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Patient and family involvement in serious incident investigations

Submission date 19/01/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/04/2021	**Overall study status** Completed	
Last Edited 28/05/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Serious incidents in health care are events where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant that they warrant our particular attention to ensure these incidents are identified correctly, investigated thoroughly and, most importantly, trigger actions that will prevent them from happening again. UK policy emphasises the need for openness following serious incidents, and that patients and families can improve learning. Examples of a serious incident are unexpected deaths, serious physical or psychological harm, or concerns of abuse or misconduct. Certainly, there is little evidence about how serious incidents, complaints and litigation are linked. The proposed research therefore aims to develop and test processes to guide the involvement of patients and families in serious incident investigations. Our ultimate aim is to improve the experience of patients and families in serious incident investigations and improve the learning from investigations.

Who can participate?
Patients and family who have experienced a ‘serious’ incident as defined by the Trust, along with experienced investigators and staff involved.

What does the study involve?
First, we will explore the experiences of patients and families, doctors and nurses, and those investigating incidents, of serious incidents, investigation processes and why litigation was or was not pursued. We will then identify 'common principles' to help us identify (with patient, staff and investigators) new serious incident investigation processes that involve and learn from patients and their families. We will design the new investigation processes across three healthcare settings - with a national investigation body, the Healthcare Safety Investigation Branch, and with two mental health Trusts and two acute care trusts. We chose these settings as they have important differences in the challenges of and opportunities for involving patients and families. Next we will test the co-designed processes over 12 months. We will observe 25 serious incident investigations, to understand how patient and family involvement changes investigations, decision to litigate and acceptability of the process to all stakeholders. In the

final stage we will refine the investigation processes and resources and share out findings with policy makers and healthcare organisations. In particular, we will work with our patient and family forums to creatively share findings with the public and patients advocacy organisations.

What are the possible benefits and risks of participating?
Possible benefits: We anticipate that, as a result of their investigator piloting the new processes and guidance, patients and family members will feel listened to, important, supported and guided through the serious investigation process. It is possible that being involved in testing these may also minimise the experience of compounded harm that patients commonly feel after traditional serious incident investigations. The information participants provide about their experiences of these new processes and guidance will help improve them for future patients, which we anticipate will ultimately contribute to national policy in this area. Therefore participants may benefit from knowing that they are likely to influence national policy.

Possible risks: Patient and family participants may find it upsetting to talk about their difficult healthcare harm experiences. Our researchers are highly skilled in sensitive research and will take great care to not exacerbate an already difficult time in people's lives. However, if the research is causing distress, participants have the right to withdraw. We will also ensure that participants are provided with relevant sources of support. Staff participants may find implementing the new guidance challenging or stressful. For example, compared to 'regular' investigations, the new approach may increase their workload, or the degree of interpersonal contact with upset patients and families. They may also feel overwhelmed by following an unfamiliar process. The researchers will be on hand to support staff with any additional emotional burden and any difficulties with following the guidance. Staff may also feel they have insufficient time to be interviewed, causing them stress. In this regard, the researchers will be very flexible in how these take place. Our partner sites are aware of the commitment involved and the research team will work with leaders to facilitate/support staff involvement in the research.

Where is the study run from?
Bradford Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2019 to June 2024

Who is funding the study?
NIHR Health Services and Delivery Research (HS&DR) Programme (UK)

Who is the main contact?
Prof. Jane O'Hara, Jane.O'Hara@thisinstitute.cam.ac.uk

Contact information

Type(s)
Scientific

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Integrated Research Application System (IRAS)
279096

Study information

Scientific Title
Patient and family involvement in serious incident investigations: Developing and testing national and local guiding processes

Acronym
PFI-SII

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/09/2020, East of England Cambridgeshire and Hertfordshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)20 7104 8096; lauragreenfield@nhs.net), ref: 20/EE/0133

Study design
Multi-centre interventional non-randomized study with qualitative data collection

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Guiding organisations to involve patients and families meaningfully in serious incident investigations, to support learning or reduce the likelihood of litigation.

Interventions

The overall research project contains 5 stages, this registration will focus on stage 4. Details on all stages are included for background and context.
In Stage 1 (0-6 months) a documentary analysis of policies within England will explore how NHS Trusts involve 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 (7-15 months) we will interview patients, families, investigators and staff (n=60) to support the development of the programme theory underpinning the co-designed processes. Data from these stages will be integrated into Stage 2B (months 13-15) to guide the co-design.
In Stage 3 (16-21 months) we will co-design three parallel processes to involve patients and families in investigations, within national (Healthcare Safety Investigation Branch; HSIB), mental health and acute care.
In Stage 4 (22-34 months) we will implement the prototype guidance and resources in 25 investigations across 5 organisations, conducting an ethnography to assess the feasibility and explore. During this time, a digital platform will be developed to house the guidance and resources.
In Stage 5 (35-39 months) the final guidance and digital platform will be produced.

Stage 4 methodology:
Methodology
The three co-designed processes (mental healthcare, acute healthcare, national level) will be assessed for feasibility and acceptability with patients, families, investigators and NHS healthcare staff within 25 real-life serious incident investigations over the course of 12 months, within 25 investigations: 5 at HSIB, and 5 at each of the four participating NHS Trusts. These 25 investigation cases will be sensitively and strategically chosen in collaboration with management at the respective organisations. We will identify and select investigation types that will serve as i) extreme / deviant cases; ii) maximum variation cases, and iii) critical cases. We will adopt a focused, pragmatic ethnographic approach to investigate how the new intervention is enacted and experienced in different socio-cultural and organisational contexts. We will use non-participant observations of investigation processes and 'in situ' ethnographic interviews with participating professionals, patients and family members. The ethnographic data will take the form of field notes, electronic summary records, interview transcripts and documents relating the investigation, report and actions.

Intervention
The intervention will be implemented by Investigators conducting the selected investigations. It will take the form of a guidance document including: (a) the relevant co-designed process, (b) a decision tree to establish with the patient and family their preferred level of involvement and (c) support materials/resources to support the investigators in implementing the new approaches.

Duration
Investigators will implement the intervention throughout the full 'life-cycle' of the sample investigations, anticipated to take around 60 days, in accordance with reporting requirements. Interviews take place before the investigation starts and on its conclusion. There is no follow-up.

Participant involvement
Upon a selected 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. Preliminary interview will be arranged with the patient and/or family members to understand their expectations of the process and views about the incident - 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 investigation meetings involving patients and family members will be observed, estimated between 3 and 5. The content and recommendations of each Investigation Report will be reviewed to determine the extent of influence of patient and family involvement. After the life-cycle has elapsed (i.e. within 60 days), a further series of interviews will be carried out with professionals and patient/family members (n=3- 5 per investigation: 75-125 in total) to understand their experiences of the investigation processes.

Intervention Type
Other

Primary outcome(s)
1. Understanding how the new intervention is enacted and experienced in different socio-cultural and organisational contexts -using 'in situ' interviews, electronic summary records and documents related to the investigation, actions and outcomes
2. Understanding how patients and families are engaged and involved in investigations, including how procedures are 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 - using non-participant observations of investigation processes
3. Interpretive thematic analysis will preliminarily include open and thematic coding to develop descriptive accounts of the common and distinct processes of investigation, the expectations and experiences of participants of these processes, and the types of learning and recommendations developed. Over a 3-6 month period, analysis will be discussed by the core qualitative team through weekly and monthly meetings (face-to-face and remote), before being presented to the wider research team for further development and then the final stakeholder event

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/06/2024

Eligibility

Key inclusion criteria
Patient and family:
1. Experienced a 'serious' incident as defined by the Trust
2. The serious incident is new (occurring in the last few days)
3. There is no police involvement
4. They are >16 years of age
5. They have capacity to consent to the interview

Investigators:
1. Experience of conducting serious incident investigations

Staff:
1. Directly involved in the serious incident

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
61

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/12/2021

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bradford Royal Infirmary
Bradford Teaching Hospitals NHS Foundation Trust
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre

Bradford District Care NHS Foundation Trust
New Mill
Victoria Rd
Saltaire
Shipley
Bradford
United Kingdom
BD18 3LD

Study participating centre
Leeds and York Partnership NHS Foundation Trust
2150 Century Way
Thorpe Park Gardens
Leeds
United Kingdom
LS15 8ZB

Study participating centre
The York Hospital
York Teaching Hospital NHS Foundation Trust
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Healthcare Safety Investigation Branch
Cody Technology Park
Old Ively Road
Farnborough
Guildford
United Kingdom
GU14 0LX

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
Health Services and Delivery Research Programme

Alternative Name(s)
Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2025	28/05/2025	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version V2.0	08/03/2021	20/04/2021	No	No