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Patient and family involvement in serious incident investigations: Developing and testing national and local guiding processes (HS&DR 18/10/02)

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Version Control Table

Document Title	Research Study Protocol Document – Patient and Family Involvement in serious incident investigations: Developing and testing national and local guiding processes (HS&DR 18/10/02)
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Version	Date Implemented	Details of key changes made to document
1.0	01.10.2019	Not applicable.
2.0	08.03.2021	This document has been modified to reflect necessary adaptations in response to COVID-19 and feedback from our Patient and Family Advisory Group. <ol style="list-style-type: none"> 1. The project GANTT chart (p. 19) has been updated to reflect adjusted timescales for individual stages in the study due to a 3-month COVID-related pause. 2. Stage 3 Co-design (p. 9-11) – change in delivery method due to COVID restrictions from face-to-face to virtual/online events and incorporating postal, digital and telephone contact. 3. Stage 2 interview study (p. 7-8) – addition of legal staff alongside healthcare staff and investigators. The target number of patients and family members has been reduced (from N=30 to N=25) and a new staff subgroup of N=5 legal staff has been created. Strong feedback from our Patient and Family Advisory Group indicated that NHS trust lawyers were a key voice missing from the study, given they significant role they play in serious incident investigations process.
3.0	21.12.2021	This document has been modified to reflect greater flexibility for patients and families in Stage 4 (specifically page 13) in how they share their expectations of the investigation process and views about the incident. Instead of asking for their

		<p>consent to being interviewed at two timepoints - before AND after the investigation - we will ask for their consent to be interviewed as a minimum <i>after</i> the investigation. We will then provide them with flexibility to <i>a/so</i> consent, should they wish, to participating in an initial interview and/or to use a diary format to capture their thoughts and experiences to share with us. Healthcare staff and investigators will also be invited to use the diary format to capture and share with the researchers their in-the-moment experiences/reflections during the investigation.</p>
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1. Full title of project

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

2. 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,[1] with enormous, ever increasing costs associated with litigation.[2] 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.[3] 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 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.

3. 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.”[4(p7)] In the UK, reported serious incidents (causing severe harm or death) are estimated to be around 10,000 annually.[1] 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.[2] 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.

Reducing litigation costs

The reasons why patients and families pursue claims are complex.[3] A significant portion of litigation is warranted and necessary, due to the life-changing or life-limiting effects of serious

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incidents.[5] However, NHS Resolution describe ‘frustrated litigants’, whose claims appear motivated by poor experiences of complaints or investigation processes.[6] They have developed a model of patient and family involvement in complaints and investigation management, based on principles of early intervention, openness and engagement. They posit that involving patients and families earlier in investigation processes will both reduce costs of administering claims, as well as divert claims pursued in search of explanation or acknowledgement.[7] These principles are shared by NHS England in their guidance on incident investigations within The Serious Incident Framework,[4] the National Quality Board in their guidance on Learning from Deaths,[8] and the Duty of Candour.[9] It is clear therefore that at a policy level, openness with, and involvement of, patients and families in processes following serious incidents is a high priority. However, the Care Quality Commission (CQC) found in their review of serious incident investigations, that only 12% of investigation reports clearly indicated involving patients or families[10] suggesting that, as yet, this policy drive is not translating into changes in practice.

Improving learning from serious incidents

Whilst NHS Resolution proposes that ‘upstream’ involvement may reduce complaints, their own data suggest that only 30% of claims start with a complaint.[6] Empirical work has also found no link between complaints and litigation rates.[11] This would suggest that focusing only on complaints to reduce the costs of litigation, is unlikely to be effective. Investigating serious incidents is a cornerstone of patient safety, but there continue to be significant challenges in prompting improvement and reducing the likelihood of future incidents.[12] NHS England are currently consulting on ways to improve guidance for local serious incident investigations, including how patients and families might become more involved. However, there is little empirical evidence, particularly within the UK context, to guide interventions seeking to improve the effectiveness of the investigation of serious incidents, and reduce the likelihood of litigation. Further, there are no known studies from the UK exploring the process of involving patients and families in serious incident investigations, no evidence that this leads to improved experience for those involved or reduction in the likelihood of litigation, and no UK-relevant structured processes for how to practically achieve involvement successfully. Our proposed research aims to address this evidence gap.

The proposed research is important to patients and healthcare services in three key ways. First, for those involved in an 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.[13-14] Thus, exploring how to improve the experience and transparency of investigatory processes for all stakeholders, is desirable both in moral and fiscal terms. Second, improving learning from serious incidents may reduce the likelihood of future events,[15] 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.

3a. Evidence explaining why this research is needed now

Despite the policy focus, the empirical evidence for patient and family involvement is scarce. Two US studies 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 suggests that patients and families could act as a key source of information to investigations. These data were then used to develop a tool (IMPACT) for structuring conversations with patients and families after an incident, to gather information to be used in investigations.[18] However, the tool has not been 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, does not appear to have been tested in practice.

Within the UK, little evidence is available. One recent paper 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, whilst evidence directly exploring the role of patients and families in serious incident investigations is limited, a related literature supports the rationale for doing so. Patients are now recognised as a source of information about patient safety and incidents,[21-22] that other error detection methods (staff reports, case note review) do not access.[23] 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 multiple healthcare presentations.[24] Current evidence therefore suggests that patients and families could, and arguably should, be involved in serious incident investigations. Whilst some research and commentary has discussed the potential challenges and opportunities for such involvement, there is a fundamental lack of empirical evidence for this in practice.

4. Aims and 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.

Research Questions:

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?
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?
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?

5. Research Plan / Methods

Design

Mixed methods: qualitative and co-design, with each stage incrementally building on the previous one.

Overall sampling and setting

This research will involve a number of key stakeholder organisations, and be hosted across four regional NHS Trusts. First, we have agreement from the Healthcare Safety Investigation Branch (HSIB) for their involvement as one of the 'host' organisations in the design, development and testing of the processes to involve patients and families in serious incident investigations. The HSIB began operating on 1 April 2017. The core role of this new body is to conduct independent investigations into the most serious patient safety issues in the English healthcare system, and to provide national investigation guidance and support for NHS organisations. Second, we have secured agreement from four regional NHS Trusts: two providing mental health care (Leeds and York Partnership NHS Foundation Trust, and Bradford District Care NHS Foundation Trust), and two providing acute health care (York Teaching Hospitals NHS Foundation Trust, and Bradford Teaching Hospitals NHS Foundation Trust). These Trusts were invited to participate as they represent diverse patient populations within a manageable distance. York is the county town of North Yorkshire and one of the most affluent areas of the UK. Bradford is one of the most deprived

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cities in the UK with an ethnically diverse population. Leeds is the third largest city by population within the UK, and is extremely diverse with over 75 ethnic groups, representing just under 11.6% of the total population. Collectively, these Trusts present a range of ethnic, socio-economic, and public health profiles, making them very suitable within which to develop and test the processes for involving patients and families in serious incident investigations.

Managing 'critical distance'

The research team are aware of the need to manage 'critical distance' with these regional partner Trusts. Before describing how we plan to manage this however, we would first suggest that there are considerable benefits to working with local partner organisations. Ethnographic research requires a lot of time spent at participating organisations, and researchers need to be able to respond quickly to invitations or opportunities to attend meetings or observe practice. Indeed, the importance of close collaboration in health service evidence development and translation has seen the widespread introduction of 'research-in-residence' models where researchers are embedded within local service organisations for sustained periods of time.[25] In more pragmatic ways, reducing the geographical distance also allows for responsiveness, and supports direct observation of processes in real-time. Further, in terms of ensuring best value, this reduces the need for extensive stays away from home, thus reducing travel and subsistence costs. A second key benefit is in the existing relationships we have with key personnel within these Trusts. This helps to facilitate access, allows leverage to be applied to ensure appropriate progress of the research programme, and provides visible senior support for the research aims and practical requirements. The research team have worked with all of the participating healthcare organisations in previous research projects, and have successfully managed to create and maintain critical challenging research relationships.

Procedure

Stage 1 (months 0-6)

The research within this stage will be led by the research team at the Bradford Institute for Health Research (BIHR) which includes two Research Fellows based at BIHR, in addition to being supported by four co-applicants (JOH, GL, LS, JW).

Addressing RQ1:

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

In this stage we will conduct preparatory, deductive work, and gain ethical and governance approvals for the subsequent empirical research. Engagement activity will be undertaken with the HSIB, Action against Medical Accidents (AvMA), and the four participating Trusts.

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. To uncover the academic literature, the following databases will be searched: Medline, Cinahl Plus, Scopus, Web of Science and Psych INFO. Development of search terms will involve the expertise of an academic librarian. A modified version of a grey literature searching methodology will be undertaken,[26] We will adhere to recently published guidelines on reporting scoping reviews.[27] Whilst we will principally focus on uncovering literature about patient and family experiences of this process, we will also include literature relevant to the decision to litigate. The scoping review will be written up descriptively, paying attention to the primary focus of patient and family involvement in serious incident investigations and the secondary focus of decision to litigate.

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. We will take into account

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material describing any forthcoming plans to involve patients and families. In order to conduct this, we will aim to gather these documents from at least 25% of all acute and mental health Trusts in England ($n \geq 50$). Ensuring a proportionate representation of mental health Trusts, Trusts to approach will then be randomly sampled from a list of all Trusts in England. Inclusion and exclusion criteria will be developed to ensure that comparable documents are being collected across all Trusts in England. We expect that some documents will be freely available and hosted on a public facing website, whereas others may be available only upon request. We will only gather documents where the Trust in question is willing to give them to us and as such we will not undertake Freedom of Information requests where the request for information is not forthcoming.

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. Therefore, our analysis will be twofold in allowing a focus on i) best practice/ exemplars, but also ii) an understanding of the different approaches Trusts take to serious incident investigation and patient/family involvement. We will begin with a traditional descriptive thematic analysis.[28] Then, analysis will focus on developing a taxonomy[29] of how, at an organisational level, policies prescribe the involvement of patients and families in serious incident investigations.

Stage 2 (months 7-15)

The research within this stage will be led by the research team at BIHR which includes a Programme Manager and two Research Fellows, in addition to being supported by three co-applicants (JOH, LS, JW).

Stage 2A (months 7-12)

Addressing RQ2-4:

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, investigators and legal staff 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, investigators and legal staff on the potential involvement of patients and families in serious incident investigations?*

We will 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, investigators and legal staff who have been involved in a serious incident and the process of serious incident investigation. These interviews will also explore the views of staff and investigators about the potential involvement of patient and families in investigations. The interviews will be semi-structured, with an emphasis placed on exploring what is important to the participants themselves. All interviews will be conducted face to face at a time, date and location most convenient to the participant.

Purposive sampling will achieve a representative sample across the four key stakeholder groups: patients and families, healthcare staff, investigators and legal staff. An additional element of sampling criteria is to ensure that we have interview some participants who have experience of litigation in the context of serious incident investigation, to ensure that we can gain a broad understanding around decisions to litigate.

Around sixty interviews will be undertaken across all the organisations taking part in the study. This will be stratified as follows: twenty-five patient and family participants, twenty healthcare staff participants, ten investigators and five legal staff. We would aim for our sample of patients and family participants proposed (n=25) 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. This is likely to require targeted sampling and recruitment through AvMA and the HSIB, although participants with experience of decisions to litigate may be recruited from any of the participating organisations. We will aim to recruit an even spread of the three different participant groups from the range of organisations we are working with; for confidentiality reasons, legal staff will not be recruited through our partner organisations, but through social media. Ultimately, the exact number of participants interviewed will depend on achieving both coding, and meaning saturation.[30] That is, we will cease interviewing when we feel that we have “understood enough” alongside having “heard enough”. This will be achieved by the fieldworkers having weekly meetings to discuss data collection and emerging ideas. Topic guides will be developed for each of the three participant groups, based in part on the findings of the scoping review and documentary analysis in Stage 1. Questioning will differ for each group although the common factor will be the exploratory nature of the interviews. An inductive thematic analysis[28] will be conducted to generate overall findings representing the commonality of experience across the participants, and to explore where the experiences between the four main sub-groups diverge.

Stage 2B (months 13-15)

Addressing RQ1-4:

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?*

Here, we will integrate the deductive and inductive findings from Stages 1 and 2A to create meta-level findings that can be taken forward to Stage 3. Analysis will be descriptive and conceptual. The descriptive analysis allows for an understanding of ‘what participants said’ whilst a higher, conceptual level analysis provides an interpretation of what this may mean for the involvement of patients and families in serious incident investigation.

Before we can undertake this integration, the findings of the scoping review, documentary analysis and in depth interviews need to be written up into the format of at least a short report for each method. Then, the core members of the qualitative research group working on this study (JOH, LS, JW and the researchers) will come together as follows:

- **Month 13:** first half day workshop with core qualitative research team (JOH, LS, JW, the researchers, and JL) to identify the key foci of the integration, using the methods described in the protocol;
- **Months 13-14:** undertaking the triangulation of the data, developing the common principles and the programme theory, and planning the design and materials for the first stakeholder event in Stage 3;
- **Month 15:** second half day workshop with core qualitative research team (JOH, LS, JW, the researchers, and JL), to agree the final version of the integration, the common principles, the programme theory and the plans for the stakeholder event.

We already know that we are interested in patient and family experience and decisions to litigate – but what particular elements are crucial to integrate across the set of findings in order to move forward to Stage 3? This is difficult to specify a priori, before tacit knowledge from the field and the

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generation of written and verbal findings is undertaken. O’Cathain and colleagues[31] describe three techniques for integrating mixed methods data. It is likely that we will use their suggestion of a ‘triangulation protocol’ which places the analytic focus on convergence, complementarity and contradiction. Using a triangulation protocol will move us from thinking about discrete findings per method and instead towards a generation of meta-findings, which cut across the scoping review, documentary analysis and interview study.

Developing our programme theory

Our working programme theory is based on that proposed by NHS Resolution as the basis of their new approach to early intervention.[7] However, to our knowledge this has not been interrogated empirically, and this research programme will seek to undertake part of this necessary critical examination. Through Stages 1 and 2 we will explore the espoused, nuanced links between the experience of processes following serious incidents – duty of candour, investigation involvement, report production etc. – and decisions to litigate. This exploration will form part of the meta-level synthesis of findings in Stage 2B, and therefore the development of the programme theory and the common principles used as a basis of the co-design in Stage 3.

Stage 3 (months 16-21)

The research within this stage will be led by co-applicant (JL), and supported by two co-applicants (RL, JOH), in addition to being supported by the research team (Programme Manager and Research Fellows) at BIHR.

Stage 3A

Addressing RQ5:

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

A Virtual 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, AvMA). This event will take place over Zoom. 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. Should anyone be unable to make this event, a miroboard will be shared. Miro is an online platform for shared work and creativity that allows multiple users to work in the same space (virtually) at the same time. This Miro board will include the content and outcomes of the event and allow others to comment and contribute. Training and support in Miro will be provided ahead of the event for anyone who would like this.

To develop these ‘common principles’, prior to the event participants will be sent a kit to complete at home. This kit comprises of ‘story telling’ games,[32] and ‘Business Origami’ (a technique where paper cut- outs are used to create physical representations of actors, artefacts and environments) [33]. This format has been chosen to provide a “tangible and interactive simulation of knowledge from a specific domain”,[34] that would engage participants, create an informal environment for interaction and enable a creative atmosphere.[35] Participants will ‘play’ with the kit prior to the event and share their outcomes and experiences in one of three ways (1) on the miroboard, (2) as part of the event or (3) with a researcher during a 1:1 virtual meeting or phonecall.

Storytelling games have been used previously in design processes. This research will follow the guidance of these experiments that suggest stories are difficult to create without any stimuli, but our natural storytelling skills can be easily triggered by simple provocations.[32] The game developed

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for this event will use vignettes and personas to inspire participants to, as a group, construct the stories of different actors in a specific serious investigation scenario. The vignettes will be drawn together by the research team based on (anonymised and modified) previous cases, avoiding any references that may be in the public domain and make the case recognisable. The vignettes will present only the initial outline of a case and leave the participants to construct the narratives, exploring the various ways that people may (or may not) be involved. These 'stories', enacted through the paper cutouts, will be recorded and used later in Stage 3B. The Co-Design Team will translate these videos into a series of 'simulated scenarios' for screening at the first co-design workshop. The use of simulated scenarios has recently been proposed as a key means of supporting the practice of serious incident investigations.[36] We anticipate that across the three groups - patients and families, healthcare staff and investigators - the set of common principles will contain both inviolable and desirable characteristics and qualities.

Stage 3B

Addressing RQ6:

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

The aim of this stage is to **co-design three parallel, but contextually relevant 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 in Stage 3A 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. Researchers will determine at the time if the workshops will be virtual, face-to-face or a hybrid. The decision will be based on current covid-19 restrictions and participant preference. For virtual or hybrid workshops, participants will receive any appropriate materials and pre-work in the post beforehand. The 'break-out' rooms function of zoom will allow for smaller group work. 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 focus will be on 'who, when and how' with exploration of i) flexibility of when and how people can engage with the process, ii) transparency of process, product and language, and iii) sensitivity, avoiding blame in favour of learning. The process and outcomes of the workshops will be recorded and shared via the Miroboard for those who are unable to attend the workshop time. Researchers will follow up with those participants via email or phone to ensure that they have been able to contribute.

Each workshop will follow this outline:

Workshop 1 will create a high-level view of each investigation process, along with descriptions of 'who', 'when' and 'how', at key points across these processes. This process will be catalysed by a screen re-play of the paper cut-outs stories derived in Stage 3A, now presented as 'simulated scenarios'. Using their reflections from the 'story telling kits' they will then be given a series of prompt cards and invited to generate visual maps of the process, stakeholders involved at each stage, forms and types of involvement, criteria for involvement, what stakeholders might and might not do. These maps will be used by the design and research team to derive a 'process flow' and an accompanying 'decision tree'. They will define context specific stakeholder maps, develop archetype and extreme personas of those stakeholders, define an ideal investigation process and key check points within it, map stakeholders to each check point, define important parameters to address how various stakeholders will be involved at each check point; form of involvement, what they will do, media/channels for communication.

Workshop 2 will run a series of activities that aim to add detail to the processes developed

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in Workshop 1, stress test the proposed processes using simulated scenarios, and revisiting the paper cut-outs and original simulated scenarios with archetype and extreme personas developed in Workshop 1. Based on the stress test, the processes will be refined. The participants will define the people, capabilities, resources and tools required at each junction of the decision tree developed in Workshop 1. The design and research team will use this to develop a template for a set of physical resources and an interactive digital platform (a website) that allows users to build their own investigation support materials according to the decision tree, signposting users to relevant pre-existing materials, developing new resources where required along with a library of help and guidance materials ('Talking heads', interviews, podcasts etc). The physical manifestation will be the version 'tested' in Stage 4. During Stage 4, the digital version will be developed.

The '**sharing event**' will bring participants and outputs of the three co-design workstreams together to elicit reflections, share learning, and finalise the agreed processes. This session will also consider the packaging, form, tone and messages that will be required to accompany the local outputs.

Stage 4 (months 22-35)

The research within this stage will be co-led by the Programme Manager at BIHR and the Senior Researcher Fellow at the University of Nottingham, and will be supported by a further Senior Research Fellow and two Research Fellows at BIHR. This stage will also be supported by three co-applicants (JOH, LS, JW).

Addressing RQ7-8:

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 – two mental health Trusts and two acute care Trusts. One researcher will be allocated to the HSIB investigations alone, as these national investigations are likely to be more complex and time consuming than those occurring locally. 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 (see section below: Sampling, Generalisability and Ethnographic Research).

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. Attention will also be paid to uncovering narratives about decisions to litigate from key actors in processes observed, and elucidating their role in guiding choices between experiences and likelihood of litigation. We will follow a methodological and analytic approach previously used by two co-applicants (JW,CM) for ethnography of investigations.[37-38]

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.[39] There are many styles of ethnographic research (realist, critical, institutional)[40] and this research will adopt a focused, pragmatic ethnographic approach concerned with investigating how new interventions to support and facilitate patient and family involvement in serious incident investigations are enacted and experienced in different socio-cultural and organisational contexts. This will involve non-participant observations of investigation processes to understand, for example, 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. In addition to using observational techniques,

the focused ethnography will involve 'in situ' ethnographic interviews with participating professionals, patients and family members.

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 an optional preliminary interview will be arranged with the patient and/or family members, if they have consented to do this, 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. Patients, families, healthcare staff and investigators will be invited to capture and share with the researchers their experiences and thoughts across the investigation using a diary format. A suggested diary format will be provided as a guide should participants wish to use this approach. 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 and patient/family members (n=3- 5 per investigation: 75-125 in total) to understand their experiences of the investigation processes.

The ethnographic data will take the form of field notes, electronic summary records, interview transcripts and documents relating the investigation, report and actions. These will be collated and managed in specialist computer software (NVivo, v10) for the purpose of interpretive data analysis. Preliminary data analysis will be carried out by the field researchers and core members of the qualitative research group (JOH, LS, JW), including 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.

Sampling, generalisability and ethnographic research

Our choice to use ethnographic enquiry to examine our research questions in Stage 4, is based on our judgement of the nature of the problem being studied, and its circumstances. As a research team, we believe the ethnographic approach on a smaller – but representative – sample of cases, is 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,[41] 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. Therefore, in this piloting phase, case selection will be important, and not left to random sampling. On that basis, the research team, in conjunction with the Steering Group will agree a strategy for 'information-orientated selection'.[41] 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".[41] We will look to identify investigation types that will serve as i) extreme / deviant cases; ii) maximum variation cases, and iii) critical cases.

Clearly, to be able to identify these cases in the 12-month study period, alongside the other constraints, practicalities and sensitivities associated with patient and family involvement (or non-involvement) in serious incident investigations, requires a reasonable sample from which to select. It is for this reasons that we have secured agreement from four NHS Trusts to participate in Stage 4.

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This supports therefore, our team's ability to appropriately select (and manage) cases across the three case 'types' to ensure that our findings from this ethnography can illuminate how the 'common principles' and co-designed processes have been used across settings, actors and time, and draw some conclusions that allow iteration of the final research outputs.

Stage 5 (months 36-39)

The research within this stage will be co-led by the Senior Research Fellow at BIHR and the Senior Researcher Fellow at the University of Nottingham, and will be supported by a further Senior Research Fellow and Research Fellow at BIHR. This stage will also be supported by three co-applicants (JOH, JL, RL).

Addressing RQ7-8:

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. This event will be based on the findings of the ethnographic work and tacit learning accumulated throughout the study. Further, during this stage we will write papers for high impact peer reviewed publications, and the final report.

6. Dissemination, Outputs and anticipated Impact

6a. What do you intend to produce from your research?

This programme will prioritise the production of tangible and practical outputs throughout the research. We expect these to be relevant to a wider national and international healthcare context for three reasons. First, the scoping review will include empirical and grey literature from across global healthcare. This evidence will feed into the meta-level synthesis that will provide the basis of identifying the set of common principles, thus shaping the three separate processes across the three healthcare settings. Second, using the approach of drawing together the data drawn from Stages 1 and 2 to develop common principles, will mean that the developed processes reflect commonality of patient and staff experience before being contextualised to the specifics of the individual healthcare settings. Finally, through our wider research networks, we will understand how the developed processes might fit within other national and international settings. The Steering Group will include Jason Etchegary (based in the US), whose work represents some of the only empirical evidence to date for the involvement of patients and families in incident investigations. Further, this research will sit within wider research programmes within the NIHR Yorkshire & Humber Patient Safety Translational Research Centre (NIHR YH PSTRC). As such, the progress, developed tools and research outputs will be scrutinised by international patient safety experts, including Kaveh Shojania, Jeffrey Braithwaite and Jessica Mesman, thus bringing in perspectives from Canada, Australia and the Netherlands.

Key research outputs

It is important to recognise the emergent nature of this intervention, and as such, we do not wish to entirely limit ourselves to what we might predict as a potential intervention. However, in recognition of the need to understand potential impact, our considered and informed best judgement at this stage is that the final outputs produced at Stage 5 will be:

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

To combine the two points above and paint a possible vision for a likely output, 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 extant 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. For the purposes of the piloting within Stage 4, the output is more likely to exist in either a purely physical form or a mixed digital and physical form.

A fundamental premise of such an output will be one of continual growth and development. We acknowledge that we are unlikely to ‘get it right first time’ but would build such an output with a view to allowing future informed curation (for example, hosted and continually monitored by a regional or national improvement body, and supported by a panel of experts reviewing on an annual basis) such that content can be added to by users and suggestions for additional resources, ‘decision tree’ routes can be modified and supporting advice added to. We would also be able to utilise the power of web analytics and direct user feedback fields built into the website to inform the curation and continual improvement processes. In recognition of this likely form of the final study resource output, we have engaged with a web development company called Making Sense, who has provided a quote that is included in the requested budget. This company has an established track record of working with healthcare organisations and research groups to support the development of web-based resources.

Additional research outputs

In terms of specific outputs, we would anticipate the following:

Stage 1 –

Academic papers: Two papers presenting the mapping of national policies, and the scoping review of the literature on patient and family experience of serious incident investigations and factors influencing decisions to litigate.

Stage 2 –

Academic papers: One paper presenting the findings from the qualitative exploration of the experience of patients, families and healthcare professionals of serious incident investigations and factors influencing decisions to litigate.

Other outputs: a suite of visual representations of the integrated findings, the common principles, and the programme theory.

Stage 3A –

Academic papers: One paper presenting the meta-level synthesis of Stage 1 and 2 findings, and how these were used within the stakeholder event to agree a set of common principles for involving patients and families in serious incident investigations.

Public-facing report: Report to policy makers summarising the common principles for involving patients and families in serious incident investigations, as agreed within the stakeholder event.

Stage 3B –

Academic papers: One paper presenting the co-design process and the processes developed to support the involvement of patients and families in serious incident investigations, and the commonalities and differences between the three healthcare settings.

Prototype guidance: Through the co-design workshops, the research team will work iteratively with the website developer to build a prototype digital platform that can support the content guidance developed within the three healthcare settings.

Stage 4 –

Academic papers: Two papers presenting the feasibility and acceptability of the prototype guidance, and the findings from the in-depth ethnography respectively.

Stage 5 –

KEY OUTPUT: Final digital platform: Following the 12-month pilot phase and the final stakeholder event, the research team will work with the web developers to iterate the final version of the guidance, including materials and media created from case studies within the piloting phase.

Academic papers: One paper presenting a summary of the final stakeholder event and the final version of the guidance produced.

Public-facing report: Report to policy makers summarising the final stakeholder event and the final version of the guidance produced.

6b. How will you inform and engage patients, NHS and the wider population about your work?

Engaging patients and the public

We will aim to engage with patients and the public via a number of key mechanisms. First, the Patient and Family Support Officer role will lead on linking into other existing Patient and Public Involvement and Engagement (PPIE) infrastructure to support creative dissemination. Through the NIHR YH PSTRC, the regional AHSN Improvement Academy (Yorkshire and Humber), and locally the Yorkshire and Quality Safety Research Group, we have established networks into national and local patient and carer groups, along with key advocacy and policy organisations such as AvMA, Healthwatch, and the McPin Foundation. We would aim to use these networks across the research programme, to disseminate emergent findings, as well as publicising opportunities to get involved. Second, we will work with our two Patient and Family Forums within this programme, to explore in what ways we might disseminate emergent findings to key audiences. We would encourage members of these forums to support our dissemination efforts directly, through activity like joint conference presentations, and articles aimed at lay and health service audiences.

Engaging evidence users

National users of this research are collaborating with us to deliver this research and will attend our Steering Group meetings. We will also develop a network of collaborators throughout the research. Further, through our links with the AHSN Improvement Academy regionally, the CLAHRC networks across England, and the UK Improvement Alliance nationally, we would promote the findings and research outputs to healthcare organisations across England and the devolved nations. We will also disseminate informally through use of social media, which has been used successfully by co-applicants in the past for this purpose.

Engaging academic audiences

The research team would seek to disseminate the research findings and outputs widely. In terms of academic dissemination, we will publish this research in high impact journals, and attend national and international quality and safety conferences, such as Health Services Research UK, and internationally at the International Society of Quality in Healthcare. The project, will sit within two of the themes of research within the NIHR YH PSTRC – involving patients and families in patient safety, and workplace engagement and safety (led by Jane O'Hara and Rebecca Lawton respectively). As such, the research outputs and findings will achieve an enhanced national and international profile as part of our wider dissemination and engagement strategy.

7. Project / research timetable

This project will run for 39 months. The key activities and milestones are described in the Project Timetable (Figure 1 on Page 20).

8. Project management

A Steering Group (SG) will be established to oversee the design and conduct of the research programme. The SG will meet every six months, totalling six times over the 39-month programme

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period. In attendance will be: PI, 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 related PhD studentship within the NIHR YH PSTRC commenced in autumn 2018. This studentship will consider the experience of patients and families raising complaints and safety concerns within acute inpatient mental health settings, and will feed into this research programme through SG attendance. The role of the SG is to ensure the research objectives are being met, provide strategic input, financial accountability, and to facilitate the progression of the project across the sites.

A Project Oversight Committee (OC) 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). The main duties are of the OC are:

- To provide advice, through its Chair, to the Project Funder, the Project Sponsor, the Chief Investigator, the Host Institution and the Contractor on all appropriate aspects of the project
- To concentrate on progress of the project, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question
- The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society
- To ensure appropriate ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
- To provide advice to the investigators on all aspects of the project.

A Project Management Team (PMT) will meet regularly over the project period. This team will comprise the PI (JOH) and the lead researchers (LS, JW, JL, CM and JB). The PMT 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 PMT will meet monthly face-face or via telecom as appropriate throughout the project. However, in practical terms, communication between the team will be much more frequent. Additional researchers will join the PMT at later stages once in post. The line management of the research staff will be spread across the academic institutions delivering the project, this is to ensure the timely escalation of any project management issues across all sites (i.e. the national investigation body and the local Trusts) and at all stages (i.e. preparatory/deductive, integration, co-design process, focussed ethnographic study) of the project.

In the lead up to Stage 3, a **Co-Design Team (CDT)** will be brought together to manage and support the co-design process throughout Stage 3 (A and B) and Stage 5. The CDT will comprise the PI (JOH), the lead researchers responsible for managing the co-design process (JL, RL), Senior and Junior Researchers. The CDT will set up and manage the stakeholder event in Stage 3A, the co- design workshops in Stage 3B and sharing event. The CDT will be convened at the start of Stage 3. The CDT will meet in Stage 3 for the stakeholder event, the three co-design workshops and the sharing event. To prepare and plan for these Stage 3 activities and for peer support purposes, the CDT will also meet a further three times during Stage 3 (start/mid/end). The CDT will also meet in Stage 5 for the second stakeholder event. Updates from the CDT will be brought to the PMT and the SG meetings by the PI.

9. Ethics / Regulatory Approvals

NHS Research Ethics Committee (REC) approval and NHS permissions will be sought via the Health Research Authority (HRA). To mitigate any potential delay, applications will commence immediately following notification of funding.

Management of ethical issues and sensitivities

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In terms of the specific processes to manage and mitigate any potential issues arising from the emotional nature of this work, we propose a three-level approach: supporting patients and families, supporting healthcare staff and investigators, and supporting researchers. Our processes for managing the sensitivities, and the potential for additional distress from research participation, will be regularly reviewed within the Steering Group, to ensure they meet the needs of participants and researchers.

Supporting research participants – patients and families

First, the design of all research materials will be co-created with our patient and family research representatives across the different study areas (acute care, mental health, and HSIB). Further, safety nets will be designed to both ensure confidentiality within the research process can be maintained, and to support patients and families should involvement in the research raise significant challenges or emotional issues. Appropriate avenues for further support for distressed patients or families involved in the research – which will be outwith the remit of this programme of work – will be identified and signposted, with checks in place to ensure that these are followed up by relevant bodies.

Supporting research participants – healthcare staff and investigators

A safety netting procedure will be developed that will ensure confidentiality for the staff and investigators involved in the research, as well as outline the rare circumstances within which this would need to be broken. Such circumstances would of course be detailed within the informed consent procedure. However, our main aim with these safety-netting procedures would be to support staff, to recognise the emotional toll of being involved in a serious incident. Rebecca Lawton in particular has expertise in supporting healthcare staff following patient safety incidents, and will support our team to identify and signpost appropriate support for staff across the research period.

Supporting researchers

Investigating the experiences of patients and families following serious incidents will also likely result in a degree of emotional labour for researchers involved in this project. This will be recognised within our research management processes, with an infrastructure for regular debriefing amongst the research team during the periods of qualitative field-work. One co-applicant – Laura Sheard – who will be overseeing the qualitative work as a whole within the project, has experience of using this successfully across a range of research projects investigating sensitive topics, such as sex work, wound care, and patient experience of safety.

10. Patient and Public Involvement

Our approach has been informed by our teams' extensive experience of successfully engaging patients and the public in research development, design, conduct and dissemination. Thus, 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; 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.

To support active and meaningful engagement of patients, families and the public in this research will require a creative approach, with a number of mechanisms employed. These proposed mechanisms have been discussed within the research team, but importantly, co-produced in liaison with the patient and family representatives.

Patient and Family Support Officer

This will be a formal role within the research team (0.1FTE). This role will be to co-ordinate the various aspects of Patient and Public Involvement and Engagement (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 the project Steering Group 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. This role will also be supported on the project Steering Group by one of the NIHR YH PSTRC's Lay Leaders.

Patient and Family Forums

Given the nature of this research, we propose a nuanced approach to the involvement and engagement of lay representation within the research design, management and dissemination. To this end, it is our intention to establish two patient and family forums, that represent, and speak for, the different healthcare settings within which the research outputs will be developed and used.

i) 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. Louise Pye, who will sit on our project Steering Group, co-ordinates the activity of this committee, and will work with our Patient and Family Support Officer to engage this group in the on-going work of the project.

ii) 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, and in collaboration with Debra Hazeldine, a member of Cure the NHS, we will seek to establish a 'virtual' network of interested individuals with experience of serious incidents, investigations and litigation. In discussion with Debra, 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. We have allocated some budget in our requested costs to support this, and an annual (face-to-face) meeting of these members. The forum will be supported by, and linked into the Steering Group via the Patient and Family Support Officer, and the Lead Patient and Family Representatives

Figure 1 – Project Timetable (revised in 2020 due to COVID-related pause)

				2020												2021												2022											
	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
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
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 Analysis of Documents																																							
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 Test processes																																							
Stage 5 Refine processes & digital platform																																							
Steering Group																																							
Oversight Committee																																							
Patient & staff involvement																																							
Final report writing																																							
Writing for publication																																							
All other dissemination																																							

* Activities commencing prior to start date.

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