

Bradford Institute for Health Research / University of Leeds

# PFI-SII Project Research Summary

Involving Patients and Families in Serious Incident Investigations



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## **Patient and family involvement in serious incident investigations: Developing and testing national and local guiding processes.**

### **Summary of Research (abstract)**

#### *Overall Research 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.

#### *Background*

Reported serious incidents (severe harm or death) are estimated to be 10,000 annually, with enormous, ever increasing costs associated with litigation. There is a need to improve the process of learning from serious incidents to reduce incidence, and the financial burden of litigation. The reasons why claims are pursued are complex and, as yet, unclear. NHS Resolution posit that involving patients and families earlier in investigations will reduce costs of administering claims, as well as divert claims pursued for explanation. Other policy and regulatory organisations have proposed greater involvement of patients and families in serious incident investigations, to support better learning. However, there is currently no UK-based evidence to guide organisations to involve patients and families meaningfully in serious incident investigations, to support learning, or reduce the likelihood of litigation.

#### *Methods*

In Stage 1 (0-6months), a documentary analysis of published policies within England will explore how NHS Trusts involve of patients and families in serious incident investigations. A scoping review will explore the involvement of patients and families in serious incident investigations and decisions to litigate. In Stage 2 (7-15months) we will interview patients, families, investigators and healthcare staff (n=60), to support development of the programme theory underpinning the co-designed processes. Data from these stages will be integrated in Stage 2B, to guide co-design. In Stage 3 (16- 21months), we will co-design three parallel processes to involve patients and families in serious incident investigations, within national (Healthcare Safety Investigation Branch: HSIB), mental health and acute care. In Stage 4 (22-34months), we will implement the prototype guidance and resources in 25 investigations across 5 organisations, conducting a focused ethnography to assess feasibility, and explore stakeholder experiences, impact on learning, recommendations, actions, and decisions to litigate. In Stage 5 (35-39months), the final guidance and digital platform will be produced.

#### *Impact and Dissemination*

Commissioners, regulators and policy makers have all been consulted in preparing this proposal, and have a keen interest in the final research outputs. The HSIB are committed to using the co-designed process, and will role model this usage for the wider NHS. We plan to disseminate widely, to a variety of audiences, through eight academic publications, two policy-facing reports, and the key research output – the co-designed guidance on a digital platform.

## **Research Team**

*Principal Investigator:*  
Dr Jane O'Hara

*Co-applicants:*  
Professor Rebecca Lawton  
Dr Gemma Louch  
Dr Laura Sheard  
Scott Morrish  
Professor Carl Macrae  
Professor John Baker  
Dr Joseph Langley  
Professor Justin Waring

*Collaborating organisations:*  
Bradford Teaching Hospitals NHS Foundation Trust  
Bradford District Care NHS Foundation Trust  
York and Leeds Partnership NHS Foundation Trust  
York Teaching Hospitals NHS Foundation Trust  
Healthcare Safety Investigation Branch

## **Background and Rationale**

The Serious Incident Framework published by NHS England in 2015 defines 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.” In the UK, reported serious incidents (causing severe harm or death) are estimated to be around 10,000 annually. In 2016-17, clinical negligence claims totalled £1.7billion, with £1.8billion to administer and settle claims, and long-term liabilities in the region of £65billion. These figures highlight two key issues: First, the significant burden of litigation on health service finances, and second, the need to improve the process of learning from serious incidents to reduce their incidence.

### *Improving learning from serious incidents*

The proposed research is important to patients and healthcare services in three key ways. First, for those involved in a serious incident – healthcare 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. Therefore, exploring how to improve the experience and transparency of investigatory processes for all stakeholders, is desirable both morally, and financially. Second, improving learning from serious incidents may reduce the likelihood of future events, 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 in, 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 may help to improve transparency and trust in investigation processes.

Despite the policy focus, the published evidence for patient and family involvement is scarce. However, patients are now recognised as a source of information about patient safety and incidents that other error detection methods (staff reports, case note review) do not access. Put simply, patients and families represent an untapped resource for investigations, particularly where events have unfolded over time (e.g. diagnostic error or delay), where they represent the common denominator across healthcare settings. Current evidence therefore suggests that patients and families could, and arguably should, be involved in serious incident investigations.

## Research 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.

## Research Plan

### Stage 1 (months 0-6)

#### *1. What is the current involvement of patients and families in serious incident investigations?*

A comprehensive **scoping review** of the literature will be conducted to understand the involvement of patients and families in serious incident investigations. This will be an international literature review. We expect the review will include academic outputs, policy situated grey literature and potentially material from third sector organisations. A desk based **documentary analysis** of serious incident investigation policies in England will be conducted. We will explore how NHS Trusts explicitly state they will perform serious incident investigations and how patients and families are currently involved. This stage of the research represents an excellent opportunity within which to identify what might be regarded as best practice, and map out the 'landscape' in terms of Trust-level policies for involving patients and families in serious incident investigations, across the entirety of the acute and mental health service in England. This stage will support the development of the programme theory underpinning the co-designed processes.

### Stage 2 (months 7-15)

#### *1. What is the current involvement of patients and families in serious incident investigations?*

#### *2. 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?*

#### *3. What is the experience of frontline healthcare staff and investigators who have been involved in a serious incident investigation, and what might have influenced decisions to litigate?*

#### *4. What are the views of frontline healthcare staff and investigators on the potential involvement of patients and families in serious incident investigations?*

In this stage, we will first conduct **an in-depth interview study** to both understand the context within which the processes for supporting great patient and family involvement in serious incident investigations will operate, and support the further development of the programme theory underpinning the co- designed processes. First, we will seek to interview patients and families, who have been involved in a serious incident and the process of serious incident investigation, who have either proceeded or not proceeded through to litigation. Second, we will seek to interview healthcare staff and investigators who have been involved in a serious incident and the process of serious incident investigation. Around sixty interviews will be undertaken across all the organisations taking part in the study. This will be stratified as follows: thirty patient and family participants, twenty healthcare staff participants and ten investigators. We would aim for our sample of patients and family participants proposed (n=30) to collectively have experiences across the range of processes following a serious incident, including the initial incident, the incident investigation (and other official investigation processes), complaints and litigation.

The second part of this stage will be to integrate what we have explored within Stages 1 and 2, and create a synthesis of the findings, to take into Stage 3.

### Stage 3 (months 16-21)

#### *5. What are the common principles necessary for involving patients and families in serious incident investigations?*

#### *6. How might these common principles be reflected in local and national processes for involving patients and families in serious incident investigations?*

First, a **stakeholder event** will be convened involving patients and families, healthcare staff, national and local investigators, legal representatives, and representatives from patient advocacy groups. Recruitment for this event will be discussed within the Steering Group, with suggested targeted invitations undertaken either directly, or through networks via our research collaborators (e.g. NHS Resolution, Action against Medical Accidents - AvMA). The aim will be to present and explore the integrated findings from Stage 2B with stakeholders, leading to the development of a set of common principles for involving patients and families in serious incident investigations.

Next, we will **co-design three parallel processes for guiding patient and family involvement in serious incident investigations** in three key healthcare settings: i) national level, ii) mental health care and iii) acute care. Participants will be recruited from the stakeholder event into three parallel co-design work streams. Each work stream will focus on one of the three settings outlined, and comprise two co-design workshops (6 in total, 3 hours each) and a final 'sharing event' (3-4 hours) with design work by the Co-Design Team before, between and after each workshop. The participants in each work stream (12-16 for each work stream) will comprise patients and families, healthcare staff, investigators, patient advocacy groups, relevant professional bodies, researchers and designers. This stage will first explore the 'common principles', before developing context and content specific details investigation processes.

The final part of this stage will be a '**sharing event**', which will bring participants and outputs of the three co-design workstreams together to reflect, share learning, and finalise the agreed processes.

#### Stage 4 (months 22-35)

*7. Are co-designed processes for involving patients and families in serious incident investigations feasible and acceptable to patients, families, healthcare staff and investigators?*

*8. How do co-designed processes influence serious incident investigations in terms of depth of learning, recommendations, action plans, and decisions to litigate?*

The **three co-designed processes will be implemented** over the course of 12 months, alongside 25 investigations: 5 at HSIB, and 5 at each of the four participating NHS Trusts. Investigation cases will be sensitively chosen in collaboration with management at the respective organisations and will be sampled on a range of specialities, and using pre-defined criteria.

A **focused ethnographic study** will assess feasibility and acceptability of the three new processes, explore the experiences of stakeholders, and the impact on depth of learning, recommendations, and actions planned. This will involve investigating the 'life-cycle' of the sample investigations. Upon an investigation being started the research team will be contacted by the relevant lead investigator from the participating NHS Trusts. An initial 'briefing interview' with the investigator will be arranged, and the schedule of meetings confirmed with the researchers. From this point, a field researcher will 'shadow' the investigator to describe the processes of evidence gathering and preliminary analysis, for example collecting witness statements. During this time a preliminary interview will be arranged with the patient and/or family members to understand their expectations of the process and views about the incident; this will be arranged after they have been contacted by the lead investigator (n=25; one per investigation). Patients and family members will also be observed where they are provided with the co-produced guidance developed through Stage 3. All investigating meetings involving patients and family members will be observed, estimated between 3 and 5. In addition, the content and recommendations of each Investigation Report will be reviewed to determine the extent of influence of patient and family involvement. It is anticipated that the life-cycle of each investigation will take around 60 days, in accordance with reporting requirements. After this period, a further series of interviews will be carried out with professionals (healthcare staff and investigators) and patient/family members (n=3- 5 per investigation: 75-125 in total) to understand their experiences of the investigation processes.

### Stage 5 (months 36-39)

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

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

During this stage the three co-designed processes will be further refined based on our findings. We will convene a **final stakeholder event** to come together and advise the research team as to how the tested processes should be revised into final versions which could be disseminated further.

### **What do we intend to produce from this research?**

#### *Key research outputs*

This study will be using co-design as a method for producing the new guidance. However, at this stage, we anticipate that the final outputs produced might be:

- (1) an **interactive decision tree** with appropriate supporting resources at each decision junction;
- (2) existing in a digital form, likely to be a fully interactive, **bespoke developed website**.

We consider that a digital, interactive decision-tree based tool will enable people to create a set of tailored resources to guide them through the process of engaging patients and families in serious incident investigations. We would aim for this website to both engage and inform the two key stakeholder groups: staff within healthcare organisations undertaking or managing serious incident investigations, and patients and families seeking to understand the process of serious incident investigation. We would aim to signpost existing information sources to avoid duplication, whilst providing newly developed supporting resources, using a variety of possible media – for example, ‘talking heads’ videos (based on case study data from the ethnographic study in Stage 4); narrative descriptions of case studies; cartoons; and tools developed through the piloting of the co-designed processes that support organisations to move beyond statements of good practice.

### **Patient and Public Involvement and Engagement (PPIE)**

Our approach to involving patients and the public is based on a recognition of three key principles: i) ensuring the priority of the patient and family perspective alongside other stakeholders within the project Steering Group and Oversight Committee; ii) providing appropriate training and support for those providing this perspective; and, iii) ensuring that our wider engagement infrastructure can reach, and engage with, those individuals with lived experience of serious incidents, investigations and decisions to litigate.

#### **Patient and Family Support Officer**

This will be a formal role within the research team. This role will be to co-ordinate the various aspects of PPIE activity, develop the methods for creating and maintaining the proposed Patient and Family Forums, and at the project Steering Groups raise issues, concerns and suggestions arising across these different mechanisms. The role will also include some evaluation of the different approaches used for PPIE activity.

#### **Lead Patient and Family Representatives**

These will be important roles, aimed at ensuring the perspective of patients and families are central to the discussions within project Steering Group and project Oversight Committee meetings. There will be two Lead Patient and Family Representatives. The first will be our co-applicant Scott Morrish, whose lived experience will support him in acting as a representative for patient and family perspectives on the Steering Group, supported by the programme’s Patient and Family Support Officer. In addition, a Lay Leader from the NIHR YH PSTRC will be invited to sit on the project Oversight Committee.

### **National Patient and Family Forum**

Given that experiencing a serious incident and the processes that follow, is a rare event, it would be difficult to draw together a group of individuals with appropriate lived experience from our local networks or participating organisations. Therefore, we will seek to establish a 'virtual' network of interested individuals with experience of serious incidents, investigations and litigation. We have shaped the idea of hosting some form of online forum to allow meetings to be scheduled, information shared and comments invited, and conversations to be supported between members. The forum will be supported by the Patient and Family Support Officer who will attend Steering Group meetings alongside a representative from the Patient and Family Forum. In addition, we have allocated some budget in our requested costs to support an annual (face-to-face) meeting of these members.

### **HSIB Patient and Family Forum**

In recognition of the uniqueness of the investigations processes at the HSIB compared to local level investigations, we will seek to work with the already established HSIB patient and family committee. Our Patient and Family Support Officer will work with our contacts at the HSIB to engage this group in the on-going work of the project.

### **Project management**

A **Steering Group** will be established to oversee the design and conduct of the research programme. The Steering Group will meet every six months, totalling six times over the 39-month programme period. In attendance will be: Principal Investigator, all co-applicants, project researchers, key collaborators (national and international) and two lay representatives (including one lay co-applicant, and one member of the virtual Patient and Family Forum).

A **Project Oversight Committee** will be established and will meet once a year. The committee will be led by an independent chair, and will include academic representation, healthcare management representation, key policy contacts and a lay representative (NIHR PSTRC Lay Leader).

A **Project Management Team** will meet regularly over the project period. This team will comprise the Principal Investigator and the lead researchers. The Project Management Team will monitor the set up and progression of the project, to ensure key milestones are achieved and deliverables met, in addition to supporting all other management arrangements. The team will meet monthly face-face or via telecom as appropriate throughout the project.

In the lead up to Stage 3, a **Co-Design Team** will be brought together to manage and support the co-design process throughout Stage 3 (A and B) and Stage 5. The Co-Design Team will comprise the Principal Investigator, the co-applicants responsible for managing the co-design process, and the research team.

### Involving patients and families in serious incident investigations (PFI-SII)

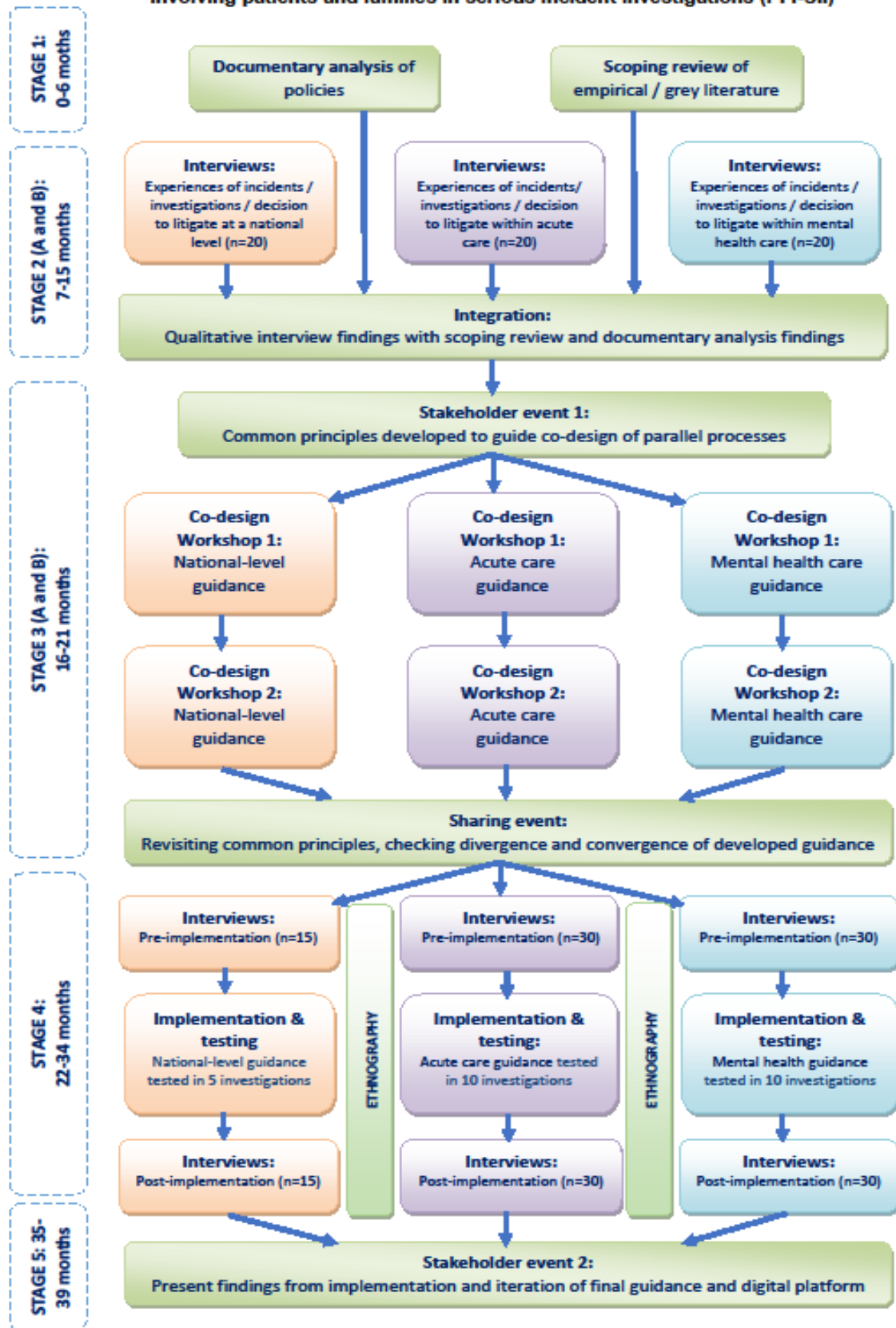


Figure 1: Flow chart of project timeline



**Table 1: Project Timetable**

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39		
Researcher recruitment*																																									
Set up Steering Group*																																									
Set up Oversight Committee*																																									
Set up Patient/family Forums*																																									
Engage sites*																																									
Ethics/ R&D Stage 2																																									
Stage 1 Scoping review																																									
Stage 1 Document analysis																																									
Stage 2A interview study																																									
Stage 2B Integration																																									
Ethics/R&D for Stage 3																																									
Stage 3A Stakeholder event 1																																									
Stage 3B Co-design workshops																																									
Stage 3B Sharing event																																									
Ethics/R&D for Stage 4																																									
Stage 4																																									
Stage 5 Stakeholder event 2																																									
Steering Group																																									
Oversight Committee																																									
Patient & staff involvement																																									
Final report writing																																									
Writing for publication																																									
All other dissemination																																									

\* Activities commencing prior to start date.