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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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Scientific summary

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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.

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