event.

22

Have a great rest of your day.

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PFI-SII
Involving Patients and Families in Serious Incident Investigations

Appendix 4 Rebuilding Investigations Kit

Rebuilding Investigations Kit

Design and Development Case Study

Background

Working with the University of Leeds and Bradford University, Lab4Living were asked to help lead a number of co-design sessions with a large group of participants who had all been involved in a serious incident at hospital - either as a patient, family member, staff member or external support group.

At the time (2019/20) a "serious incident" was defined as an adverse event that happens while a person is under the care of a Trust. If an event is defined as "serious" then it requires an investigation by the Trust to discover and learn from what happened. The aim of the wider project was to explore how to better involve patients and families in these investigations and prevent the investigation from being another cause of harm.

Lab4Living wanted to involve the co-design participants in a meaningful way from the start; to give everyone a shared understanding of what the project had learned so far. The research team had pulled together literature reviews, interviews, and other forms of evidence and from these had created three "stories". These were fictional descriptions of serious incidents using invented characters but inspired by true events.

These stories formed the starting point of our work. They were an efficient way of getting Lab4Living up to speed with the realities of serious incidents. As much as we were trying to inform the co-design participants, we first had to inform ourselves. Our long-term goal was to make these stories more interactive and to encourage people to interact with them physically and spatially, rather than simply reading them. The intention was that by thinking critically and engaging in a form of making, the participants would come to the co-design sessions primed and empowered, with a common vocabulary and understanding of the entire process of a serious incident investigation. They would also be exposed to the 'other side' of these stories, by seeing events from multiple points of view.

Creative limitations

With the restrictions of Covid-19 still in place we needed to be able to deliver this interactive story to people by post so from the start we decided that whatever we produced had to fit through a standard letterbox. Previous work by Lab4Living has explored the use of card games as a way to gradually introduce people to complex information, whilst allowing them to group, organise, prioritise or hide this information in a way that makes sense to them. The card format also proved easy to design and prototype without access to university workshop facilities as staff were working remotely during this time.

Inspiration

From the beginning, Chris Ware's graphic novel 'Building Stories' resonated with the team. Building Stories is presented like a board game. It comes in a box and includes various components; comic strips, booklets, newspapers and game boards that can be read in any order. Each component tells its own story whilst contributing to a larger narrative. Some components of the box might tell the story of the main character; a woman living alone in an apartment block, but others shift the focus to the other residents of the building, or the bee that hovers outside her window. Even the building itself has a voice and a story to tell

Taking inspiration from Building Stories we wanted to shed light on the people and places involved in serious incident investigations. We wanted there to be a sense of exploration and investigation present in the experience, a process of piecing together a narrative. Not only this but we wanted there to be an element of chance, that some information might never surface during your time with the story, something common to any type of investigation.

Chris Ware's 'Building Stories'

The stories we started with

The research team at the University of Leeds and Bradford University distilled their literature reviews, interviews and other evidence into three stories. These stories were fictional and told the events surrounding a serious incident investigation. The team settled on three stories to show a broad range of incidents and investigations.

Story 1: An elderly patient suffers a hip fracture after receiving too high a dose of morphine.

Story 2: A hearing impaired female patient with PTSD is surprised by a staff member and pushes them away. The result is injury to the staff member and distress to the patient.

Story 3: Maternal death during a complex caesarean.
We started by taking each story and mapping it out visually and spatially to better understand at a glance the main characters and events and how they linked to each other.

Serious Incident Investigation 1

Incident 1 – Acute Trust

Brief description of incident: A medication error. At night, on the acute elderly care ward, a nurse gave a female patient too high a dose of morphine. This caused the patient considerable disorientation and confusion – to the extent that she got out of bed, agitated, was so unstable that she fell, fracturing her hip. This subsequently required surgery.

- The patient was originally admitted for a UTI which was causing confusion and pain.
- The incident happened during a night shift which typically has fewer members of staff working.
- There were staff shortages on this particular night shift (there was only the matron and nurse working). Therefore the required protocol of double-checking medication was not undertaken.
- A male nurse administered the incorrect dose.

Key agents involved in this incident:

- Patient, age 79, female (recently widowed)
- Patient's son, aged 45 and family.
- Male nurse administering medication
- Matron on the ward
- Clinician in charge of this patient
- Pharmacist who prepared the medication
- Falls coordinator for the ward
- Investigator.
- Orthopaedic surgeons who operated on the hip.

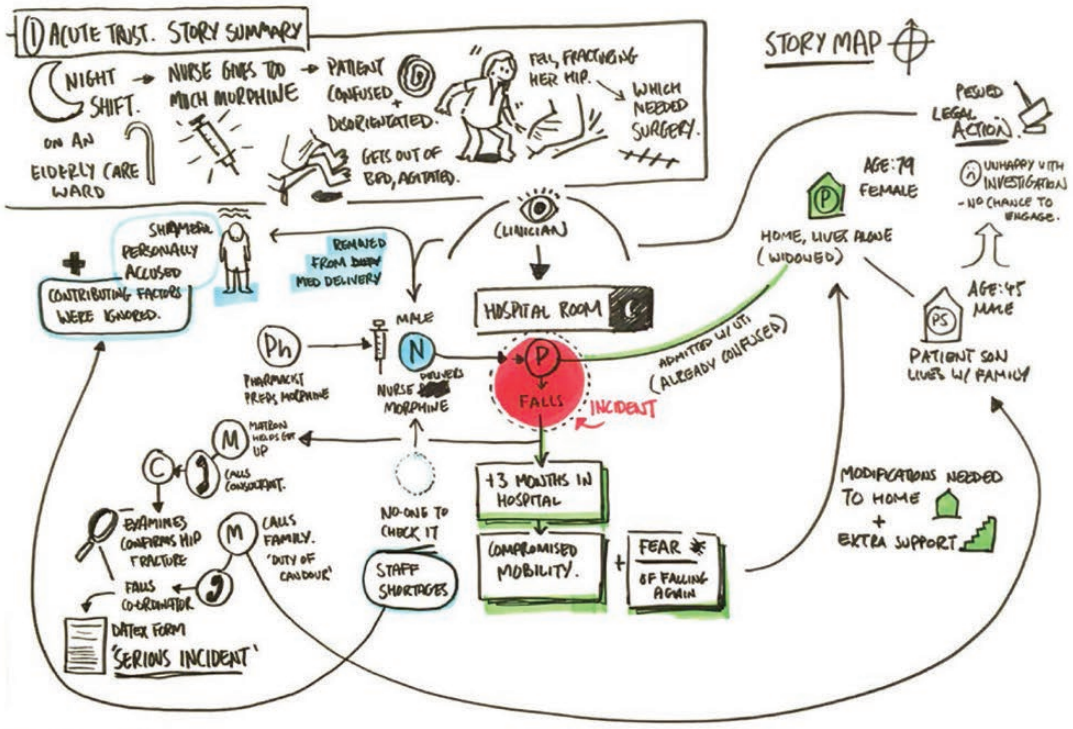
Impact of the incident/long term effects:

- Cumulative period of hospitalisation - 3 months (i.e. significantly extended from original reason for admission)
- Permanent compromised mobility (i.e. requiring adaptations at home/care)
- Fear of falling/anxiety
- Extra support with activities needed at home

Extract from Story 1

Visual Maps

To help us see the events, locations and people in these stories we created some visual maps. This meant it was easier to focus on each person's role by looking at an image instead of having to find their part in the story. We could also link events or people together using lines and arrows. This helped us to understand the complex relationships at work in these scenarios.



Visual Map of Story 1

Deciding on a single story

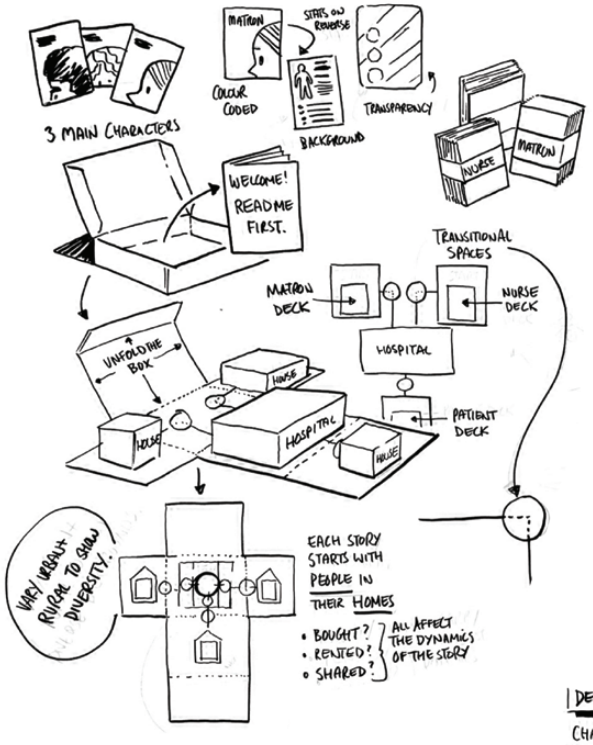
Our first instinct was to include all three stories in the activity we designed. We soon decided that we would only use Story 1. This was for a number of reasons:

- To reduce the development time
- It was the most straightforward narrative, something made clearer by its visual map. It was important for us to reduce the complexity of the activity and time expected of the partners.
- Story 1, although very serious, featured the fewest instances of injury and made no mention of patient death - something many of our co-design partners had experienced first hand. Whilst still a very triggering subject, we hoped that this would reduce the emotional burden on our partners.

It is worth mentioning that before we decided on a single story we wrote up our intention and inspiration as a design brief for second year Graphic Design students at Sheffield Hallam. The only limitation we placed on their work was to ensure the final product would fit through a letterbox. With such a wide scope, the resulting projects were interesting and demonstrated novel approaches but the short project length didn't let them get beyond very rough drafts.

Design Concepts

With a single story to focus on we started sketching potential ways of telling it. We explored many ideas and were presented with many questions at this time, including:



What order should the story be told? Chronological or should the incident come first?

How can we make it easy for people to know what to do next? Are there instructions?

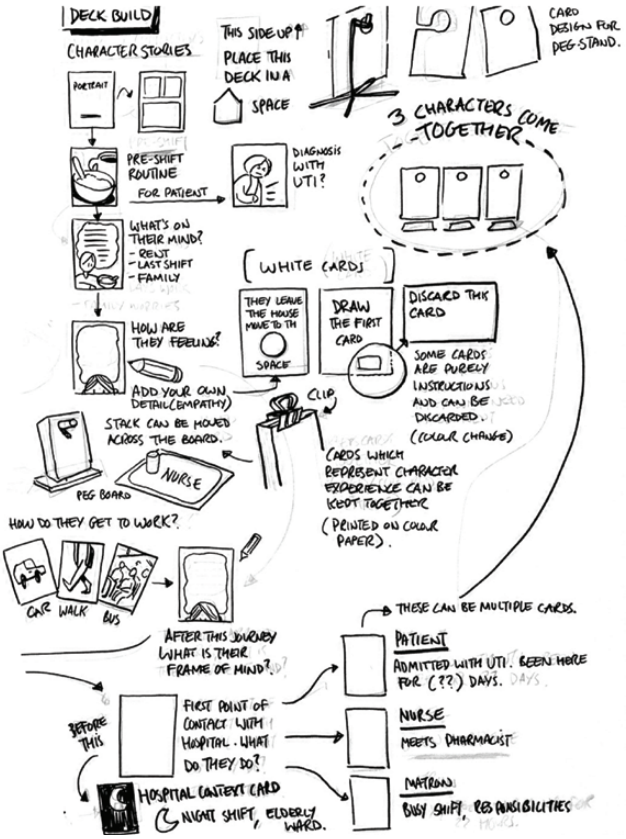
How can we represent a complex system in a simple way?

How can we hide information from the participants? Can we use transparency or windows that reveal or block information from view?

Can we represent the locations in the stories as top down maps that the characters move through?

How can we get an insight into the complexity of the characters' everyday lives. How can we show their moods, emotions or any other behaviour that might have contributed to the incident or how they responded to it?

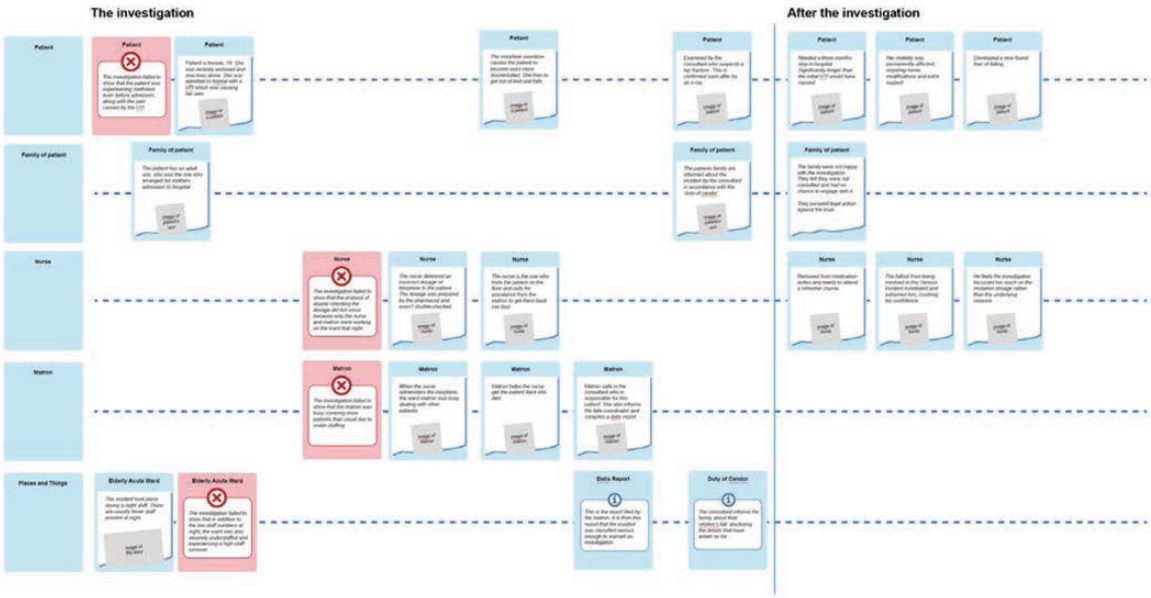
Is the activity actually a recreation of an investigation? Is it told from the point of view of the investigator?



Version 1

One of the earliest decisions was not to make a 'playable map' where characters moved through locations in the story. We decided it was more important to see how events unfolded through time, and that by the end of playing you should have an overview of the event from start to finish. This way it will be possible to then jump back into specific points in time and question why things happened the way they did.

We settled on the idea that the game board would be a timeline split roughly into 2 main phases; the **investigation** and **after the investigation**.



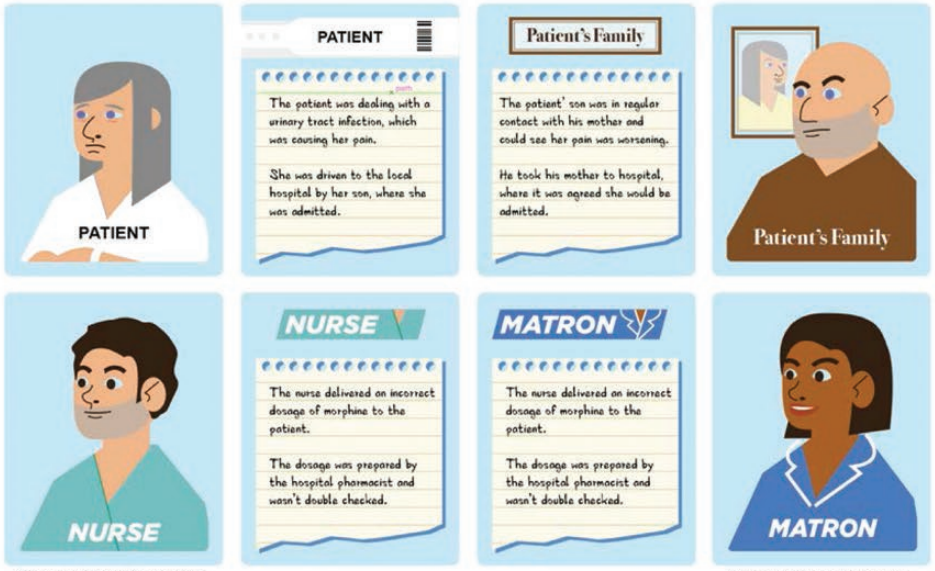
Each character in the story has their own 'lane' in the timeline (almost like a swimming pool). The final lane was initially assigned to 'places and things' as a way of capturing anything that didn't relate to a specific character. We thought this might cover the ward or Trust or some policy document might have been involved in the event.

In version 1 we used blue cards to represent the notes made by the investigator. The game is played almost as though you are reading the investigators notes over their shoulder. Each card drawn reveals a new piece of information that the player needs to place on the timeline. After completing the blue deck, the player would be directed to complete a blue form where they can record their conclusions, thoughts and reflections.

Next the player would then start drawing a certain number of red cards which represent 'information the investigation missed'. Now they would complete a red form which asks how their opinion might have changed.

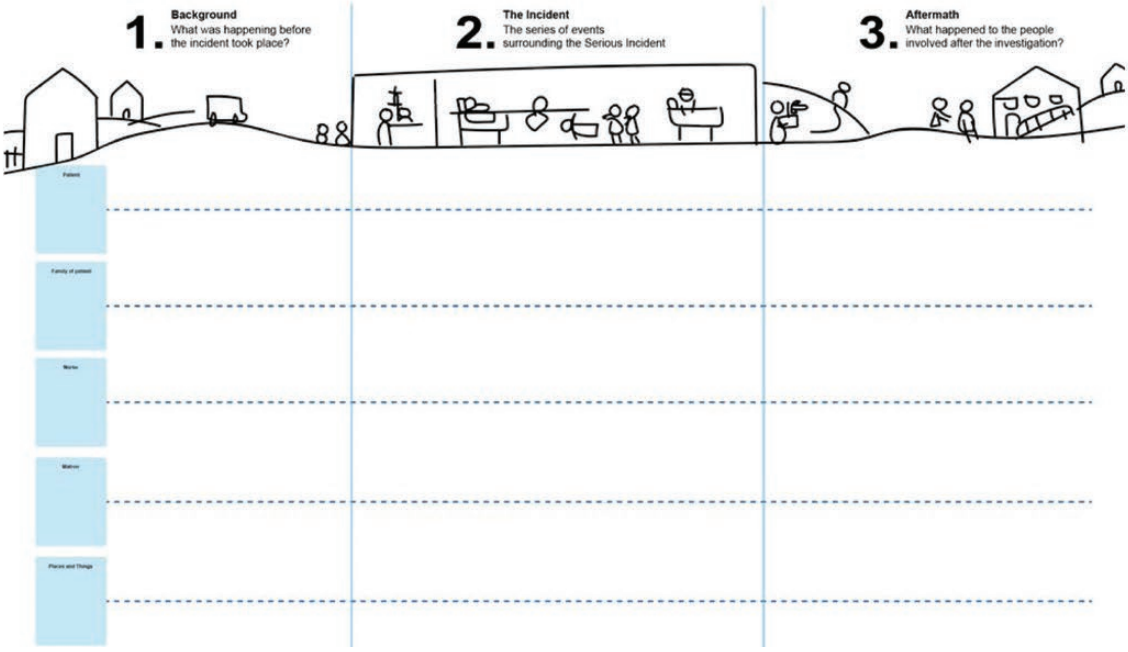
Version 2

Version 2 refined the design and added more depth to the characters. Each character has a double sided card with a portrait and a very small bio that might give some idea of their mindset before the event starts to unfold.



Character info on the reverse *Character info on the reverse*

For this more character driven appoach we added a section called **background** to give each character time to 'arrive' before the incident takes place. Version 2 also marked a shift in how we viewed the experience. In version 1 we were reading investigation notes presumably after the incident. Now we are experiencing events as they happen. This more objective point of view helped us to see the incident more holistically - and to be able to make a better judgement on the findings of the investigation.

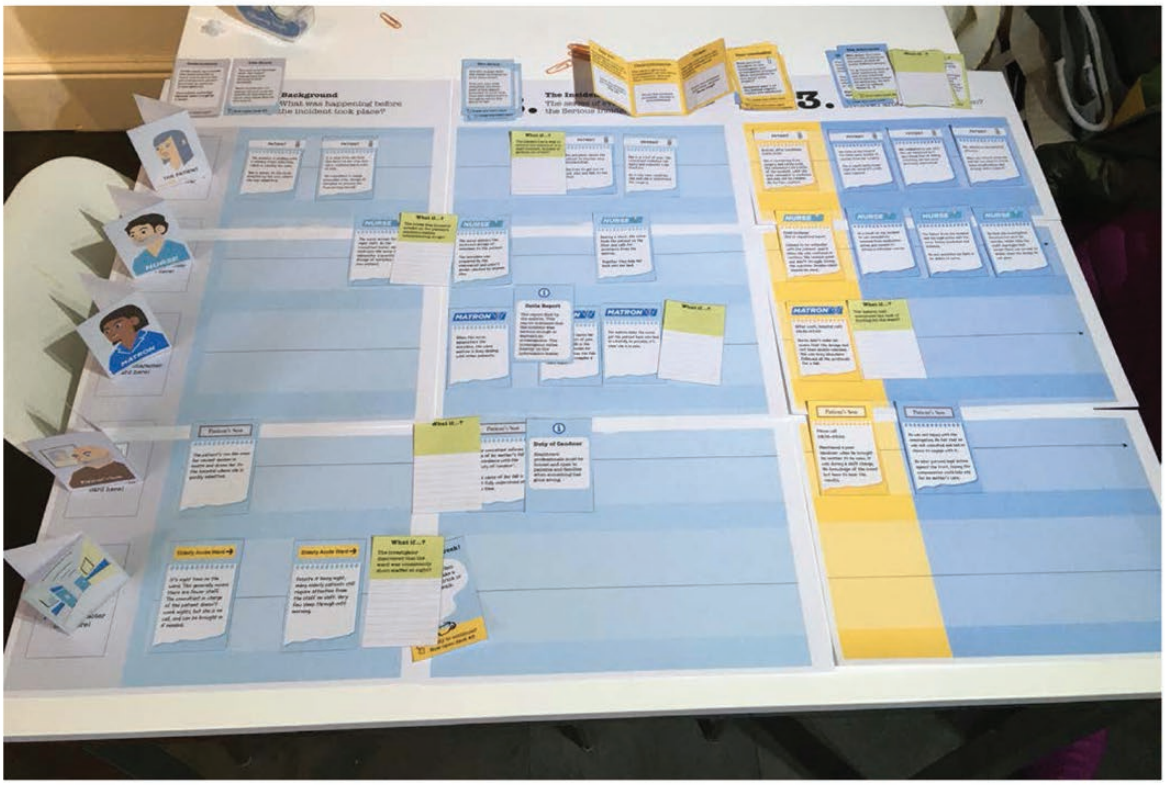


Version 3

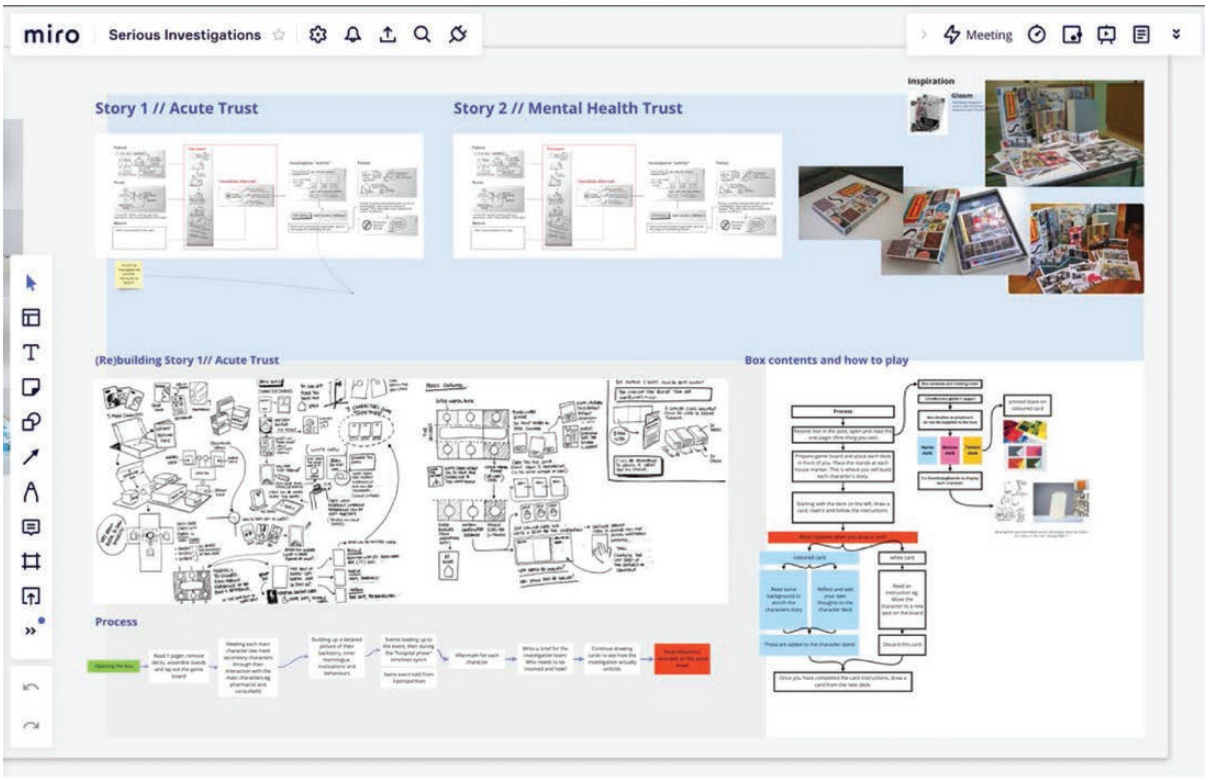
With the changes made in Version 2 we felt like we had lost the important focus on the investigation process. So we added an **investigation phase** (the yellow bar).

The investigation phase kicks in once the incident has concluded (in this case the patient has received an injury, but is now safe and under observation). After discussions with the wider research team we learned that investigations are never a consistent length - they could be over very quickly or be very detailed. We wanted to represent this in the game by having players draw through their deck until they hit a card that says 'The investigation is over'. Each player would hit this point at different times and mean that their experience of the investigation would be completely different. We believed this would be a good way to spark conversation between participants when we eventually came together to discuss the activity.

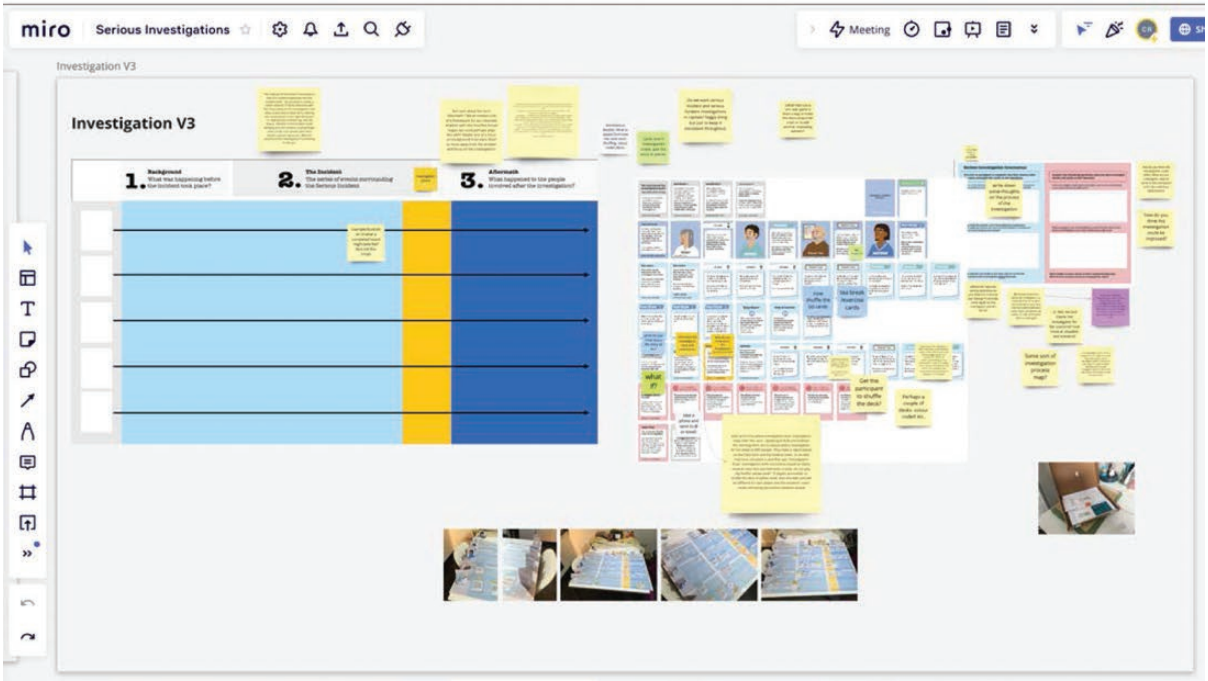
During this version we also started to question the validity of the red cards. The language we used "the investigation failed to show…" placed an unfair focus on the supposed failure of the investigator, even though this may have been no fault of their own. We decided that the next version should give more insight into the investigator as a person, that they should be seen as human and on the same level as the patients and staff involved.

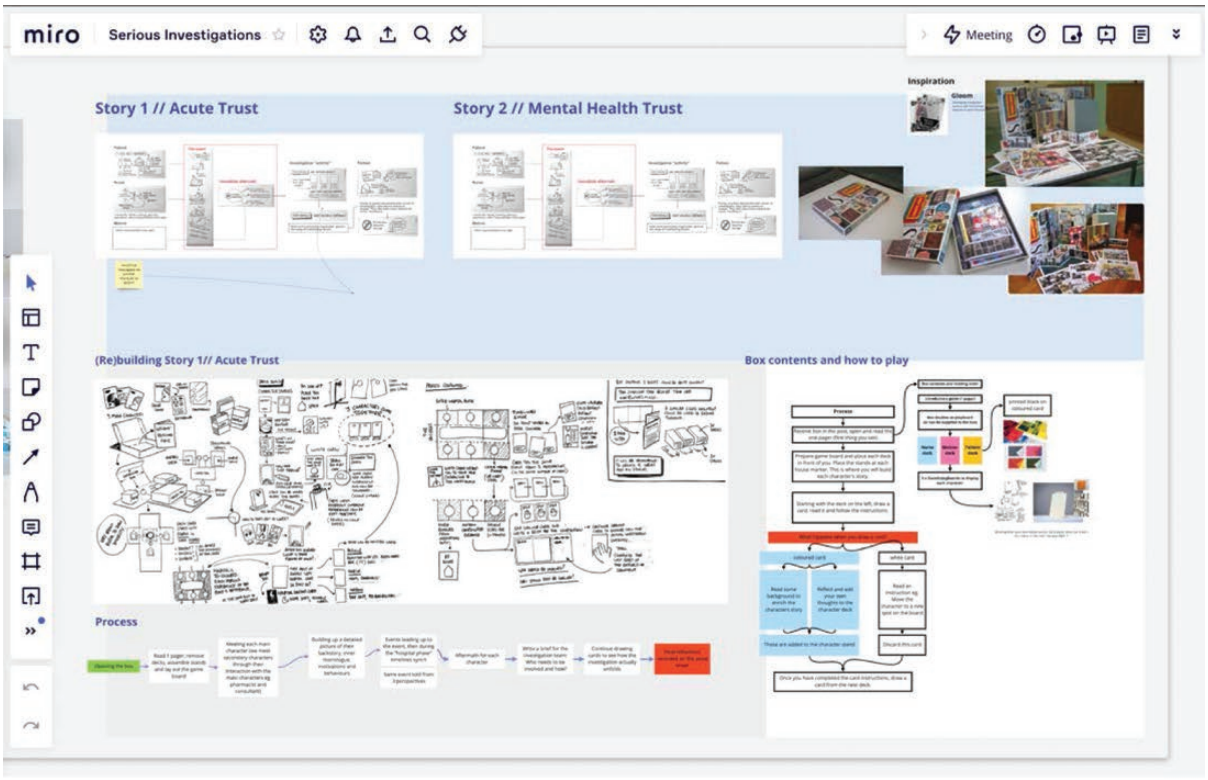


Playable prototype of Version 3



Throughout the design process we shared our progress and ideas on Miro, which we found to be the easiest way to collect images, photos and scanned sketches in one place and allowed annotation via sticky notes whenever was convenient for the team, or a more in depth discussion during a video call.





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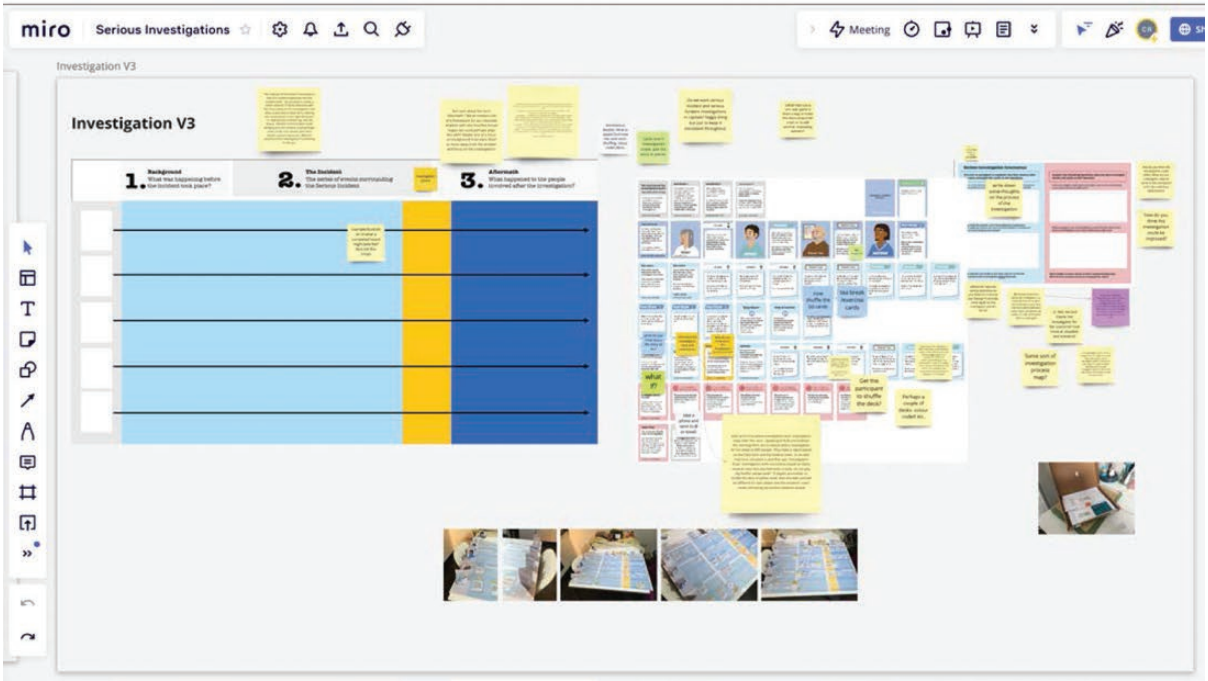
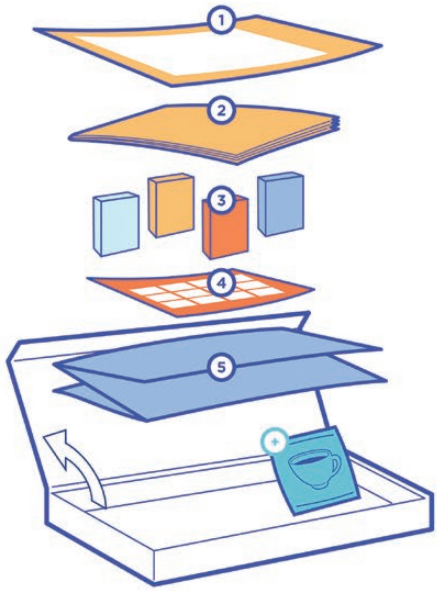


The Rebuilding Investigations Kit (Version 5)

The kit we sent out to the participants contained the elements mentioned previously as well as some additional pieces to help them play the game and record their experiences. The complete contents of the kit are as follows (this is also the order that they are seen as the box is opened):



1. Double-sided instruction - We kept the introductory instructions to a single sheet.

2. Activity booklet - At various points in the activity participants are asked to record their thoughts in this book.

3. 4 decks of cards - All cards are numbered and worked through one at a time to complete the activity.

4. Sticker sheet - Used as part of the activity

5. Timeline mat - Cards are placed onto this mat

+ Individually wrapped teabag - Something we include in all our postal packs

The kit could be played without any extra instruction from us, all the instructions were contained on the double-sided sheet and included on the cards. We play tested many times to ensure there was no point where people hit a dead-end or got lost.

Playtesting the game during a Lab4Living studio day

The Rebuilding Investigations Kit (Version 5)

Feedback and future usage

After receiving and working through the Rebuilding Investigations Kit we received positive feedback from the co-design partners. Some commented that they found completing the activity emotional, saying that it helped them empathise with staff members and helped them feel less angry. They also reflected that everyone in the story seemed to have issues with a lack of information, understanding and support, which they thought was a sad indictment. They also said how powerful this could be for training purposes.

As mentioned at the very start of this case study the main role of Lab4Living in this project was to design and run a number of co-design sessions. The Rebuilding Investigations Kit, although time consuming, was created for the co-design partners to help them come together through a shared experience (despite working in isolation). The co-design sessions later highlighted a need for information and support which we developed into a set of resources for staff. Here the Rebuilding Investigations Kit found its second life as a training tool to help introduce staff members to the intricacies of serious incident investigations.

A note on language

Internally we have referred to the method described here as 'Research Games' but externally it depends on the context. For the work described here 'games' feels insensitive, as does the word 'story'. Although we might use these words to help us explain the project we didn't use them in the work itself. Instead we found the words 'activity' or 'kit' more suitable.

The Lab4Living team:

Joe Langley - Principal Research Fellow
Rebecca Partridge - Design Researcher
Chris Redford - Designer

Appendix 5 Survey questions (substudy)

1. What was your relationship to the person who died? (e.g. spouse, parent, friend, colleague)
2. Below is space for you to tell us a bit more about the person who died, and/or your relationship with them, if you would like to. This question is completely optional.
3. Please tell us as much as you feel comfortable about what happened to the person who died (this might include how/where/when they died).
4. Did the person who died have any history of medical treatment with the NHS (this might include any health concerns they had, or any access to physical or mental health care)? You can tell us as much as you feel comfortable here, and do not need to go into detail. This information will help us understand whether they were (or ever had been) linked to NHS or other healthcare providers.
5. How often were you in contact with the deceased? There is also space to tell us about the nature of this contact (e.g. online/telephone/face to face) if you would like to. You can provide as much or as little information as you feel comfortable with here.
6. Was there an investigation carried out by the NHS after the person died?
   - 6a. Who carried out the investigation? (e.g. an NHS Trust, the HSIB, an independent investigation team).
   - 6b. How, and at what point, were you involved in the investigation?
   - 6c. Was there anything you feel you could have/wanted to contribute to the investigation that you did not get the opportunity to say?
   - 6d. How did you feel about the outcome of the investigation?
   - 6e. How effective do you feel the investigation was to find out what happened, why it happened, and what the NHS might have done differently?
7. Was there an inquest after the person died?
   - 7a. How were you involved in the inquest?
   - 7b. Was there anything you feel you could have/wanted to contribute to the inquest that you did not get the opportunity to?
   - 7c. How did you feel about the outcome of the inquest?
   - 7d. How effective do you feel the inquest was to find out what happened, why it happened, and what might have been done differently?
8. Was there police involvement following the death?
   - 8a. How were the police involved after the person died?
9. Was there anything you were concerned about in the months or years leading up to the point the person died? You can tell us as much or as little as you feel comfortable with.
10. Did you, or the person who died, contact or speak to any support services (including health services, charities, community groups, friends or family members, etc.) in the months or years before they died? Please only tell us what you are comfortable with sharing.
11. What, if anything, do you feel could have been done better to support or protect the person who died? You can tell us as much or as little as you feel comfortable with.
12. Is there any other information about the deceased or the processes that happened after their death that you want to share with us?
13. How old are you?
14. What is your gender?
15. What is your ethnicity?

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HTA
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