Research Protocol

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Title: What changes following the launch of the Patient Safety Incident Response Framework in the English NHS? A formative and summative evaluation of the implementation of a national patient safety policy

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Version Control Table

Document Title	Research Protocol – What changes following the launch of the Patient Safety Incident Response Framework in the English NHS? A formative and summative evaluation of the implementation of a national patient safety policy (HSDR 133742)
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Version 4 superseded	
Version 3 superseded	
Version 2 superseded	

Version	**Date implemented**	**Details of key changes made to document**
V1	**24/06/2022**	**Not applicable**
V2	**31/01/2023**	1) Updated research plans with respect to PSIRF publication timelines and national level implementation activities. 2) Delivery of stakeholder engagement activities: Stakeholder engagement activities principally involve establishing and co-ordinating two stakeholder groups 1) Citizens' Panel and 2) Patient Safety Leads Panel. The activities associated with the Patient Safety Leads Panel will now be delivered by the core research team, in collaboration with two Co-Investigators – Professor Suzette Woodward and Professor Rebecca Lawton. The activities associated with the Citizens' Panel will now be delivered by Angela King (collaborator) and James Titcombe (PPIE Lead Co-investigator). Angela will be the independent chair of the Citizens' Panel. Angela and James will be supported by the core research team. 3) WP1 interviews: As an alternative to convening a workshop to invite participants to comment on the

		proposed logic model, for pragmatic reasons, participants will be invited individually to member check assumptions.
V3	**28/09/2023**	1) WP2 rapid review: Updated the focus of the rapid review to more clearly outline the key concepts expected of included papers. This has been updated following internal conversations about the intended scope of the review to define the inclusion criteria. 2) Updated WP3 research plans with respect to national level implementation activities (i.e. FutureNHS Patient Safety workspace). 3) The Citizens' Panel will now solely comprise of members of the public representing themselves as individuals, and we will engage separately with patient advocacy organisations.
V4	**22/10/2024**	1) Updated Chief Investigator institution. 2) WP3 documentary analysis: Increased sample size from 20 to 40. 3) Updated WP4 fieldwork timeline and recruitment.
V5	**01/03/2025**	1) Programme timeline updated in line with a contract variation. 2) Co-Investigator (Sheard) institution updated.

1. Full title of project

What changes following the launch of the Patient Safety Incident Response Framework in the English NHS? A formative and summative evaluation of the implementation of a national patient safety policy.

2. Summary of Research (abstract)

Overall Research Aim

To explore the implementation of a new national patient safety policy, the Patient Safety Incident Response Framework (PSIRF), within the English NHS across the multiple layers of the regulatory and health service context, to understand how to support future patient safety policy development and implementation.

Background

Large numbers of patients continue to be harmed as a result of safety incidents, and current approaches to responding to and learning from safety incidents are increasingly questioned for their effectiveness in reducing harm. Many types of incident are frequently repeated across the NHS and organisations struggle to implement policies to improve safety and share learning. As a result, NHS England is launching a new national policy framework (PSIRF) that has far-reaching implications at all levels of healthcare by seeking to create incident response and learning processes that are more proactive, proportionate, flexible, learning-focused, equitable and fair. The launch of PSIRF offers a unique opportunity to explore and learn from the real-time implementation of a new national patient safety policy, including the logics and objectives underlying the policy, how the policy is interpreted and enacted across a range of stakeholder groups, what the policy changes and improves, and what lessons might be learned for future policy design and implementation.

Methods

This multilevel, mixed-methods evaluation will explore PSIRF implementation nationally with a longitudinal survey and documentary analysis, and organisationally through in-depth ethnography at six case study organisations from three NHS regions. The programme is divided into three empirical phases. After a set-up period, Phase 1 (pre-implementation, months 4-12) will examine the policy context before the PSIRF is introduced. The logic underpinning the policy will be analysed through interviews (n=30) with policymakers. A mixed-methods evaluation of pre-implementation context will involve a rapid review of how incidents are currently investigated and learned from, and rapid qualitative data collection at six case study organisations to understand pre-PSIRF context (n=10-12 per site). Phase 2 (post-implementation, months 13-39) will examine policy roll-out. A national longitudinal survey of all English NHS Trusts and Integrated Care Boards (ICBs) (n≤ 223) will explore key indicators and aspects of PSIRF implementation; documentary analysis of selected Trust implementation plans (n=40) will examine how PSIRF is interpreted and enacted; and 3 stakeholder workshops with patient safety leads (n=25) will explore safety metrics and local experiences. Organisational ethnography will be conducted across the six case study sites to explore PSIRF implementation (three 8 week cycles of fieldwork per case). Phase 3 (empirical synthesis, months 40-47) will integrate all findings to understand what worked in the implementation of the PSIRF and why.

Impact and Dissemination

Key policymakers and stakeholders have been extensively consulted in preparing this proposal. NHS England is strongly supportive, and formative findings will be regularly shared to support ongoing implementation. We plan to disseminate widely through 7 journal articles, 3 practice-facing reports and other mechanisms including blogs and podcasts. A key output will be a ‘Patient Safety Policy Implementation Handbook’ detailing actionable strategies and recommendations for future policy implementation.

3. Background and Rationale

3.1 Implementing national patient safety policy

Large numbers of patients continue to be harmed during the course of their care,[1] and improving patient safety remains a deeply challenging problem globally. In the UK, numerous patient safety policies have been developed, leading to national and local systems for reporting incidents, investigation processes, and a complex system of oversight and scrutiny. However, current approaches are increasingly questioned for their effectiveness in reducing harm.[2-3] Common types of patient safety incidents are repeated, and organisations struggle to implement policies and share learning.[4-5] Arguably, these policies have imposed an increasingly bureaucratic and resource intensive burden on the healthcare system, with little evidence of impact or learning over time. Not only is this frustrating for healthcare staff, it also diminishes confidence and trust in the health service by patients and the public.

3.2 The Patient Safety Incident Response Framework (PSIRF)

In response, NHS England has launched a new NHS Patient Safety Strategy[6] and is now undergoing a review of organisational responses to safety incidents. This has culminated in a new national policy framework, the PSIRF, which represents an important strategic shift with far-reaching implications for safety improvement practice at all levels of healthcare. These changes can be summarised as follows: i) broader scope: moves away from reactively investigating all incidents over a certain threshold, to a proactive approach to learning from incidents, promoting a range of proportionate responses; ii) investigation approach: now tightly defined with quality the main concern, and the selection of incidents for safety investigation based on opportunity for learning and range of incident outcomes; iii) experience for those affected: clear expectations for equitable and fair engagement and support for patients, families, and staff involved in incidents and investigations.

Collectively, the PSIRF affords far greater local flexibility in investigating and learning from incidents, removing a range of centrally mandated requirements. Whilst this decentred approach has the potential to strengthen safety improvement capacity, it may also pose significant challenges for different stakeholder groups across the health system. Put simply, organisations will no longer be required to investigate all reported patient safety incidents. However, this seemingly small statement arguably represents the most significant shift in two decades in NHS patient safety management, creating potential issues for equity and fairness in incident response for both patients and staff. The draft PSIRF was piloted with early-adopter NHS Trusts prior to the publication of a revised PSIRF for national implementation in August 2022. This therefore provides an unparalleled opportunity to explore, document, and learn from the real-time implementation of a national patient safety policy, including what it aims to achieve, how it is interpreted and enacted across a range of stakeholder groups (including patients and the public), what changes and improves as a result, and what lessons might be learned for future policy implementation.

3.3. Review of existing evidence

Evidence concerning the implementation of patient safety policy is disparate and piecemeal. In developing this proposal, we brought this evidence together, and can describe the current knowledge base in a series of key conclusions:

<u>i) The intent of patient safety policy might not be shared by those implementing it.</u>

In complex healthcare systems the effects of safety policy depend on how it is interpreted by different groups.[7] What policy makers intend may not be shared or understood by managers or front-line staff, with impact shaped through interaction with other policies, organisational contexts and cultures. For example, an exploration of NHS incident investigations found that whilst incident reporting systems were designed to promote learning, they became seen as a governance tool with the aim of regulating healthcare professionals.[8] It is clear therefore, that the implementation of the PSIRF will lead to reinterpretation of policy intention, contextual adaptation of practice, and the possibility of unintended consequences – both positive and negative.

ii) Patient safety policy is absorbed and modified by different stakeholder groups.
Since its inception, patient safety has been absorbed and reconstructed by medical and nursing professionals, and professional bodies.[3] This has been termed 'adaptive regulation', describing the capture and modification of new regulatory policy and practice.[9] This adaptation is particularly evident when new policy is at odds with existing professional identities and beliefs.[9-11] The implementation of the PSIRF will need to be attuned to these issues, in order to achieve the desired changes to practice and outcomes.

iii) Patient safety practice is multifaceted, multi-level, and contextually embedded.
There is a wealth of evidence that the practice of patient safety is a complex set of activities both influenced by, and influencing the context within which they operate.[12-16] Less is known about the role of regulatory bodies in shaping the implementation of patient safety policy,[17] although some evidence suggests that regulators both shape, and are shaped by, incident investigation approaches in healthcare.[18-22] It is clear therefore, that any implementation of patient safety policy will need to be considered at multiple levels of the healthcare 'system', from frontline staff through to commissioners and regulators.

iv) Significant evidence gaps exist on the successful implementation of patient safety policy.
Whilst there is an academic discipline devoted to enhancing the implementation of evidence-based guidelines, less is known about what happens to patient safety policy initiatives at a national level, and what supports their implementation.[23] A number of studies have considered the role of national policy and individual national alerts.[24-26] However, these have largely been retrospective, with less research studying policy implementation in action. Other research has examined facets of the patient safety policy,[8-11,15] but this largely explores the problem rather than directing future action. Implementation frameworks [27] are likely to support generalisable recommendations for a range of future policy initiatives.

Taken collectively, the evidence suggests implementing the PSIRF will be challenging, with a range of unintended consequences. Following this implementation in real time will support a greater understanding of this complexity, allowing policy makers to better design and support future patient safety policy implementation, and ultimately improve patient safety.

3a. Evidence explaining why this research is needed now
There remains a real need to reduce patient harm and improve the safety of care.[1] As a public service, patients and the public need to know there is a fair, equitable and effective system for learning from patient safety incidents within the NHS, in order to prevent future harm. Therefore, understanding (and supporting) the implementation of the PSIRF is an important step in ensuring the long-term success of this policy, as well as future patient safety policy initiatives. This programme will have significant interest for the wider healthcare community, through generation of new knowledge about how patient safety policy (in this case the PSIRF) actually changes practice and improves safety management, and key success criteria for future patient safety policy implementation. Through the combination of research methods comprising both 'breadth' and 'depth', this research will create generalisable knowledge that will directly benefit patient outcomes and future care, through supporting better patient safety policy development and implementation.

4. Research aims and objectives

4.1 Overall Aim: To explore implementation of the PSIRF within the English NHS, across the multiple layers of the regulatory and public service context, to understand how to support future patient safety policy development and implementation.

4.2 Research questions

1) What does the PSIRF change in relation to patient safety management?

1a) How are patient safety incidents responded to, investigated and learned from within the English NHS prior to PSIRF implementation?

1b) What is the underpinning logic of the policy? How does this logic interact with local norms, culture and context?

1c) What are the changes arising from introduction of PSIRF? What are the positive and negative unintended consequences of the policy?

1d) What are the implications for equity and fairness in incident response, for patients and staff?

2) How is the PSIRF policy implemented across the English NHS?

2a) How is the policy experienced, interpreted and enacted by different professional groups and teams?

2b) How and in what ways do local actors alter or adapt the policy? Why?

2c) How is the policy interpreted and experienced by patients, patient groups, and the public? How does this shape policy implementation?

3) What supports the effective implementation of the PSIRF?

3a) How does implementation and use of the policy change over time, and in what ways?

3b) How does the organisational, commissioning, regulatory and wider policy context influence the implementation?

4) What might be the opportunities for, and challenges of monitoring and measuring the impact of the PSIRF in the medium to long-term?

5. Research plan and methods

5.1 Overall study design and flow

This programme of work is a **multilevel, mixed-methods evaluation**[28] combining qualitative methods, a longitudinal survey, documentary analysis, formative and summative elements, and inductive and deductive analyses. The programme comprises evaluation **'depth'** and **'breadth'**, exploring the implementation of the PSIRF nationally with a longitudinal survey, documentary analysis, qualitative exploration of responses to webinar content delivered by the NHS England National Patient Safety Team and content on the FutureNHS Patient Safety workspace, and ethnography within six case study organisations from three NHS regions in England.

The programme is divided into three key empirical phases, which are 'bookended' with three-month set-up and completion periods. The first empirical phase is **the pre-implementation phase**, before the PSIRF is introduced nationally. The second phase is **the post-implementation phase**, which follows the national roll-out of the policy. The final empirical phase is **the synthesis phase,** where we bring our findings together across these phases to refine and further develop our understanding of what has worked in the implementation of the PSIRF, and why.

In the pre-implementation phase, WP1 and WP2 will run concurrently for eight months starting at Month 4. WP1 will explore and **articulate the logic** of the PSIRF. WP2 will comprise a **mixed-methods evaluation** of the pre-implementation context. We will first undertake a rapid review of the empirical and grey literature on how safety incidents are currently responded to, investigated and learned from in the English NHS. Then we will use a rapid qualitative approach within six case study organisations to understand their pre-PSIRF safety landscape and PSIRF transition. The findings of this first phase will feed forward into the post-implementation phase. In WP3 we will undertake the **national-level evaluation activity,** comprising a longitudinal survey, documentary analysis, qualitative exploration of responses to webinar content delivered by the NHS England National Patient Safety Team and content on the FutureNHS Patient Safety workspace, and stakeholder workshops with patient safety leads to explore candidates for metrics and monitoring methods for ongoing impact assessment. In WP4 we will conduct an **organisational ethnography** across the same six case study sites, to explore what happens as organisations progress further in their PSIRF implementation. The post-implementation phase will comprise both **formative and summative elements.** Emergent findings from both WP3 and WP4 will be

fed back to the NHS England Patient Safety Team, and the six case study sites, at three formative 'checkpoint meetings'. Finally, summative findings from all work packages will be brought together in the final synthesis phase. In WP5 we will **synthesise all data** to understand and articulate the complex mechanisms that influence the implementation of patient safety policy, and to develop guidance for successful implementation.

5.2 Conceptual framework

The implementation of the PSIRF represents the most significant change to healthcare safety management in the last two decades. Following Turner and colleagues (2016),[29] we conceive the implementation to be a 'major system change', which they describe as "…interventions aimed at coordinated, system-wide change affecting multiple organisations and care providers, with the goal of significant improvements in the efficiency of healthcare delivery, the quality of patient care, and population-level patient outcomes."[29: p.87] The authors go on to suggest that major system change should be informed by a range of different theory, to represent the multi-faceted and longitudinal nature of large-scale change across a system. The PSIRF represents a policy change that is embedded in both long-standing (e.g. 'Safety I' [30]) and more emergent (e.g. 'Safety II' [31]) theories of safety management. However, these 'grand' theories have little to offer on how changes in safety management attitudes and behaviours might be achieved. To this end, we will also draw upon a 'mid-range' theory – Normalisation Process Theory (NPT:[32]) - that seeks to understand and explicate the mechanisms that support and inhibit the implementation, embedding and integration of health techniques, technologies and other complex interventions.

Figure 1 illustrates how these theories will be applied to our multilevel, mixed-methods evaluation. We will seek to understand how, and if, the PSIRF changes the narrative about patient safety, and the methods for managing it. We will do this by examining the PSIRF implementation as a multilevel process[33] involving change in: i) the macro level *safety infrastructure* (e.g. regulators, professional bodies, policy makers); ii) the meso level *safety governance* systems (organisational level safety governance infrastructure); and, iii) the micro level *safety management processes* (e.g. deciding on incident response, conduct of investigations, identification of safety priorities). We will then seek to understand how the narrative of the policy is interpreted, enacted and implemented across the multilevel system using the NPT constructs of i) *coherence* – the sense-making work that promotes or inhibits the coherence of the policy; ii) *cognitive participation* – the relational work that people do to build and sustain a community of practice around the policy; iii) *collective action* – the operational work that people do to enact the policy; and, iv) *reflexive monitoring* – the appraisal work that people do to understand the ways in which the policy affects them.[34] Finally, in keeping with Turner and colleagues' assertion that "…change can be interpreted as either episodic (i.e. radical or exceptional) or continuous (i.e. as an ongoing process of becoming)",[29; p.91] we will undertake this multilevel, mixed methods, theory informed evaluation across a longitudinal timeframe. This will allow us to explore not just if, how and why the PSIRF implementation achieves its aims, but also whether this changes over time.

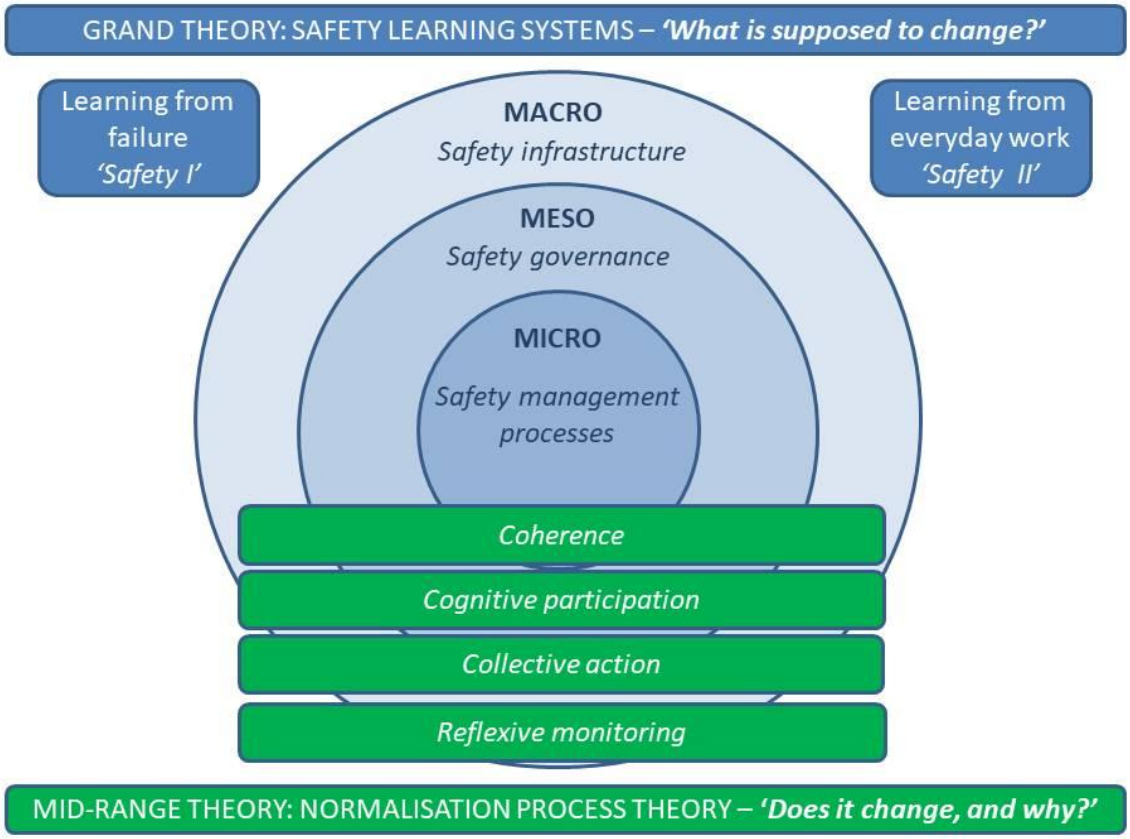

Figure 1. Conceptual framework for examining a major safety system change using grand, and mid-range theory, within a multilevel mixed-methods evaluation.

5.3 Sampling

The detail of our sampling approach is provided within each work package.

5.4 Summary of patients/service users/carers/public as research participants

Where patients, service users, carers and members of the public will be recruited as research participants, we have included detail in the individual work packages. However, across the programme of research we are committed to ensuring that there is fair and equitable access to research participation, and therefore we will make every effort to ensure that our sampling processes result in a fair representation of hospital communities. Inclusion and exclusion criteria, recruitment approaches and materials will be discussed and agreed with our PPIE-Lead and our affiliated PPIE infrastructure (described below in section 6.2) or Citizens' Panel to ensure they are fair and equitable. Our plans to share study findings with study participants are detailed in Section 6.7.

5.5 Setting and context

The details for the setting and context are provided within each work package.

5.6 Guidance for applicants on Equality, Diversity and Inclusion for study participants

We recognise the need to gather data on, and be sensitive to a range of factors for study participants. As mentioned in Section 5.4 above, we will scrutinise all sampling strategies and materials with our affiliated PPIE infrastructure (described below in section 6.2) or Citizens' Panel to ensure they provide fair and equitable access into the study. However, we will also seek to gather data about study participants on a range of demographics, to understand the success of these approaches across the research programme. We will be mindful to balance our need to understand the inclusivity of our approaches, with

the desire for individual privacy, and allow participants to opt out of questions regarding demographics if they wish to do so.

5.7 Stakeholder engagement approach

There are two stakeholder groups who are critical to engage with in this programme: patients, families and the public, and those implementing the PSIRF within organisations. We therefore propose a dual stakeholder engagement approach. First, we will establish a **Citizens' Panel** at the start of the programme, to oversee progress, shape the research design and conduct, and provide oversight and accountability. Additionally, this panel will have an important role to support the research team in interpreting emergent findings, particularly with respect to issues of equality, diversity and inclusion. This panel will comprise up to 20 members of the public. This recognises that the implementation and impact of PSIRF are important for public discussion more broadly, and people will therefore be recruited to the Citizens' Panel as individuals representing themselves, and not on behalf of an organisation. However, we also recognise that patient advocacy organisations and patient safety organisations (e.g. Action against Medical Accidents (AvMA), Patients Association, Healthwatch, Harmed Patients Alliance) will bring invaluable insight to discussions concerning the implementation and impact of PSIRF. Therefore, separate to the work of the Citizens' Panel, we will engage with patient advocacy and patient safety organisations throughout the programme to capture intelligence and insights. This will likely take the form of invited facilitated discussions and feedback on at least two occasions. Second, we will establish a **Patient Safety Leads Panel** from across NHS Trusts in England. This is likely to be drawn from the network of Patient Safety Specialists that has been established as part of the national patient safety strategy. This group would be up to 25 people undertaking these roles in NHS Trusts, with representation across all regions of England.

5.8 SET-UP PHASE (Months 1-3)

In this phase we will undertake the necessary foundational activity for the full programme of research. In order to proceed with the first work package as scheduled, we will start this activity ahead of the start date.

5.8.1 Identifying participating NHS Trusts

Ahead of the start date, and concluding in this set up phase, we will identify six participating NHS Trusts to act as our 'organisational cases' within WP2 and WP4. We will use this phase to build relationships with key staff within these trusts, and work with them to shape the details of the ethics and governance approvals.

5.8.2 Ethics and governance approvals

We will undertake to submit a full application for all the qualitative research activity in WP2 and WP4 through the Health Research Authority process at the beginning of this phase, in order to ensure that the following work packages can proceed as scheduled.

5.9 PRE-IMPLEMENTATION PHASE: Work Package 1 - Articulating the logic of the PSIRF (Months 4-12; Leads: Macrae, O'Hara, Sheard, Jones, Woodward)

RQ1b) What is the underpinning logic of the policy? How does this logic interact with local norms, culture and context?

To address this research question, WP1 will seek to explore and **articulate the logic** of the PSIRF, and **develop a dynamic logic model** for the policy implementation.

5.9.1 Sample

Policy-makers, patient representatives, regulators and others involved in the PSIRF development.

5.9.2 Method

Qualitative approach: In depth interviews will be undertaken in order to inductively explore and articulate the underlying programme theory of the PSIRF, and what those developing the framework envisage will change as a result of its introduction.

Data collection and sample: We will conduct in-depth interviews (n=30) with core personnel directly or peripherally involved in the PSIRF development and piloting, including staff from NHS England and Improvement (NHSEI), Care Quality Commission (CQC), Healthcare Safety Investigation Branch, patient safety experts, patient groups and patient representatives, and representatives from early adopter sites. We will purposively sample participants to ensure inclusion of opinion from across the range of groups described above. We are particularly interested in inviting people to interview who were part of the NHS Improvement engagement programme in 2018 and those who took part in national workshops regarding the PSIRF formation. All interviews will be semi-structured and use an adaptive topic guide. This means that there are certain topics the researcher would like to cover during the interview but there will be an emphasis placed on exploring what is important to participant themselves. The topic guide will be partially based on learning derived from: the rapid review and reading of the publicly available documents about PSIRF development, hosted by NHS England. Questioning may be tailored slightly differently dependent on the participant group being interviewed.

The topic guide will broadly include the following explorations of: i) what problem(s) it is hoped PSIRF will work towards solving; ii) contextual factors which may influence – both positively and negatively – the implementation of PSIRF across different levels and groups of people; iii) anticipated success criteria – what does this look like?; and, iv) anticipated problematic elements. Interviews may take place face-to-face, over phone or over video call dependent on participant preference and at a time and date most convenient to the participant. We expect interviews to last between around 30 to 50 minutes. They will be recorded and transcribed verbatim. To achieve our target sample size of 30 interviews within the time allocated to this WP, each of the three researchers will conduct around 10 interviews each. Researchers will meet weekly to discuss data collection and emerging findings.

Analysis: In order to generate headline findings, reflexive thematic analysis will be conducted.[35] Then, the thematic findings will be used to develop a dynamic logic model [36]. Dynamic logic models offer a unique perspective in being able to flex and adapt to context as opposed to traditional logic models and/or driver diagrams which remain rigid and inflexible [36]. The first draft of the dynamic logic model – developed from the thematic findings – will propose the overall programme theory of PSIRF. We will share our assumptions about the dynamic logic model and programme theory with interview participants to member check our assumptions. The logic model will inform all subsequent work packages and will be iteratively revised after headline findings are known from WP3 and WP4.

5.10 PRE-IMPLEMENTATION PHASE: Work Package 2 – Understanding the pre-implementation context (Months 4-12; Leads: Jones, Sheard, Macrae, O'Hara)

RQ1a) How are patient safety incidents responded to, investigated and learned from within the English NHS prior to PSIRF implementation?

To address this research question, in WP2 we will undertake a **mixed-methods evaluation**, providing a 'breadth' and depth' exploration of the current approach to patient safety management in NHS organisations in England, and the pre-implementation landscape within six case study organisations.

5.10.1 Pre-implementation: the national picture

To understand how the PSIRF changes the general approach to patient safety management within the English NHS, we need first to understand how this is undertaken currently. We will be describing in the next section how we will explore this issue within our case study sites. However, the topic of how healthcare organisations manage patient safety is one that has been well studied to date. To inform our programme therefore, we will undertake a rapid review with the title**: "How are patient safety incidents responded to, investigated and learned from within the English NHS?**" A rapid review supports a streamlined approach to data identification, extraction and synthesis.[27] We will use an adapted version of the Rapid Review approach advocated by the World Health Organization,[37], and the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist.[38] A protocol will be drafted and agreed upon with the wider research group prior to commencing the review.

We will limit our searches to two bibliographic databases (MEDLINE and EMBASE) as advised for rapid reviews.[37] Targeted search terms will seek to identify literature on how NHS organisations

respond to patient safety incidents, and how incidents are investigated and learned from. Searches will be limited to literature published since 2015, as this date saw the last revision of the Serious Incident Framework[1] within England (where data was collected under this framework). Results will be combined and duplicates removed. We will screen reference lists of included articles to identify additional relevant publications, and hand search other relevant databases, such as the Kings Fund library to draw in relevant grey literature in addition to empirical papers. In keeping with rapid review approaches, only one researcher will screen titles and abstracts, with a 20% random cross-check of articles included at title and abstract and full-text stages. Data will be extracted and charted using a matrix prior to synthesis: author, year of publication, country of origin, aims/purpose, study population, methodology and sample description, concept, outcomes and key findings relating to the research objectives. Data synthesis will then be achieved through qualitative content analysis.[39]

5.10.2 Pre-implementation: the organisational experience

Sample: Six NHS Trusts will be sampled across three different NHSEI regions (North East & Yorkshire, North West, Midlands). Following conversations with the NHS England National Patient Safety Team, it was felt that sampling across three different NHSEI regions would be crucial as the rollout of PSIRF will be strategically led in potentially different ways at a regional level. Two Trusts (1 acute and 1 mental health) will be purposively sampled on a number of factors (size, deprivation, geography) from each of the three regions. We will aim to 'pair' the Trusts within each region to a broadly similar geographical area, which will optimise fieldwork processes. Trusts involved in the pilot phase of the PSIRF rollout will not be approached. The research team already have relationships and links with many NHS Trusts due to our longstanding patient safety research portfolio, which will help to support the recruitment of organisations into the study. The NHS England National Patient Safety Team have advised us that they might implement the PSIRF in a staggered way, meaning that identification of potential sites will need to be undertaken in conjunction with them and nearer to the planned start date.

Method:

Qualitative approach: We will aim to understand the pre-policy context [40] at each of the six Trusts by undertaking a rapid qualitative approach.[41] Understanding this pre-policy context will enable us to longitudinally interpret what happens during and following implementation of the PSIRF. We can only truly understand how PSIRF has been implemented if the research team know what the landscape looked like before it was rolled out across the six Trusts.[41] Rapid qualitative approaches as developed by Vindrola-Padros and colleagues,[42] allow for the collection of qualitative data in a timely manner, and will provide the research team with a static snapshot of data leading to the quickly generated headline findings. This method is suited to answer research question 1A.

Data collection and sampling: Rapid qualitative data collection will occur over a six to eight week period in the six participating trusts. The predominant method will be short, semi structured interviews or focus grouplets [43] (dependent on participant preference), alongside relevant document collation. Focus grouplets are an applied health research method which allows for shorter discussions with fewer focus group members without demonstrable loss of quality in data collection. They are particularly suited to time or resource poor settings such as the NHS. Sampling for data collection will be theoretical with the aim of identifying participants across different groups that allow insight regarding pre-policy approaches and practices for managing safety incidents, and how these vary within and between organisations. We expect to involve between 10-12 participants per site who can provide meaningful insight. The topic guide will broadly look to understand pre-policy routines and processes across clinical teams, patient safety teams, risk management teams and relevant committees at each site, as well as PSIRF transition activities. Fieldwork will also be used to establish relationships with participating organisations and build rapport prior to the main ethnographic enquiry in WP4.

Interviewing foci: We will explore the broad management and processing of patient safety incidents at each site pre-policy, in relation to the organisational context of patient safety. This is likely to involve an examination of the 'who', 'what' and 'how' of investigations – personnel, processes and procedures,

[1] https://www.england.nhs.uk/patient-safety/serious-incident-framework/

priorities, decision making, actions, responsibilities etc. We will also look at pre-policy understandings of fairness and equity in investigations at each site to understand how they are constructed.

Analysis:
Data will mainly be in the form of audio recorded interviews. Analysis of this WP will be comparative between the Trusts, focusing on core similarities and differences. It will also be used longitudinally together with data from WP4 to understand change over time in order to compare incident investigation before, during and after PSIRF implementation. In keeping with our rapid ethos, researchers will generate a RAP sheet after each interview.[44] RAP sheets are a semi-standardised tool which allows emerging discoveries to be shared almost immediately within the research team.[44] Framework analysis will be used to develop headline themes.[45]

The following two work packages will run concurrently, providing both 'breadth' and 'depth' of understanding across the post-implementation evaluation.

5.11 POST-IMPLEMENTATION PHASE: Work Package 3 – Evaluating the PSIRF implementation – the national picture (Months 13-35; Leads: O'Hara, Macrae, Lawton, Woodward)
RQ1c) What are the changes arising from introduction of PSIRF? What are the positive and negative unintended consequences of the policy?
RQ1d) What are the implications for equity and fairness in incident response, for patients and staff?
RQ3a) How does implementation and use of the policy change over time, and in what ways?
RQ4) What might be the opportunities for, and challenges of monitoring and measuring the impact of the PSIRF in the medium to long-term?

5.11.1 Sample: All NHS Trusts and ICBs within the English NHS (n≤ 223).

5.11.2 Method: In this work package we will explore and document key indicators for the PSIRF implementation and across the NHS in England. We will do this in three ways: through a longitudinal survey of all NHS Trusts and ICBs in England, a documentary analysis of a sample of PSIRF Patient Safety Incident Response Plans, and qualitative exploration of responses to webinar content delivered by the NHS England National Patient Safety Team and content on the FutureNHS Patient Safety workspace. Further, we will work with a representative group of those implementing PSIRF within NHS Trusts across England to explore possible candidate metrics and monitoring methods for the ongoing and future evaluation of policy impact.
Survey
We will work with the NHS England National Patient Safety Team to support the logistics of distributing a longitudinal post-implementation survey to all NHS Trusts and ICBs across England (n≤ 223), aiming to achieve a 50% response rate. To avoid any potential social desirability bias in responses, the survey will be clearly marked as originating solely from an independent research team and that no identifiable response information will be shared with NHSEI. The survey will be administered twice – once earlier on in the implementation phase (likely Month 18), with the second survey administered after a period of embedding of the policy (likely Month 33). Capturing these data twice across an 18-month period will allow us to understand how the policy is initially operationalised and implemented, as well as how this changes over time. Using the database of contacts held by the NHS England National Patient Safety Team, we will send a named survey to each PSIRF Lead, to be completed on behalf of the organisation. The content of this survey will include a range of items pertaining to the research questions.

First, **we will ask respondents to answer items relating to the 'normalisation' of the policy using the Normalisation Process Theory NoMAD survey**.[27] This survey is a 23-item instrument for measuring implementation processes from the perspective of professionals directly involved in the work of implementing complex interventions in healthcare. This survey has been validated and used extensively in health services implementation research and is customisable for the particular intervention or policy in question.[46] Using this approach will allow us to explore and understand what people in organisations do to implement the PSIRF, rather than their attitudes or beliefs about it.

Second, the survey will include **items relating to the indicators of implementation activity based on the developed logic model,** for example: i) appointment of a patient safety specialist; ii) training of staff; iii) type of investigation method; iv) range of incident response types; v) what metrics or monitoring methods they use to monitor implementation. This will allow us to understand the extent to which key components of the PSIRF have been implemented.

Third, we will ask a series of questions pertaining to **how organisations are preparing for, identifying and managing the impact on equity and fairness of the policy implementation**. Items here may include: i) what public and patient oversight has been established locally; ii) how they are working with Patient Safety Partners within their governance and safety infrastructure; and, iii) what metrics or monitoring methods they are using to identify equity and fairness in incident response.

Finally, in the second survey at Month 33, we will include **items relating to outcomes of the new PSIRF**. These outcomes will be defined by the dynamic logic model, but are likely to include: i) number and type of investigations conducted; ii) number and type of other 'responses' to incident; iii) demographic breakdown of investigations and other response types; iv) local safety priorities identified; and, v) degree of involvement of staff, patients and families in incident investigations and responses. We will also collect free text data concerning unintended consequences (positive and negative), perceived challenges for implementation, and changes to the infrastructure for safety governance.

Documentary analysis of Patient Safety Incident Response Plans

As part of the PSIRF implementation, NHS Trusts will be required to develop a formalised plan to support the changes to local policy and practice. We will undertake a documentary analysis of a selection of these new plans (n=40), that explores how the policy is interpreted and enacted across organisations. Through the NHS England National Patient Safety Team list of contacts, we will approach PSIRF Leads in NHS Trusts directly to ask for a copy of their Patient Safety Incident Response Plan for implementation. Candidate Trusts will be identified purposively to achieve variation in a range of criteria from geographic location and Trust size, to teaching and foundation status, ensuring proportional representation of plans from acute healthcare and mental health/community trusts. We will purposively sample until reaching our target number of 40 Patient Safety Incident Response Plans.

Qualitative exploration of responses to webinar content delivered by the NHS England National Patient Safety Team and content on the FutureNHS Patient Safety workspace

Following the publication of PSIRF in August 2022, the National Patient Safety Team at NHS England will deliver a series of webinars to support providers to prepare, transition and work under PSIRF, a dedicated Patient Safety workspace on the FutureNHS platform will also be available. The webinars will include question and answer discussions via an online chat function. We have agreement from the NHS England National Patient Safety Team to use the information posted via the chat function as data, to add to our national level understanding PSIRF implementation. The information will be anonymous when we access it via the FutureNHS workspace, a virtual public workspace, we will also explore the workspace to understand how the PSIRF narrative changes over time and to identity relevant artefacts. We will seek advice from the University of Leeds - Faculty of Medicine and Health Faculty Research Ethics Committee regarding the appropriate level of ethical scrutiny required, and will be guided by a 2016 British Sociological Association publication on the topic of Researching Online Forums[2].

Exploring candidate metrics and monitoring methods for evaluating policy impact

We will work with our Patient Safety Leads Panel (described in Section 5.7) to explore and document the possible metrics and monitoring methods for longer term evaluation of the PSIRF. To do this we will convene three workshops with members of the group, held at Month 15, Month 22, and Month 34. The first workshop will explore the current metrics and monitoring methods used to assess safety within organisations. Members will be asked to consider the validity of these, what challenges there are in their interpretation, and their utility for understanding the fairness and equity of current safety investigation processes. The second workshop will ask members to reflect on their experience of implementing the PSIRF, and what they are doing locally to understand how the policy has changed practice.

The final workshop will revisit the questions from the first event, but through the lens of the new PSIRF. Specifically, members will be asked to identify the new metrics and monitoring methods used

[2] https://www.britsoc.co.uk/media/24834/j000208_researching_online_forums_-cs1-_v3.pdf

within their organisations, their validity and utility for assessing the impact and effectiveness of their safety management system. Candidate metrics and methods will be discussed and ranked against the Institute of Medicine's five principles for assessing performance measures: (1) importance (policy relevance, covering the population of interest, amenable to change); (2) scientific soundness (validity and reliability); (3) feasibility (in this case – publicly available); (4) alignment (interpretable, stable definitions over time); and (5) comprehensiveness (safety, effectiveness, patient-centredness, timeliness, efficiency, and equity).[47] Based on these rankings, we will work with members at the final event to co-produce a revised version of the dynamic logic model, to be taken forward into the data synthesis and stakeholder event in WP5.

5.11.2 Analysis

Survey

Quantitative data (e.g. NPT items, frequency data) will be analysed using a series of independent t-tests and descriptive statistics to identify changes to scores across the post-implementation period. Free-text qualitative data will be analysed using content analysis.[39]

Documentary analysis of PSIRF implementation plans

We will follow a similar analysis approach used within a current HS&DR funded programme led by Co-PI O'Hara (18/10/02). We will use a flexible inductive approach, applying framework analysis, which is recommended for applied policy research where there are specific research questions, a priori issues, and where there is potential to create actionable outcomes.[48] We will follow a defined five-step process of analysis: 1) familiarisation, 2) identifying a thematic framework, 3) indexing, 4) charting, and 5) mapping and interpretation.[49] Interpretation of the policies will pertain to the key research questions in this work package. In particular, we will seek to understand how and if NHS Trusts report tackling the management and monitoring of fairness and equity issues in incident response arising from the policy change.

Qualitative exploration of responses to webinar content delivered by the NHS England National Patient Safety Team and content on the FutureNHS Patient Safety workspace

The information posted via the chat function during the webinars and content on the workspace will be analysed such that anonymity of the individual's the information came from is maintained. We will analyse the information thematically at a broader level, in addition to a more detailed discourse analysis where appropriate.

5.12 POST-IMPLEMENTATION PHASE: Work Package 4 – Evaluating the PSIRF implementation – the organisational experience (Months 24-39; Leads: Sheard, Jones, Macrae, O'Hara)

RQ1c) What are the changes arising from introduction of PSIRF? What are the positive and negative unintended consequences of the policy?

RQ1d) What are the implications for equity and fairness in incident response, for patients and staff?

RQ2a) How is the policy experienced, interpreted and enacted by different professional groups and teams?

RQ2b) How and in what ways do local actors alter or adapt the policy? Why?

RQ2c) How is the policy interpreted and experienced by patients, patient groups, and the public? How does this shape policy implementation?

RQ3a) How does implementation and use of the policy change over time, and in what ways?

RQ3b) How does the organisational, commissioning, regulatory and wider policy context influence the implementation?

5.12.1 Sample: Six NHS Trusts (as per WP2), with each of the three researchers undertaking ethnographic fieldwork at one acute Trust and one mental health Trust.

5.12.2 Method:

Qualitative approach: We will explore the implementation of the PSIRF over time and across the multiple levels of an NHS Trust within its wider regulatory and public service context, using an organisational ethnographic case study approach [50]. The goal of this approach is to better understand social interaction and cultures of organisations and is particularly well suited to studying organisational policies, practices, processes and dynamics [50]. We will use this approach to provide depth, authenticity and

richness whilst simultaneously addressing applied health research priorities of generating rapid insight and actionable knowledge [50]. It allows the researcher to capture the "messy reality" of organisational life in health care,[51] whilst focusing on 'how' and 'why' research questions. Our approach to data collection is therefore exploratory and primarily inductively driven, with the recognition that we are aiming to answer applied research questions.

Data collection: Over 16-months, we will conduct three 8-week cycles of fieldwork across six 'cases', each representing an NHS Trust, their patients/families and staff, and the various regulatory levels that each Trust operates within, including the CQC, commissioners and NHSEI regional area. Our approach will allow access to organisational processes that may be displayed beyond tangible boundaries – such as regulatory bodies that exist geographically apart from a Trust but are inextricably linked to its PSIRF implementation and experience.

Data collection will predominantly take the form of observations and interviews (which may be in-person and/or virtual). Observations will be non-participant as the organisational ethnographic case study approach aims for the researcher to disturb the empirical field as little as possible [33] Field notes will be used to record descriptive and analytic reflections. Interviews will include both short, opportune, informal interactions and longer, planned encounters (face to face, video or phone depending on participant preference) which may be audio recorded to maintain an accurate record of the conversation. Specific attention will be paid in field notes and interview topic guides to: equity and fairness; consequences, experiences and implementation of the policy; adaptations to it; change over time. Researchers may also collect documentary sources pertinent to the focus of enquiry which are encountered opportunistically during observational periods (formal analysis of PSIRF plans/policies is a focus of WP3).

The 8-week fieldwork period for all six case sites will run simultaneously in order for data to be comparable between Trusts. This means all researchers will collect data during the same time period and then work together on interim, formative analysis. As a general rule of thumb, we expect each of the three researchers to take consistent ownership for fieldwork at the same two sites (one acute Trust and one mental health Trust) throughout the 16-months of this work package. Over the 8-week fieldwork cycle, they will each spend one to two days per week at the acute Trust and the same timeframe again at the mental health Trust. Days of the week and times of visits will be variable dependent on local focus of interest. This will equate to a minimum of eight days and a maximum of 16 days spent collecting data at each site, for each of the three fieldwork periods. Eight weeks is not an exact length of time researchers may spend on data collection at each case site and this will depend on whether or not there is sufficient and meaningful enough data to exit the field. Headline findings after each 8-week data collection period will be fed back at two levels: 1) each of the six Trusts 2) NHS England National Patient Team. See Figure 2 for a visual depiction of data collection plans.

Observational foci: The potential participant pool is wide and exists on several levels. We expect to purposively sample for the following groups of people: patients, their families and carers, Patient Safety Partners, frontline clinical staff, patient safety, risk management and clinical governance staff, incident investigators, senior managers, legal teams, medical examiners, commissioners, ICB staff and people from relevant external organisations e.g. CQC staff, coroners and Health Services Safety Investigations Body (HSSIB). We will strive to include participants from all of the above identified groups for each site, acknowledging that some groups may take time to build rapport and relationships with the researchers. All observations and interactions will be undertaken after express consent has been gained from potential participants.

Examples of the type of observations and interactions the researchers may encounter include: i) risk management meetings, patient safety meetings, quality improvement meetings, board meetings, committee meetings; ii) discussions with patients, families, carers and staff following an incident and during learning responses; iii) support of staff, patients, families and carers following incidents and during learning responses; iv) contact with commissioners, the CQC and ICB v) shadowing of personnel who are central to PSIRF implementation and learning responses including Patient Safety Specialists, PSIRF Leads, investigators and Patient Safety Partners (lay representatives on safety and governance committees). Particular attention will be given to any equity and fairness issues arising across stakeholder groups. One key group to involve will be patients and the public to understand how they receive and experience this policy change. We will do this by observing implementation activity with

public representatives within each ‘case’. For example, this could be through newly created ‘patient boards’ that support PSIRF implementation, or any liaison with existing patient or public groups. It is difficult to specific exactly how many meetings or interactions each researcher will observe in advance as, per ethnographic tradition, this is usually flexible dependent on local context and data/analytic sufficiency. The richness of a researcher’s experience in the field is more important than the length of time spent at a site,[52] which is why we have allowed for range of 8 to 16 days fieldwork per cycle.

5.12.3 Analysis*:* The data collected will take the form of 1) ethnographic field notes 2) interview transcripts/notes 3) documents relating to meetings, incidents and processes. All data sources will be collated and the research team will use NVivo 10 for data management and storage. Both formative and summative data analyses will be carried out by the field researchers in collaboration with the core members of the qualitative research team (LS, LJ, JOH). The three researchers will meet regularly to maintain ongoing dialogue about their time spent at the case sites. These meetings will foster reflexivity, provide peer support, and contribute to analysis.

Formative evaluation: Formative analysis will be descriptive and thematic [35] with headline findings fed back after each 8-week ethnographic cycle to each Trust. Interim findings will also be fed back to the Patient Safety Team at NHS England at a series of three ‘checkpoint meetings’ to provide ongoing feedback at a strategic level. This formative approach supports learning about the iteration of the implementation approach, not just the overall summative learning following implementation completion. We will view the analysis of data for this work package as ‘constantly iterative’, with the above team members meeting fortnightly throughout the fieldwork period to discuss emergent findings. See Figure 2 for a visual depiction of analysis plans.

Summative evaluation: In the final four months, summative findings will be generated attending to the longitudinal nature of PSIRF implementation. Summative analysis will be both inductive and deductive. Inductively, we will use techniques from case study research [53] to produce rich multi-case analyses and reach high level conclusions whilst paying attention to our research questions and understanding change over time. Deductively, we will analyse the data based on NPT [27] to gain a conceptual understanding regarding the normalisation of PSIRF, including whether its use has become routinely embedded over time (or not) and why. This NPT analysis will be taken forward into the next workpackage (WP5) by translating the NPT construct findings into simple statements which hold relevance and meaning for healthcare staff, patient safety staff, policy makers, regulators and patient representatives.

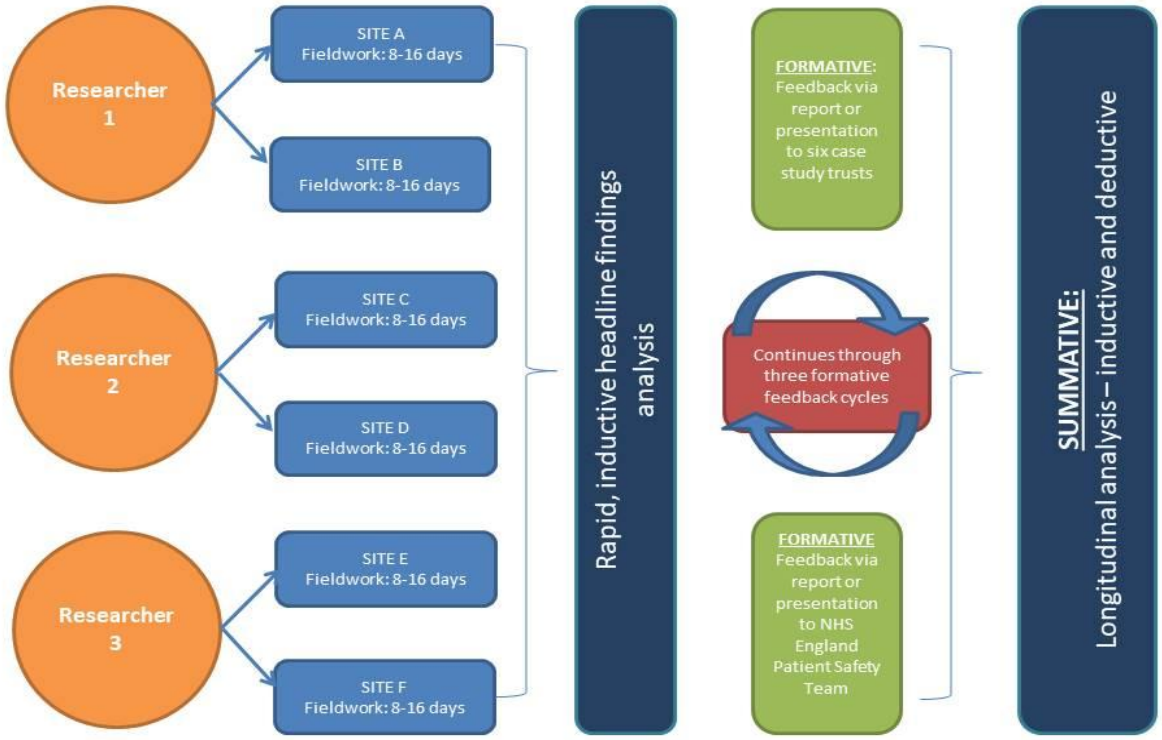

Figure 2. Visual representation of formative and summative evaluation.

5.13 SYNTHESIS PHASE: Work Package 5 – Understanding and articulating successful implementation of a patient safety policy (Months 40-47; (Leads: O'Hara, Macrae and all co-applicants)

RQ3) What supports the effective implementation of the PSIRF?

5.13.1 Sample

Six participating NHS Trusts, patient representatives, policy-makers, regulators, staff.

5.13.2 Method

In the first four months of this phase of work, we will bring the data from the preceding four work packages together to understand and articulate the key issues for successful implementation of a patient safety policy. We will proceed with the synthesis through drawing the full research team together (using remote video conferencing) **for three half-day synthesis workshops**. In these, we will consider the available data, and bring together to answer the question - *what supports the effective implementation of the PSIRF?* We will also revise the dynamic logic model based on the data from WP3 and WP4. Finally, we will seek to present in a series of simple statements what conditions and approaches maximised the success of the PSIRF implementation. In Month 44 we will bring representatives from all six case study sites, policy makers, regulators and patient representatives in **a large stakeholder workshop** (n=50) where the research team will present this synthesis and the revised logic model. The aim of this event will be to discuss the findings, and bring together in a format and language that is accessible to a range of audiences. The main output from this work package will be the **'Patient Safety Policy Implementation Handbook'**, which will be based on this workshop and the synthesis of our findings. This policy-facing report will provide an empirically-grounded, theoretically-informed 'manual' that reflects the findings of the programme, through the lens of NPT. This will present key recommendations in the form of problem-oriented practical strategies, mapping the key challenges in policy implementation to indicative strategies, practical options and specific recommendations, supplemented by illustrative

vignettes. This will ensure that the recommendations are meaningful and actionable for a policy and practice audience.

5.14 COMPLETION PHASE: Completion of programme deliverables (Months 47-49)
Whilst write up and dissemination activity will be ongoing, this phase will focus on completion of outstanding writing deliverables (final report, academic papers, policy-facing documents), and other engagement and dissemination activity (see section 7).

6. Dissemination, Outputs and Anticipated Impact

6.1 What do you intend to produce from your research?
This programme of work is embedded in the movement of policy into practice, and as such, our outputs will need to target the range of audiences involved in this process. We will disseminate findings to key stakeholders in creative and accessible ways, with costs for design support included in the requested budget to support this. We will publish in high impact journals, and attend key quality and safety conferences. The project will form part of the wider programme of the NIHR Yorkshire and Humber Patient Safety Research Collaboration (YH PSRC), and thus achieve national and international visibility as part of their dissemination and engagement strategy. We will also disseminate informally through social media, which has been used very successfully by the team previously.
Key research output
Our principle research output will be the synthesis of the learning from across the programme, undertaken within WP5. Through our academic synthesis, and engagement with a range of stakeholders as part of the stakeholder event, we will draw together what is known about the implementation of patient safety policy. This learning will form the basis of our key research output – the **'Patient Safety Policy Implementation Handbook'**. This policy-facing report will reflect the findings of the programme, through the lens of NPT, ensuring that the recommendations are meaningful and actionable for a policy and practice audience. We will augment this written report with other mechanisms for engaging audiences, including blogs and podcasts.
Additional research outputs
In terms of specific outputs, we would anticipate the following:
<u>Pre-implementation Phase</u>
WP1:

1) **one academic paper** presenting the development of the dynamic logic model for the national policy;
2) **one policy-facing report** presenting the dynamic logic model in an accessible format;

WP2:

3) **one academic paper** presenting the rapid review of the literature on how patient safety incidents are responded to, investigated and learned from within the English NHS;

<u>Post-implementation Phase</u>
WP3:

4) **one academic paper** presenting the national implementation, based on the national survey and documentary analysis;
5) **one academic paper** presenting the candidate metrics and monitoring methods for assessing longer term impact of the PSIRF;
6) **one summary report** presenting the national level data and documentary analysis;

WP4:

7) **two academic papers** presenting a summative, rich, longitudinal account of all three waves of ethnographic data collection in order to present change over time, and an in depth exploration of a particularly impactful theme;

<u>Synthesis Phase</u>
WP5:

8) **one academic paper** presenting the synthesis of the programme of research, and the key recommendations for patient safety policy implementation;

9) **one brief report for Patient Safety Specialists** on best practice for implementing patient safety policy.

6.2 How will you inform and engage patients/service user, carers, NHS, social care organisations and the wider population about your work?

Engaging patients and the public

We will engage with patients and the public via a number of mechanisms. First, the Stakeholder Engagement activity will link into other existing Patient and Public Involvement and Engagement (PPIE) infrastructure to support dissemination. Through the NIHR YH PSRC, the regional Improvement Academy, 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. Second, as described in Section 6.7 below, we will work with our two stakeholder panels (Citizens' Panel, Patient Safety Leads Panel) 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

The principal evidence users for this research will be healthcare organisations and policy makers. We have developed this programme of research with evidence users, and will continue to collaborate with them to deliver this research, with representatives attending our six-monthly Steering Group meetings. We will also develop a network of collaborators throughout the research, which will include regulators, professional bodies and public healthcare advocacy groups. Further, through our links with the Improvement Academy regionally and NIHR Applied Research Collaborations (ARCs) and Academic Health Science Networks (AHSNs), 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, if funded, will be embedded centrally within the NIHR YH PSRC, addressing one of our priority areas of research, namely improving safety management. Through this affiliation, our research outputs and findings will achieve an enhanced national and international profile as part of their wider dissemination and engagement strategy.

6.3 How will your outputs enter our health and/or social care system or society as a whole?

There are three key ways in which our outputs will enter into the healthcare system. First, this research programme has been **conceived and developed in collaboration with the NHS England National Patient Safety Team**. They are committed to working with us to provide access to necessary networks, but most importantly, have requested the formative feedback element specifically to be able to hear, and act on, both emergent and summative findings from the evaluation. A letter of support from the NHS England National Patient Safety Team has been uploaded with this application. This commitment to engage with the research across the programme represents the key mechanism for the findings of our research to enter the healthcare system. Second, this research will be translated and disseminated through **our existing academic and improvement networks.** The research will be primarily based within the NIHR YH PSRC and as such, will be reported to and engaged with by a range of national and international stakeholders. Further, through our existing presence on a range of academic partnership and improvement networks (the regional Improvement Academy, the Yorkshire and Humber ARC, the Yorkshire and Humber AHSN) we will be able to reach and engage with a range of healthcare professionals, senior managers, and improvement scientists, who can collectively support the translation of our findings into healthcare system change. Finally, through our academic research outputs, we will **engage with wider international audiences, influencing the discussions about patient safety policy development and implementation**, as well as theory regarding how patient safety can be

measured, monitored and managed. Two applicants (O'Hara, Wiig) are founding members of the International Resilient Healthcare Society, and as such, this work will have international academic visibility in shaping discussions about how to change patient safety narratives as a result of national policy implementation.

6.4 What further funding or support will be required if this research is successful (e.g. from NIHR, other Government departments, charity or industry)?

The outputs from this programme of research will not require further funding or support. We anticipate that our key research output – the **'Patient Safety Policy Implementation Handbook'** – will stand alone as a foundational blueprint for supporting the development and implementation of future patient safety policy.

6.5 What are the possible barriers for further research, development, adoption and implementation?

We believe there to be limited barriers for future research, development, adoption or implementation of this programme. The work we will undertake in this programme is self-contained, representing as it does the evaluation of a patient safety policy implementation. The outputs will enter into the policy and academic domains allowing them to be built upon and utilised by those developing and implementing policy, as well as those researching this effort. We have reduced the usual 'impact gap' between research and policy through our early engagement with policy makers, who have shaped this research programme and will be central to it throughout.

6.6 What do you think the impact of your research will be and for whom?

We anticipate that the impact will be significant in the short- and longer terms. The NHS England Patient Safety Team is fully supportive of this work, and actively engaged in its development. The team requested the formative evaluation approach to allow them to be responsive in the implementation, in turn maximising the opportunity to improve patient safety management across the English NHS, and increasing the chances of its successful implementation and sustainability. The longer-term potential impact is high, with the possibility of the research outputs to close the gap between patient safety policy and practice, and therefore improve patient safety across the English NHS. Additionally, the findings of this research will have significant wider policy relevance, and for patient safety policy implementation nationally and internationally.

6.7 How will you share with study participants the progress and findings of your research?

The study sample will reflect the range of stakeholders involved in, and impacted by, the implementation of the PSIRF. We therefore need to ensure our mechanisms for sharing findings reflect this. The mechanisms for sharing study findings are listed by key stakeholder groups below:

1) Policy-makers

The two mechanisms for sharing our findings will be i) through the policy-facing report developed within WP1 and the final key output; and, ii) through the formative feedback checkpoint meetings.

2) Participating organisations

There are two groups of participating organisations to consider here – those acting as case study sites (WP2 and WP4), and those providing data for the national survey and documentary analysis (WP3). Those acting as case study sites will be fed back formative feedback through the course of WP4 and be involved in the synthesis event in WP5. However, we will also develop a short summary report for organisations bringing together the findings of WP3 for disseminating findings nationally.

3) Healthcare professionals, patients and the public

Sharing study findings with those impacted by the implementation of the PSIRF will be paramount. We have costed in fees for design support to enable us to be creative in how we share study findings with this group, which is important given the sometimes abstract nature of policy implementation. We will work with our two stakeholder Panels to develop messages that summarise the findings across the programme in easily accessible ways. This will then be shared at the end of the study with participants. Further, our learning from this process of creating meaningful messages will feed forward into the final 'Patient Safety Policy Implementation Handbook'.

7. Project / research timetable
This programme of research will run for 49 months from May 2022. A detailed project timetable including key milestones and deliverables is included at the end of this research plan.

8. Project management
There will be four key mechanisms for managing the programme of research.

1) Project Management Team
A Project Management Team (PMT) will meet regularly over the project period. This team will comprise the Co-PIs (JOH/CM) and the lead researchers (LS, LJ, SWiig, SWoodward, RL, JT). 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 as part of the Steering Group, in addition to more frequent meetings if required. Additional researchers will join the PMT at later stages once in post (i.e. the Senior Researchers and the Junior Researcher). The line management of the research staff will be spread across the academic institutions delivering the project.

2) Steering Group
A Steering Group will be established to oversee the design and conduct of the research programme. The group will meet every six months, totalling eight times over the 49-month programme period. In attendance will be the Co-PIs, all co-applicants, project researchers, a key contact from each of the participating organisations, and research collaborators. Collaborators on this group will include representation from key institutions, and academics with experience of patient safety policy development and implementation. We currently have agreement for membership from, Dr Tracey Herlihey (Head of Patient Safety Incident Response Policy, NHS England), Lauren Mosley (Head of Patient Safety Implementation, NHS England), Professor Justin Waring (Loughborough University). The role of this group will be to ensure the research objectives are being met, provide strategic input, financial accountability, and to facilitate the progression of the project across the sites.

3) Oversight committee
We will establish an oversight committee to ensure independent oversight and overall scrutiny of the research programme as it proceeds through the 49-month study period. We will appoint a Chair of this committee that has experience of the academic phenomenon in question, and members that reflect the range of stakeholders involved in patient safety policy implementation.

4) Patients and the Public
The links to the PPI engagement infrastructure have been described in the specific Patient and Public Involvement questions within the online form.

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

10. Project / research expertise
This research will sit within the NIHR YH PSRC directly addressing our research priority on improving safety management. The team includes extensive expertise in patient safety, incident investigation, human factors, policy research, research methods, patient and staff involvement, and lay representation. The research will be jointly led by Professor Jane O'Hara and Professor Carl Macrae.

Co-Principal Investigators:

Professor Jane O'Hara (0.2FTE) is Director of Research at THIS Institute (The Healthcare Improvement Studies Institute), University of Cambridge and Visiting Professor of Healthcare Quality and Safety (University of Leeds). Jane will lead the programme of research and will be responsible for the overall management of the project, stakeholder engagement and research activity. Jane has over a decade of experience leading patient safety research, and a further eight years of applied psychological research prior to that. She currently leads a large HS&DR programme (Ref: 18/10/02) in a related area, and is Theme Lead for the Safer Systems, Cultures and Practices (SSyCaP) theme within the YH PSRC.

Professor Carl Macrae 0.1FTE) is Professor of Organisational Behaviour and Psychology, based at the Nottingham University Business School. Carl will chair the Steering Group, establish and maintain contacts within patient safety networks, lead on the development of the Patient Safety Policy Implementation Handbook, and will lead WP1. Carl's research focuses on the policy and practice of patient safety improvement, with a particular focus on investigating and learning from incidents. His work led to the establishment of the Healthcare Safety Investigation Branch and to translate research into real-world impact. Since 2009, he has combined academic research with various national patient safety advisory roles including at the NHS National Patient Safety Agency, Healthcare Safety Investigation Branch, the Public Administration Select Committee and (from summer 2021) as national advisor on patient safety to the CQC. Carl is Theme Co-Lead for the SSyCaP theme within the YH PSRC.

Co-Investigators:

James Titcombe (0.05FTE) has campaigned for patient safety since 2008, when his son Joshua died shortly after being born. Since then, James' career changed from working in the nuclear industry to a career in patient safety – championing improvements in culture and learning. James has worked with the CQC as their National Advisor on Patient Safety and recently has advised on the establishment of the new Healthcare Safety Investigation Branch. James will be PPIE-Lead for the programme of research, supporting the Co-PIs and wider stakeholder engagement activity.

Dr Laura Sheard (0.1FTE) is a Reader based at the University of Manchester. She is a qualitative methodologist, applied health services researcher and medical sociologist who has been conducting patient safety research for almost 10 years. Laura will be overall Qualitative Lead for the programme of research and manage Researchers based at the University of York.

Dr Lorelei Jones (0.1FTE) is a Senior Lecturer in Health Sciences based at Bangor University. Her research is on the social organisation of health care in the context of contemporary policy reform, and uses organisational ethnography to enhance the understanding of cultural processes and contexts, develop theory and inform practice. Lorelei will be the lead for WP2 and provide expertise in ethnographic methods and policy implementation throughout the programme of research.

Professor Rebecca Lawton (0.05FTE) is a Professor in the Psychology of Healthcare, based at the University of Leeds. Rebecca is Director of the NIHR YH PSRC and Improvement Science lead for the Yorkshire and Humber ARC. She has 27 years' experience of patient safety research. Rebecca will provide Human Factors expertise throughout the programme of research, and links into our affiliated networks through her roles as Director of the YH PSRC, and the Improvement Science theme within the Yorkshire and Humber ARC.

Professor Siri Wiig (0.05FTE) is Centre Director of the SHARE Centre for Resilience in Healthcare at the University of Stavanger Norway, and Professor of Quality and Safety in Healthcare Systems. She is a safety scientist with extensive experience in healthcare regulation, safety investigation and multilevel studies in different healthcare contexts and sectors (emergency preparedness, healthcare, petroleum industry). Siri will provide expertise on the impact of the regulatory context on patient safety policy implementation, as well as wider safety theory input. Siri will be match-funded through her role at University of Stavanger, with funds only requested to support three annual visits to the University of Leeds to support data analysis and writing for publication.

Professor Suzette Woodward (0.05FTE) is a Visiting Professor for the Institute of Global Health Innovation at Imperial College University London. Currently an independent patient safety consultant, Suzette has over 25 years of patient safety expertise, with the vast majority of this at patient safety policy level. She has held Board Director posts at the National Patient Safety Agency (NPSA), and NHS Resolution plus clinical and professional advisory roles for the Department of Health and Social Care

and Public Health England. Suzette undertook a professional doctorate while at the NPSA in which she investigated the factors that help and hinder implementation of national patient safety guidance. She will provide expertise in the practice and study of patient safety policy development and implementation, and support engagement of, and dissemination to, a wide range of key stakeholder audiences. Suzette will have a specific role in our public and policy facing engagement activity, and in particular the stakeholder event planned for WP5.

Collaborator:
Angela King has significant patient and public involvement and engagement experience. Angela will be the independent chair of the Citizens' Panel, working closely with James Titcombe (PPIE Lead Co-Investigator) to progress the set-up, support, and delivery of the Citizens' Panel activity, supported by the core research team.

11. Success criteria and barriers to proposed work

11.1 Success criteria
There are defined objectives and outputs for every phase of the programme that will be used by the Steering Group and Oversight Committee to measure and monitor progress. Our key success criteria include: i) recruiting research staff; ii) achieving ethical and governance approvals; iii) recruiting 30 participants into WP1; iv) successfully recruiting six NHS Trusts across three NHS Regions to act as case study sites; v) undertaking ethnographic work in six case study organisations pre- and post-implementation of the PSIRF in WP2 and WP4; vi) achieving a response rate over 50% to the national survey in WP3; vii) successfully sampling 40 Patient Safety Incident Response Plans to inform the documentary analysis in WP3; viii) identification of candidate metric and monitoring methods for ongoing impact assessment of the PSIRF in WP3; ix) development and ongoing support for the Citizens' Panel and Patient Safety Leads Panel; x) completion of a comprehensive synthesis of the findings and production of the final key output; xi) submission of seven publications in peer-reviewed journals, and production of three policy-facing reports.

11.2 Identified barriers
a) **Changes to the political and policy landscape** during the course of the project might impact on the key collaborating case study organisations' willingness or ability to participate in the programme of research. To mitigate this we will work closely with the NHS England National Patient Safety Team to understand which organisations will be implementing the PSIRF at what times, so that we can ensure the timetable of research fits with the timetable of implementation.
b) As with all health services research, **engagement of staff** within case study organisations could represent a risk, due to lack of time, or lack of understanding of the likely design of, or benefits for engaging in the research programme. Across the research team we have a wealth of experience and expertise in engaging stakeholders within research, and a collective track record in delivering research to time and budget. Further, we will work hard in the early phases of the programme to engage key individuals within participating organisations, who will then sit on the project Steering Group to both support the steer of the research, as well as acting in a 'boundary spanner' role for the research in their respective organisations.
c) There is an ongoing challenge within health services research due to the recent **COVID-19 pandemic.** It is possible that ongoing restrictions might cause issues for data gathering. We will mitigate the problems associated with these by ensuring our ethics and governance approvals accommodate a range of data collection methods that can be flexed where necessary if restrictions are put in place over the course of the programme.

Research timetable

	2022								2023												2024												2025												2026				
	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	April	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	April	May
Researcher recruitment*																																															
Set up Steering Group*																																															
Set up Oversight Committee*																																														
Set up stakeholder panels*																																														
Site engagement*																																														
Ethics and R&D for WP1, WP2, WP4*																																														
WP1: Interviews (n=30)																																														
WP1: Logic model development																																														
WP2: Interviews																																														
WP2: Rapid Review																																														
WP3: Survey T1																																														
WP3: Documentary Analysis																																														
WP3: Establishing candidate metrics																																														
WP3: Survey T2																																														
WP4: Ethnography																																														
WP4: Summative Analysis																																														
WP5: Synthesis Workshops																																														
WP5 Stakeholder Event																																														
WP5: Development of final output																																														
Writing of academic outputs																																														
Writing of public / policy facing outputs																																														
Final report write up																																														
Final report delivery																																														

*Activity that commences ahead of start date in May 2022.

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