THIS.Institute The Healthcare Improvement Studies Institute

Made possible by The Health Foundation

Protocol

The Patient Safety Specialist and Patient Safety Partner programmes: a national evaluation (PSS-PSP)

Version 1

Summary

Patient safety remains a major challenge in the United Kingdom and globally. Accounting for recent developments in the theory and evidence behind patient safety, the National Health Service (NHS) in England has introduced two new roles: the patient safety specialist and the patient safety partner. Patient safety specialists are a locus for activity around safety and improvement, acting as "experts to lead on safety" and developing their skills through advanced training, and working collaboratively within and beyond their organisations. Patient safety partners are patients, carers and other 'lay' people who provide a critical external perspective on patient safety. Together, the two roles represent a major investment for the NHS. They have much promise but they have yet to be subjected to sustained critical scrutiny.

This study will involve an evaluation of the two roles and the interactions between them, combining elements of formative, summative and developmental evaluation, to help optimise the roles, support role-holders, and secure best value from the NHS's investment. Over four workstreams, we will: (i) synthesise learning for healthcare from other high-risk industries that have deployed similar roles in pursuit of improved safety, using qualitative interviews; (ii) building on an existing baseline survey, track the development of patient safety specialists through time with further surveys, and examine the extent to which specialists are translating advanced knowledge around safety into practice by analysing work they have produced in the course of training; (iii) develop a theory of change for patient safety partners through document analysis, interviews and workshops, and develop and administer a survey at two time points to track the evolution of that role through time; and (iv) examine the work of specialists and partners together in practice through longitudinal ethnographic work in six purposively sampled case study organisations across different sectors of the NHS.

Our work will be guided throughout by an expert collaborative group, bringing together stakeholders who will support the investigator team throughout the study, and by joint

UNIVERSITY OF CAMBRIDGE

interpretive forums that convene wider groups of stakeholders to enrich analysis and interpretation at key junctures. We will communicate our findings as they arise from the study in a variety of formats appropriate to different audiences; thanks to our close links with NHS policy, practice, education and research communities, our findings will reach the right audiences quickly and help to inform the ongoing development of the specialist and partner programmes, maximising their contribution to the safety of patients.

Key words

Patient safety; Evaluation; Professionalism; Expertise; Patient and public involvement; England

Contents

1 Research Team

Chief Investigator

Professor Graham Martin, Director of Research, The Healthcare Improvement Studies Institute (THIS Institute), University of Cambridge

Co-Investigators

Professor Jane O'Hara, Director of Research, The Healthcare Improvement Studies Institute (THIS Institute), University of Cambridge

Dr Farhad Peerally, Associate Professor, Department of Population Health Sciences, University of Leicester

Professor Justin Waring, Dean of Social Sciences and Humanities, Loughborough University

Professor Thomas Jun, Professor of Sociotechnical Systems Design, School of Design and Creative Arts, Loughborough University

Dr Michael Fray, Senior Lecturer in Human Factors and Design, School of Design and Creative Arts, Loughborough University

Professor Carl Macrae, Professor of Organisational Behaviour and Psychology, Nottingham University Business School

Dr Robert Pralat, Research Associate, THIS Institute, University of Cambridge

Ms Kiri Dargaville, Research Engagement and Involvement Advisory, THIS Institute, University of Cambridge

Project manager and lead researcher

Dr Robert Pralat, Research Associate, THIS Institute, University of Cambridge

Patient & public involvement (PPI) lead

Ms Kiri Dargaville, Research Engagement and Involvement Advisory, THIS Institute, University of Cambridge

Sponsor

Ms Carolyn Read, School of Clinical Medicine, University of Cambridge

Funder

National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research (HSDR) programme (reference NIHR164453). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

Protocol contributors

Development of the protocol was led by Professor Martin and Dr Pralat, with critical input from other investigators. All investigators approved the final version of the protocol. The funder and sponsor had no role in protocol development.

Study steering committee

The study steering committee will include eight members in total (two from the study team and six independent members, including the chair. The membership is as follows:

- Frances Healey (chair) – independent
- Graham Martin – study team
- Robert Pralat – study team
- Ceri Davies – independent
- Peter Hibbert – independent
- Hilary Lloyd - independent
- Jenni Murray – independent
- Laura Pozzobon – independent

Role of study sponsor and funder

The study sponsor and funder have no role in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. In line with its policy, NIHR will be notified of outputs arising from this study ahead of publication.

Roles and responsibilities of committees

The role of the Steering Committee is to provide overall supervision for a project on behalf of the study's Sponsor and Funder and to ensure that it is conducted to the rigorous standards set out in the UK Policy Framework for Health and Social Care and the Guidelines for Good Clinical Practice. Further information of the role of the Steering Committee can be found on the NIHR's website.

An expert collaborative group, including contributors from a range of public, clinical, managerial, policy and academic backgrounds, will work closely with the research team to guide the direction of the study. More information on its role can be found in Section 10.

2 Background

In common with healthcare systems globally, the National Health Service (NHS) in England faces persistent challenges in ensuring the safety of the patients it treats. Harms to patients that might have been prevented are not as rare as they should be. The problem is substantial: around five per cent of patients in all settings worldwide are harmed (Panagioti *et al.* 2019). Problems with patient safety also have important negative consequences for healthcare systems. In England, the costs of settling litigation claims relating to clinical negligence, for example, stood at £2.7 billion in 2022/23, with a further £69.6 billion set aside by HM Treasury for possible future claims (NHS Resolution 2023). These astonishing figures have been called a "major threat to the sustainability of the NHS" (Yau *et al.* 2020).

Improving patient safety has proved challenging in practice, in the UK and elsewhere. Through time, it has become apparent that the healthcare setting poses distinctive challenges and that what works in other contexts may not readily result in improvements in patient safety (Bosk *et al.* 2009; Catchpole and Russ 2015; Dixon-Woods 2010; Treadwell *et al.* 2014). 'Technical fixes', from checklists to prevent harm to techniques for investigating root causes when things go wrong, have thus frequently failed to have the impact anticipated when implemented in healthcare settings, running into the realities of organisations that are complex and fragmented (Waring *et al.* 2016). More than this, there is increasing recognition that the proliferation of safety-related interventions and activities may bring its own risks (Allen 2017; Braithwaite *et al.* 2015; Clay-Williams and Colligan 2015; Sujan *et al.* 2019). Increasing recognition of the downsides of conventional approaches to safety, in healthcare and other settings, has led to the development of new approaches. Most prominently, the theory of 'Safety-II' posits that too much effort is spent on learning from those occasions when things go wrong (rather than understanding why and how things go right most of the time), that the predominant 'find and fix' approach to safety improvement is inefficient, ineffective and unsustainable, and that human adaptability is a crucial *resource* in achieving safety (rather than primarily a risk to be managed) (Braithwaite *et al.* 2015; Hollnagel *et al.* 2015). However, while the ideas put forward in Safety-II and similar new approaches have important potential (Lawton 2018; Woodward 2019), putting them into practice is far from straightforward.

In short, patient safety has turned out to be a much more complicated and protracted problem than originally imagined—and one that requires high levels of expertise and coordination, and the involvement of the breadth of relevant perspectives. In 2019, NHS England launched its first *NHS Patient Safety Strategy* (NHS England and NHS Improvement 2019). Covering three areas of activity—insight, involvement, and improvement—it set out a vision to improve patient safety through a more nuanced approach to culture and systems, and reduce safety-related mortality by 1000 lives by 2025. At the centre of the *Strategy* were two new roles: the patient safety specialist and the patient safety partner. **Patient safety specialists**, designated by all NHS organisations (providers and integrated care boards) since 2020, are intended to be a locus for activity around safety and improvement, acting as "experts to lead on safety" (NHS England and NHS Improvement 2019), developing their skills through advanced training, and

working collaboratively within and beyond their organisations (NHS England 2021). **Patient safety partners** are patients, carers and other 'lay' people recruited by NHS organisations to provide a critical external perspective on patient safety, helping to ensure that patients and carers are "present, powerful and involved at all levels of healthcare" in the way envisaged by experts following the Mid Staffordshire inquiry (National Advisory Group on the Safety of Patients in England 2013). They are to be trained, appraised, and given safety-related goals for their work (NHS England and NHS Improvement 2021a), and will contribute to the advancement of patient safety in their organisations at senior levels—for example, as members of Safety and Quality Committees and groups focused on learning from deaths, by working with organisations' boards and regional bodies, and by contributing to key safety-related activities such as audits and improvement projects (NHS England and NHS Improvement 2019).

Together, the two roles reflect an increasing recognition that patient safety is a complex priority that requires dedicated focus, effort and ingenuity. They recognise the importance of specialised expertise, and of the critical role that patients make in realising safety in practice (O'Hara *et al.* 2018). The two roles represent a major investment for the English NHS (employing specialists alone is likely to cost around £25 million a year). Yet to date, other than a small-scale formative evaluation of the patient safety specialist role conducted by this team (Martin *et al.* 2025), they have not been subject to critical scrutiny. This study will evaluate the two roles as they work individually and in concert, combining elements of formative, summative and developmental evaluation (Gamble 2008), to help optimise the roles, support role-holders, and secure best value from the NHS's investment.

2.1 The patient safety specialist and patient safety partner roles

Around 800 patient safety specialists are now in post, across all NHS organisations including acute hospitals, mental health services, community health services, ambulance trusts, and integrated care boards (ICBs). Many non-NHS organisations providing NHS services have also taken up the role. Similarly, all NHS organisations are expected to appoint patient safety partners, though progress towards recruitment to date is less advanced, with implementation less centrally driven (NHS England and NHS Improvement 2021b).

At a high level, the objectives for the two roles are clear. Patient safety specialists are to act as "captains of the team" who "provide dynamic, senior leadership, visibility and expert support" to patient safety work (NHS England 2023), co-ordinating action across their organisations and working to embed evidence-based, scientifically informed approaches to safety, such as the methods and approaches offered by Safety-II (NHS England and NHS Improvement 2019). Patient safety partners are to contribute to service and pathway design, the governance of safety, and organisational strategy and policy (NHS England and NHS Improvement 2019), embedding for the first time the views of patients, carers and others from outside the healthcare system in safety management—views which are acknowledged as vital and distinctive (Ocloo and Matthews 2016; Sheard *et al.* 2017; Sutton *et al.* 2015; Wiig *et al.* 2020),

but for which to date there has been no formal and consistent platform. Updates to the *Patient Safety Strategy* have further emphasised the place of both roles in addressing inequalities in patient safety problems and outcomes, which came into sharp focus during the Covid-19 pandemic (NHS England and NHS Improvement 2021b).

At the level of detail, however, it is much less clear exactly what patient safety specialists and patient safety partners will do, and how those activities should translate into meaningful improvements in the safety of care. The plans set out in the *Strategy* and subsequent guidance offer a high-level outline, not a detailed blueprint, for the roles. Therefore timely evaluation of the roles in practice—how they have been realised in different circumstances and contexts, how their work interacts with other activities, and with what consequences—is vital, in order to learn from the roles' successes and failures, produce guidance to support role-holders as they seek to develop their contributions further, and identify broader implications for similar future initiatives.

Using funding from the Health Foundation's grant to support The Healthcare Improvement Studies Institute (THIS Institute), and in close collaboration with the team leading the programme at NHS England and with other key stakeholders including patients and staff, we have completed a small-scale formative evaluation of the patient safety specialist programme. This one-year mixed-methods study generated a baseline understanding of how patient safety specialists and organisations have put the roles into practice, and of variation in how the role has been implemented in different organisations (Martin *et al.* 2025). It involved the development of a theory of change and accompanying logic model for the patient safety specialist role, produced collaboratively with patient safety specialists, which provided the basis for further theory-based evaluation of the role and programme.

We propose to build on this preliminary project through longitudinal study of the patient safety specialist role. We will use similar methods to characterise the theory of change for the patient safety partner role, to examine how it is being put into practice, and to follow its evolution through time. For both roles, we will carry out detailed longitudinal case studies of their work in practice in a range of organisations, including both their distinct activities and the ways in which they work together to advance patient safety.

Our work is led by a multidisciplinary team with methodological, safety science and clinical expertise. It will be underpinned by close collaboration with the full range of stakeholders throughout, including patient safety partners and specialists, other NHS staff, patients and carers, wider experts in patient safety, the teams at NHS England leading the programmes, and other key organisations, including those with strong records in communicating research findings to audiences that matter. This will enable us to produce an evaluation that resonates with key audiences, delivers key findings in a timely fashion to inform development of the roles, and produces useful summative insights to inform future plans.

3 Study aims and objectives

3.1 Aim

Our aim is to inform policy and practice by evaluating the development, implementation and evolution of the patient safety specialist and patient safety partner roles in the English NHS, underpinned by close collaboration with stakeholders.

3.2 Objectives

To achieve this aim we will pursue three objectives:

- To undertake a programme of four linked, mixed-methods sub-studies relating to the implementation of the two roles.
- To collaborate closely with stakeholders including specialists, partners, policymakers, patients, the public and others to ensure the study is informed by their priorities, insights and experiences.
- To produce novel, insightful, practically useful outputs for policy, practice and academic audiences, including actionable recommendations for role-holders, managers, and future policy.

3.3 Research questions

We ask four sets of research questions, each of which maps onto one of the four workstreams that we detail in the following sections:

1. (a) How have **specialised safety roles** in other high-risk industries been designed and implemented, and how have they evolved?
   (b) What are the implications for optimising such roles in healthcare?

Research question 1 will be addressed through Workstream 1 over months 1–12 of the study.

2. (a) What is the profile of **patient safety specialists** in terms of their background, knowledge, experience, skill set and seniority?
   (b) What challenges do they encounter and what are their achievements?
   (c) How is this changing through time?
   (d) To what extent are they drawing on advanced developments in patient safety knowledge to deliver their roles?

Research question 2 will be addressed through Workstream 2 over months 1–27 of the study.

3. (a) What is the programme theory of change for the **patient safety partner** role?
   (b) What is the profile of patient safety partners in terms of their background, knowledge, experience, and organisational role?

(c) What challenges do they encounter and what are their achievements?
(d) How is this changing through time?

Research question 3 will be addressed through Workstream 3 over months 1–36 of the study.

4. (a) How have the **patient safety specialist and patient safety partner** roles been realised across NHS organisations?
(b) What objectives are specialists and partners pursuing in practice?
(c) What influences their ability to pursue these objectives effectively, for better or worse?
(d) What is needed (from role-holders, those supporting them, host organisations and the wider NHS) to maximise their likelihood of positive impact?

Research question 4 will be addressed through Workstream 4 over months 10–30 of the study.

Findings from each workstream will be fed back to the range of interested audiences as they emerge, with cross-workstream synthesis and the development of overarching findings and implications in the last six months of the study.

4 Study design and methods

The study will take place over 36 months, starting in May 2025 and concluding in April 2028. Each workstream will have dedicated leads drawn from the investigator team, indicated below. Co-investigator Dr Robert Pralat will be the lead researcher for all workstreams, supported by the chief investigator Professor Martin and the other co-investigators. The four workstreams are described in more detail in Sections 5–8 below. Standalone protocols for the purposes of submissions for ethical and other regulatory review will be produced for workstreams as appropriate.

The study will use a complementary set of methods, including interviews (Workstreams 1, 3 and 4), longitudinal surveys (Workstreams 2 and 3), and ethnographic case studies (Workstream 4). We will take a theory-based approach to evaluation that includes formative, developmental and summative elements (Gamble 2008; Patton 2010; Weiss 1995), while the range of data sources will shed light on the theory behind the roles (e.g. Workstreams 1 and 3), the activities involved in putting them into practice (Workstream 2–4), and changes through time in role-holders' views on the impact of the roles and self-reported impact (Workstreams 2 and 3). The study will be supported throughout by an 'expert collaborative group', a collection of people with a wide range of relevant expertise who will come together at various points to inform the design, direction and interpretation of the study, and by 'joint interpretive forums' that bring a wider community of stakeholders together to make sense of the findings and help to engage key audiences within and beyond the NHS.

Theoretical frameworks underpinning the study include theory-based evaluation (e.g. Davidoff

et al. 2015; Weiss 1995), institutionalist theory (e.g. Abbott 1988; Friedland and Alford 1991; Powell and DiMaggio 1991; Thornton and Ocasio 2008), especially as this relates to the roles and jurisdictions of professions and other occupational groups (e.g. Martin *et al.* 2009b; Nancarrow and Borthwick 2005; Waring and Currie 2009), scholarship on leadership in healthcare including distributed leadership (e.g. Martin *et al.* 2009a; Martin and Waring 2013; McKee *et al.* 2013) and safety leadership (e.g. Adra *et al.* 2024; Jubault Krasnopevtseva *et al.* 2024; Pilbeam *et al.* 2017), and the literature on patient, public and service user involvement in the organisation and delivery of healthcare (e.g. Maguire and Britten 2017; Martin 2008; Martin *et al.* 2024).

5 Workstream 1: Learning from specialised safety roles in other sectors

Led by Professor Waring and Dr Peerally, with further assistance around recruitment and analysis from Professor Macrae, Workstream 1 will address the first set of research questions. It will take place over 12 months from May 2025 to April 2026. It will involve semi-structured interviews with stakeholders and expert commentators from other high-risk industries in the UK and other contexts where there is an established history of using specialised safety roles. It will also involve the collection of relevant documents pertaining to these roles, including publicly available documents identified through desk-based searching, and other documents (containing non-confidential information with no personal data) supplied by participants.

A literature review carried out as part of our formative evaluation found examples of these specialist roles, including those that have been established following specific legal or regulatory requirements (e.g. Hale 1995), those that have evolved more informally (e.g. Anker and Lurie 2022), and those in the process of moving towards formal, professionalised frameworks (e.g. Hale and Booth 2019). However, lacking from this literature is a clear analysis of the contextual drivers and antecedents of these roles, the required knowledge, skills and competencies of role-holders, the work done, the priorities addressed, the impact on operational safety, and the challenges and opportunities faced. Such an analysis would locate the patient safety specialist and partner roles in a broader context that might inform the evaluation, as well as offering important learning to role-holders in itself.

This workstream will:

- identify and characterise specialised safety roles in high-risk industries outside healthcare
- document the origins of the roles, how they have developed through time, and the nature and extent of professionalisation
- explore the organisational, regulatory, cultural, and structural influences that enable or

hinder the development, implementation and effectiveness of those roles
- examine the strategies, practices, and support mechanisms deployed in these roles to drive safety improvement, including educational and training support and career pathways
- synthesise insights and best practices from other high-risk industries to inform the ongoing development of the patient safety specialist and patient safety partner roles in healthcare—including the development of a typology which will serve as an interpretive resource for the other workstreams.

5.1 Study setting

Workstream 1 will cover high-risk industries other than healthcare, including (but not limited to) civil aviation and other transport sectors, natural resource exploitation, and energy and other utilities. Specific organisations through which participants will be sampled include national safety bodies (for example the Air Accidents Investigation Branch), professional networks (for example the World Association of Nuclear Operators), academic organisations and businesses. While recruitment will focus on organisations based in the United Kingdom, there will be no formal limits on geographical scope, and participants may be recruited from organisations based in countries around the world that offer potential for learning through comparison.

5.2 Sample and recruitment

5.2.1 Eligibility

Individuals will be eligible to participate in the study if they work in a safety-related role in a high-risk industry outside healthcare, and/or if they hold knowledge relating to the development, scope and impact of those roles on account of their professional or personal experience. This will include, for example, senior stakeholders (e.g. regulators, educators), expert commentators (academic and professional leaders), and current safety specialist role-holders from other high-risk industries, including those in other national contexts (such as transport, natural resource exploitation and energy).

5.2.2 Inclusion and exclusion criteria

Inclusion criteria are as follows:

- Has at least two years' work experience in safety-related roles in high-risk industries other than healthcare, or has extensive knowledge of such roles (e.g. through expertise derived from regulation or research)
- Able to communicate in English

Exclusion criteria are as follows:

- Aged under 18
- Unable or unwilling to give consent

5.2.3 Sampling

We will take a purposive sampling approach. We will develop a sampling frame to support identification of participants from a wide range of industries that have made use of specialised safety roles towards a range of objectives, with a view to understanding the features of context that enable or inhibit their work, the skill sets and activities of role holders, and the wider question of how such roles are institutionalised (for example, the regulatory frameworks, career pathways, skills development frameworks and approaches to professionalisation taken). We will also seek to include participants with knowledge relating to more than one sector who might be able to provide broad, comparative overviews.

5.2.4 Size of sample

We aim for a total sample size of approximately 30 participants. Our exact sample size will be kept under review over the course of recruitment, data collection and analysis, and finalised in accordance with the principles of theoretical saturation—the point when no new insights emerge from analysis of data sources (Charmaz and Belgrave 2007).

5.2.5 Recruitment

We will take three principal approaches to recruitment. First, we will draw on the networks of our investigator team (especially Waring, Peerally, Jun and Macrae) to identify relevant organisations and points of contact, and potential participants within those organisations. Second, we will supplement these contacts through targeted Internet searching for relevant organisations. Third, we will make limited use of snowball sampling, asking recruited participants to recommend others with relevant insights.

Potential participants already known to the team, and those whose contact details are publicly available, will be contacted directly by e-mail with written information about the study (in the form of a participant information sheet provided as an e-mail attachment or weblink) and asked to indicate whether they might be interested in participating. They will be given an opportunity to ask questions of the team, and if they remain interested in participating, will be asked to provide consent via a webform.

For potential participants not known to the team (for example, those identified through contact with an external organisation, or those identified through snowball sampling), the individual who has suggested the potential participant will be asked to contact them on behalf of the team with information about the study (either a short summary or the participant information sheet), and to ask if they are happy for their contact information to be shared with the team (either by the individual contacting the potential participant or the potential participant her/himself). Those who agree will be contacted directly by e-mail by the team with written information about the study (in the form of a participant information sheet provided as an e-mail attachment or weblink) and asked to indicate whether they might be interested in participating, as above. They will be given an opportunity to ask questions of the team, and if they remain interested in participating, will be asked to provide consent via a webform.

Where potential participants do not respond to initial contact, a maximum of three further attempts to contact them will be made.

5.2.6 Consent

Each participant will be required to give informed written consent before the interview commences. They will be provided with a participant information sheet, and will be given the opportunity to ask questions by e-mail or by phone before consenting. Once they have had their questions answered to their satisfaction, they will be sent a link to an online consent form where they will be asked to indicate their agreement to data collection, recording and transcription, and use of the data in outputs from the study.

After consent has been provided but before the interview starts, the purpose of the interview will be restated verbally by the researcher and the participant will be given the opportunity to ask further questions. Recording and data collection will then commence. The participant will be able to stop the interview and withdraw consent at any point during the interview. Following the interview, the participant will be able to withdraw consent until the point at which data are anonymised (during the transcription process).

5.3 Data

5.3.1 Data collection

Interviews will be conducted remotely via video-conferencing (e.g. Microsoft Teams) or telephone, lasting on average 60 minutes. They will be structured around an interview topic guide informed by our literature review and findings from our previous research, and co-designed with our expert collaborative group, which includes patient, public and professional perspectives (see Section 10). All interviews will be audio-recorded and professionally transcribed verbatim by a third-party transcription company with an existing contract and confidentiality agreement with THIS Institute.

Documentary data collected from web searches and provided by participants will take a variety of forms, but are likely to be predominantly in the form of word-processing files (e.g. .docx files) or portable document files (PDF files).

5.3.2 Data analysis

Interview transcripts and documentary data will be analysed using the Framework approach (Ritchie and Spencer 1994). An approach designed to enable the rapid and consistent identification of key themes and policy implications from interview and other sources of data, Framework is well suited to this part of the study. Our initial analytical framework will be developed based on the existing literature and the objectives for the workstream outlined in Section 5. Through analysis we will focus in particular on the ways such roles have been designed, the contextual influences on them, and how safety professionals themselves interpret and enact their roles. Data analysis will be assisted by Nvivo software.

5.3.3 Data protection and storage

Recordings of interviews, which are likely to contain identifiable data, will be stored on a University of Cambridge safe haven (an ISO 27001-certified trusted research environment). They will then be transferred via Secure File Transfer Protocol (SFTP) to the third-party

transcription company. The company will anonymise transcripts in the process of transcription, providing a separate anonymisation key. Transcripts will be transferred back to the team via SFTP and stored on the safe haven, pending checking for the removal of any identifying data. Once full anonymisation has been confirmed, they will be transferred to a dedicated folder on THIS Institute's SharePoint storage system. Only the research team and other relevant staff within the institute (e.g. its data manager) will have access to the folder. Anonymisation keys will be kept in a separate folder and password-protected.

Publicly available documentary data sources will be kept in a dedicated folder on THIS Institute's SharePoint storage system. Documents supplied by participants will be checked for identifying or sensitive information. Any found will be removed, and then documents will be added to the dedicated folder on THIS Institute's SharePoint storage system.

Names and contact details of participants will be stored for a maximum of two years after completion of the study and then destroyed. Research data will be destroyed seven years after completion of the study.

5.4 Ethical and regulatory considerations

Workstream 1 constitutes research according to the definitions provided by the Health Research Authority (HRA). Therefore ethical review and approval will be required prior to the commencement of recruitment and data collection. Since data collection will not involve recruitment through the NHS, ethical approval will be sought from a University of Cambridge ethics committee, and review will not be required from the HRA or from NHS trust research and development departments.

5.4.1 Assessment and management of risk

We consider Workstream 1 to pose low risks to participants and researchers. All participants will be provided with written information prior to data collection and given the opportunity to seek clarification in writing and verbally, will give informed consent, and will have the opportunity to withdraw consent up until the point of anonymisation of data collected. Participants will not be drawn from vulnerable populations and so safeguarding concerns are unlikely.

The data to be collected are not personal or sensitive in nature, although it is conceivable that participants might raise concerns regarding safety in their organisations. If in the course of an interview, it appears that participants are raising issues that may pose current safety risks, the interviewer will first seek to clarify the nature of these issues. They will encourage the participant to raise concerns using the usual channels relating to their organisation or industry. If the participant is reluctant to do so, the interviewer will discuss with other colleagues on the research team whether the concerns are of a nature that requires disclosure by the research team. The participant information sheet will make clear to potential participants that while participant confidentiality will usually be respected and upheld in outputs from the study, if serious and current concerns are raised in the course of interviews, the research team may be

obliged to break confidentiality.

5.4.2 Research Ethics Committee (REC) and other regulatory review

An ethical opinion will be sought from a University of Cambridge research ethics committee, most likely its Psychology Research Ethics Committee.

5.4.3 Sponsorship, insurance and indemnity

The University of Cambridge will act as the sponsor for this sub-study. The university's usual indemnity insurance arrangements for research studies will apply.

6 Workstream 2: Tracking the evolving role and function of patient safety specialists

Led by Professor Martin, Professor Jun and Dr Fray, Workstream 2 will address the first set of research questions. It will take place over 27 months from May 2025 to July 2027. It includes two key components: two national surveys of patient safety specialists to create, alongside an existing survey conducted in early 2023, a longitudinal dataset relating to the changing profile of patient safety specialists; and an examination of the work undertaken by patient safety specialists as part of their advanced training in the theory and practice of safety, which is led by two of the team members based at Loughborough University.

As part of our earlier small-scale evaluation of the patient safety specialist role, we undertook a survey of all patient safety specialists in England in early 2023, examining their demographic and professional backgrounds, the implementation of the role in NHS organisations (e.g. numbers of patient safety specialists, time allocated to the role), and the activities, successes, challenges and expectations for the role (Martin *et al.* 2025). By running two follow-up surveys at roughly two-yearly intervals (mid-2025 and mid-2027), we will provide insight into how the work and profile of specialists is changing through time.

Jun and Fray are part of a team commissioned to design and deliver advanced training for patient safety specialists as part of the Patient Safety Syllabus introduced in the *NHS Patient Safety Strategy* (NHS England and NHS Improvement 2019). The training focuses on four pillars of knowledge that support the practical application of patient safety in healthcare: human factors; systems thinking; risk management; and safety culture. At the end of this course, patient safety specialists are required to write a reflective case study report showing how they use this learning in their roles. Additionally, throughout the course, specialists undertake various other assessments, including self-reported knowledge before and after learning for each component of the course, and assessments of confidence in applying various tools. These assessments, completed by over 800 specialists so far, offer a rich

resource for gaining insight into the extent to which theory and evidence relating to patient safety and the broader field of safety science is being translated into practice by patient safety specialists.

6.1 Study setting

The two surveys will be open to patient safety specialists working in NHS organisations across England. In addition, individuals who completed the earlier survey but are no longer working as patient safety specialists will be able to respond to the two new surveys (with a separate section relating to their experiences). In a similar manner, individuals who respond to the first of the new surveys and then cease to work as patient safety specialists will be able to respond to the second.

The materials to be used to examine the impact of specialised training on the work of patient safety specialists in practice are held by the School of Design and Creative Arts at Loughborough University.

6.2 Sample and recruitment

6.2.1 Eligibility

Potential participants in the surveys are those working as a patient safety specialist in an NHS organisation (or an independent-sector organisation providing NHS services) at the time of the survey, and those who responded to the earlier survey or the first new survey and who are no longer working as a patient safety specialist.

Materials to be used to understand the impact of training on the work of patient safety specialists include anonymised versions of case studies of their work submitted by specialists in the course of their training on advanced levels of the Patient Safety Syllabus, and cohort-level (non-identifying) data on before-and-after assessments of confidence and competence provided at various points during the training.

6.2.2 Inclusion and exclusion criteria

Inclusion criteria for the surveys are as follows:

- Currently working as a patient safety specialist in an NHS organisation or other organisation providing NHS services in England, or previously working as a patient safety specialist at the time of an earlier survey

Exclusion criteria are as follows:

- Aged under 18
- Unable or unwilling to give consent

Inclusion criteria for the analysis of the impact of training on patient safety specialists' work are

as follows:

- Working as a patient safety specialist at the time of undertaking the training
- Completed the full training course

Exclusion criteria for the analysis of the impact of training on patient safety specialists' work are as follows:

- Opted out of the use of their data for research purposes

6.2.3 Sampling

No formal sampling criteria will be used for the surveys: they will be open to all those who meet the eligibility criteria given in Section 6.2.1.

For the analysis of the impact of training on patient safety specialists' work, we will include data relating to self-reported confidence and competence across all patient safety specialists who mee the eligibility, inclusion and exclusion criteria.

We will construct a stratified random sample of the reflective case study reports produced by patient safety specialists during their advanced training, covering a total of 50 reports (15 from those in acute settings, 15 from those in community and mental healthcare settings, 5 from those in ambulance trusts, and 15 from those in ICBs).

6.2.4 Size of sample

While all individuals meeting the eligibility criteria for the surveys will be able to join, in the earlier survey, a response rate of 24% was achieved (Martin *et al.* 2025).

The sample for the examination of case study reports is not informed by a formal sample size calculation, since it will involve content analysis rather than statistical comparison across groups.

6.2.5 Recruitment

For the surveys, we will approach potential participants using two methods: (i) by e-mailing respondents to the earlier survey who agreed to further contact, whose details are held on the Thiscovery platform; and (ii) via NHS England, which maintains an up-to-date register of patient safety specialists and which has kindly agreed again to contact them on our behalf. This will maximise the coverage of current and former patient safety specialists; registration on Thiscovery will minimise the risk of duplicate responses.

E-mails to individuals recruited through both routes will include brief information on the survey and a link to a page on the Thiscovery platform providing more detailed information. It will also include contact details for the team should potential participants have further questions.

Potential participants (including those who have been contacted following participation in an earlier survey, and those who have part-completed a current survey) will receive up to three

reminders to complete the survey. Each reminder will include a link to allow them to unsubscribe from reminders.

6.2.6 Consent

Brief information on the survey and its purpose will be included in the e-mail to potential participants, and more detailed information will be provided on a webpage on the Thiscovery platform linked from the e-mail, which participants will be asked to review prior to consenting. Participants will provide consent by indicating that they have read and understood this information, agree to use of the data in outputs from the study, and agree to participate. Those who have not previously registered on the Thiscovery platform will also need to register an account and agree to the platform's terms and conditions. Participants will be able to withdraw consent up until the point of anonymisation of data and transfer to the University of Cambridge by e-mailing the Thiscovery team or the study team.

Consent to use of materials submitted in the course of their training for research purposes is routinely collected from those enrolled in Loughborough University's Patient Safety Syllabus training courses. Materials submitted by those who have opted out will not be used in this study.

6.3 Data

6.3.1 Data collection

The two surveys will use questionnaires that include a mixture of categorical, ordinal and open-response questions. They will take as their starting point the questionnaire used in the earlier survey (published as an online appendix to Martin *et al.* 2025), incorporating adjustments arising from insights from other workstreams, changes suggested by the study's expert collaborative group, and wider developments in patient safety (for example relating to equity and speaking up). Data collected will relate to participants' backgrounds (including information relating to their demographic characteristics, such as age, ethnicity and sex, as well as their professional background), experiences, day-to-day work, expectations for the role, self-reported views on the potential of the role, and self-identified impacts. We will review the questionnaire from the earlier survey with our expert collaborative group and consider which questions to retain, which to alter, and what questions to add, taking into account the need for continuity to maximise longitudinal comparability, the development of the role, and emerging evidence from the rest of the study. The questionnaire will include a sub-set of questions for participants who have moved on from patient safety specialist roles, focusing on their reasons for leaving the role and their onward career trajectory. In early 2027, we will revisit the questionnaire with the expert collaborative group and again consider what questions to retain, alter and add before the second round of the survey.

The two surveys will be administered in early summer 2025 and in late spring or early summer 2027. Each survey will be open for a minimum of two months to maximise participation.

Data collected for the analysis of the impact of training on patient safety specialists' work will

include self-reported confidence and competence before and after modules and the whole course along with individual characteristics (e.g. type of organisation, professional background), and anonymised versions of case study reports submitted for assessment in the course of their training.

6.3.2 Data analysis

Data from the surveys will be analysed using descriptive and analytical statistical methods, with a prospective plan for analytical statistics agreed with the expert collaborative group ahead of each analysis process. It will include, for example: relationships between patient safety specialists' activities and self-reported success, and various potential explanatory variables, including professional background, seniority, length of service and organisation type, as well as the balance of work and how it changes through time. We will examine the nature and scope of reported impacts and how this develops through time, as well as the overall self-reported impact of the role. Free-text responses will be analysed using content analysis.

For the analysis of the impact of training on patient safety specialists' work, we will examine data relating to confidence and competence before and after completion of the course and of individual modules and examine whether this is associated with key characteristics of the patient safety specialists, including seniority, professional background, and organisation type. We will undertake a content analysis of the 50 case study reports sampled from patient safety specialists in different kinds of organisation with a view to identifying the most prominent kinds of knowledge being deployed (for example, systems thinking, human factors, design thinking, and so on). Categories of knowledge will be specified prospectively and then reviewed in light of analysis of one report from a specialist from each organisation type (acute, community and mental healthcare, ambulance trusts and ICBs).

6.3.3 Data protection and storage

The online survey tool Qualtrics is used by Thiscovery to obtain consent and collecting survey data. All data are processed in accordance with the relevant data protection regulations. The system has high-end firewall protection for its data, and is security certified to a verified standard (ISO-27001). In addition to Qualtrics, Thiscovery uses **four** third-party supplier services to store personal data to support the functions of the website:

- *Amazon Web Services (AWS)* – holds the main Thiscovery contacts database, online consent and link keys between unique identifiers and individual usernames.
- *HubSpot* – allows us to communicate with users through Thiscovery, rather than having to export lists of email addresses to University email accounts. HubSpot maintains a Privacy Shield certification with the US Department of Commerce to ensure that adequate safeguards are in place when transferring personal data from the EU to the US.
- *Google Analytics* – to collect standard internet log information and details of visitor behaviour patterns. Google Analytics complies with certain legal frameworks relating to the transfer of data, such as the EU-US and Swiss-US Privacy Shield Frameworks.
- *Auth0* – is a password service used so that Thiscovery does not need to hold users' password details. It also allows for password recovery, should a user forget their

password.

Access to the Thiscovery database on AWS is limited to the Thiscovery technical development and support team. Each Thiscovery user will have multiple IDs:

- A Thiscovery user ID – this is unique and never changes. It is associated with their Thiscovery account (including name and email). It is not used by projects and persists as long as a user remains involved with Thiscovery.
- For each project a user participates in: a project-specific user ID used only by the project. It is deleted from Thiscovery after 24 months. It remains as the user ID in the research data indefinitely. It is the deleting of this ID from the core Thiscovery database that breaks the link between Thiscovery user data and research data.

Following the close of each survey round, anonymised data will be transferred securely from the Thiscovery team to the research team. It will be stored on a dedicated folder on THIS Institute's SharePoint file storage system. Any links between the personal data held in Thiscovery and the data generated by the project will be destroyed 24 months after the end of the study. Personal data used to register for Thiscovery will remain in the Thiscovery personal data stores, as set out in the Thiscovery terms and conditions.

Material used to examine the impact of specialised training on the work of patient safety specialists in practice will be transferred securely from Loughborough University to the University of Cambridge and stored in a dedicated folder on THIS Institute's SharePoint file storage system.

All research data will be destroyed seven years after completion of the study.

6.4 Ethical and regulatory considerations

Based on the HRA's criteria and decision tool, the surveys undertaken for Workstream 2 constitute service evaluation, and are therefore not eligible for ethical review as research projects. As outlined above, good-practice approaches including the provision of information on participation and the provision of informed consent prior to data collection will be followed. The status of the surveys as service evaluation will be made clear to participants.

The analysis of the impact of training on patient safety specialists' work constitutes research. This part of Workstream 2 will be included in an application to a Loughborough University research ethics committee, covering this work and other analyses planned for this dataset. Since data collection will not involve recruitment through the NHS, review will not be required from the HRA or from NHS trust research and development departments.

6.4.1 Assessment and management of risk

We consider both elements of Workstream 2 to pose low risks to participants and researchers. For the survey, participants will be provided with written information prior to data collection and

given the opportunity to seek clarification in writing and by e-mail, will give informed consent, and will have the opportunity to withdraw consent up until the point of anonymisation of data and transfer to the University of Cambridge.

For the analysis of the impact of training on patients safety specialists' work, no personal or identifiable data will be collected. Submissions will previously have been reviewed by lecturers on the course: therefore, should they contain any sensitive information or content suggesting current concerns relating to patient safety, these will have been dealt with appropriately.

6.4.2 Research Ethics Committee (REC) and other regulatory review

An ethical opinion will be sought from a Loughborough research ethics committee.

6.4.3 Sponsorship, insurance and indemnity

Loughborough will act as the sponsor for this sub-study. The university's usual indemnity insurance arrangements for research studies will apply.

7 Workstream 3: Developing the theory of change for patient safety partners, and tracking their evolving role and function

Led by Professor O'Hara and Professor Martin, Workstream 3 will address the third set of research questions. It will take place over 36 months from May 2025 to April 2028. Following similar work done previously for the patient safety *specialist* programme (Martin *et al.* 2025), it will involve the development of a theory of change for the patient safety *partner* programme, and the development and administration of two rounds of a survey of patient safety partners (one year into the study, in mid-2027, and near the end of the study, in early 2028). This will help to generate understanding, first, of how the patient safety partner role translates into practice, how partners' activities are expected to give rise to the intended results, and what might help and hinder this, and second, of the profile, activities and self-identified impacts of patient safety partners and how they are evolving through time.

In developing the theory of change for patient safety partners, we will combine analysis of relevant documents, interviews with key stakeholders, and a joint interpretive forum focused on collaborative sense-making from our emergent findings. Similar to the survey of patient safety specialists in Workstream 2 described in Section 6, the survey will be administered on the Thiscovery platform and will seek to develop a longitudinal understanding of the development of the patient safety partner role, activity and impacts.

7.1 Study setting

Workstream 3 will cover the activity of patient safety partners across England, in NHS organisations and other organisations providing NHS services (such as independent-sector providers) where they are appointed. Interviews to inform the construction of the theory of change will include participants from NHS England and from elsewhere in the health and care system (for example, Department of Health and Social Care, regional offices of NHS England, regulatory bodies, organisations consulted in the development of the patient safety partner role).

7.2 Sample and recruitment

7.2.1 Eligibility

Individuals eligible to contribute to the qualitative interview-based component of Workstream 3 include those involved in the ideas behind the role, the design and development of the patient safety partner programme, its implementation, and support for patient safety partners.

Eligible to respond to the two surveys are those working as a patient safety partner in an NHS organisation (or an independent-sector organisation providing NHS services) at the time of the survey, including those who respond to the first survey who are no longer working as a patient safety partner at the time of the second. The formal relationship between patient safety partners and their organisations may vary in form, including employment, indirect contracting and voluntary arrangements; patient safety partners will be eligible to participate regardless of the form taken by their relationship.

7.2.2 Inclusion and exclusion criteria

Inclusion criteria for the theory-of-change interviews are as follows:

- Directly or indirectly involved in one or more of the following activities: contributing to the idea of the patient safety partner role; design and development of the role; implementation, delivery and oversight of the role, *or*
- Patient safety partners and others involved in early implementation of the role

Exclusion criteria are as follows:

- Aged under 18
- Unable or unwilling to give consent

Inclusion criteria for the surveys are as follows:

- Working as a patient safety partner in an NHS organisation or other organisation providing NHS services in England at the time of the first or second survey

Exclusion criteria are as follows:

- Aged under 18
- Unable or unwilling to give consent

7.2.3 Sampling

For the theory-of-change interviews, we will take a purposive sampling approach. We will seek to include participants involved in all stages of the development of the patient safety partner role, with a view to being able to track its history and the rationale behind key choices regarding, for example, person specification, role scope, organisational relationship, and so on. We will also seek to include a small number of participants from early-adopter organisations, including patient safety partners themselves and others involved in the role's local realisation, with a view to understanding the implementation process and the in-course changes made to the role.

The surveys will not involve a formal sampling approach: all individuals who meet the eligibility criteria set out in Section 7.2.1 will be able to participate in the study.

7.2.4 Size of sample

For the theory-of-change interviews, based on our experience in developing the theory of change for the patient safety specialist role, we anticipate that around 15 interviews will be sufficient to flesh out the theory of change for patient safety partners. Our exact sample size will be kept under review over the course of recruitment, data collection and analysis, and finalised in accordance with the principles of theoretical saturation—the point when no new insights emerge from analysis of data sources (Charmaz and Belgrave 2007).

The ultimate size of the sample for the surveys is difficult to predict, for two reasons. First, unlike the patient safety specialists, there is no central register of patient safety partners, therefore the denominator for calculating the response rate for the surveys is uncertain. Second, we do not have any obvious antecedents for this work, though as above, we note that we achieved a sample size of just under 200 in our earlier survey of patient safety specialists (a response rate of 24%) (Martin *et al.* 2025). We hope that similar levels of response will be possible for the patient safety partner surveys.

7.2.5 Recruitment

We will identify potential participants in the theory-of-change interviews through existing contacts, using our links in NHS England to ensure that we are able to access those involved in the original thinking behind the programme but no longer actively contributing. Using documentary sources (e.g. webpages, newsletters for patient safety partners, and accounts of activity in conference abstracts and posters and submissions to the *HSJ*'s annual Patient Safety Awards scheme), and via both NHS England and other networks to which we have access (such as Patient Safety Learning, which provides resources for and convenes networks of healthcare staff with an interest in patient safety, including patient safety partners), we will also identify patient safety partners and organisational representatives who are seen to have been at the forefront of putting the role into practice and informing further development.

We will supplement this recruitment process with snowball sampling as appropriate.

Where potential participants are already known to the team, we will contact them directly by e-mail with written information about the study (in the form of a participant information sheet provided as an e-mail attachment or weblink) and ask them to indicate whether they might be interested in participating. They will be given an opportunity to ask questions of the team, and if they remain interested in participating, will be asked to provide consent via a webform.

For potential participants not known to the team (including those identified by collaborators and those identified through snowball sampling), the individual who has suggested the potential participant will be asked to contact them on behalf of the team with information about the study (either a short summary or the participant information sheet), and to ask if they are happy for their contact information to be shared with the team (either by the individual contacting the potential participant or the potential participant her/himself). Those who agree will be contacted directly by e-mail by the team with written information about the study (in the form of a participant information sheet provided as an e-mail attachment or weblink) and asked to indicate whether they might be interested in participating, as above. They will be given an opportunity to ask questions of the team, and if they remain interested in participating, will be asked to provide consent via a webform.

Where potential participants do not respond to initial contact, a maximum of three further attempts to contact them will be made.

For the first survey, we will use multiple routes to identify and contact potential participants. As noted above, unlike patient safety specialists, there is no definitive central register of patient safety partners. This will make identification and recruitment of respondents to the survey more challenging. We will take a pluralistic approach to recruitment for the patient safety partner survey, involving recruitment via the networks of partners involved in our expert collaborative group including NHS England representatives and others, direct contact with NHS organisations asking that they distribute the survey to their own patient safety partners, advertising in newsletters aimed at patient safety partners (such as that run by NHS England, which currently has around 400 subscribers), and distribution to members of Patient Safety Learning's Patient Safety Partners Network. We will take a similar approach to the second survey; in addition, participants in the first survey will receive direct e-mail notification of the launch of the second survey if they have consented to further contact when participating in the first.

Communications in the form of e-mails, newsletter entries, forum posts, etc. will contain brief information on the survey and a link to a page on the Thiscovery platform that provides more detailed information. Both the initial communications and the webpage will include contact details for the team should potential participants have further questions. Potential participants in the second survey, and those who have partially completed each survey, will receive up to three reminders to complete the survey. Each reminder will include a link to allow them to unsubscribe from reminders.

7.2.6 Consent

Each participant in an theory-of-change interview will be required to give informed written consent before the interview commences. They will be provided with a participant information sheet, and will be given the opportunity to ask questions by e-mail or by phone before consenting. Once they have had their questions answered to their satisfaction, they will be sent a link to an online consent form where they will be asked to indicate their agreement to data collection, recording and transcription, and use of the data in outputs from the study.

After consent has been provided but before the interview starts, the purpose of the interview will be restated verbally by the researcher and the participant will be given the opportunity to ask further questions. Recording and data collection will then commence. The participant will be able to stop the interview and withdraw consent at any point during the interview. Following the interview, the participant will be able to withdraw consent until the point at which data are anonymised (during the transcription process).

Brief information on the survey and its purpose will be included in the initial communications about the survey (e-mails, newsletter entries, forum posts etc.), and more detailed information will be provided on a webpage on the Thiscovery platform linked from the communications, which participants will be asked to review prior to consenting. Participants will provide consent by indicating that they have read and understood this information, agree to use of the data in outputs from the study, and agree to participate. Assuming they have not previously registered on the Thiscovery platform for other studies, they will also need to register an account and agree to the platform's terms and conditions. Participants will be able to withdraw consent up until the point of anonymisation of data and transfer to the University of Cambridge by e-mailing the Thiscovery team or the study team.

7.3 Data

7.3.1 Data collection

Ahead of undertaking the theory-of-change interviews, we will compile documents relating to the patient safety partner programme, including those developed by NHS England, those published by local organisations, and others identified through our expert collaborative group. These documentary sources will form our first dataset, and the insights derived from these sources will inform the interviews.

Interviews will be conducted remotely via video-conferencing (e.g. Microsoft Teams) or telephone, lasting on average 60 minutes. They will be structured around an interview topic guide informed by the documentary sources and findings from our previous research, and co-designed with our expert collaborative group, which includes patient, public and professional perspectives (see Section 10). All interviews will be audio-recorded and professionally transcribed verbatim by a third-party transcription company with an existing contract and confidentiality agreement with THIS Institute.

The two surveys will use questionnaires that include a mixture of categorical, ordinal and

open-response questions, as with the surveys of patient safety specialists. Questionnaire development will be informed in part by analysis of the theory-of-change interviews (see Section 7.3.2 below), including a joint interpretive forum bringing in critical perspectives from those outside the research team, including patient safety partners themselves. Questionnaire content will cover the activities, self-assessed impacts and demographic characteristics of patient safety partners, including diversity of ethnicity, age, sex, disability, other protected characteristics, and professional and experiential background. As with the second survey of patient safety specialists, prior to administering the second survey of patient safety partners, we will revisit the questionnaire from the first survey with the expert collaborative group and consider what questions to retain, alter and add. The second questionnaire will include a sub-set of questions for participants who have moved on from patient safety partner roles, focusing on their reasons for leaving the role and their onward career trajectory.

The two surveys will be administered in summer 2026 and in early 2028. Each survey will be open for a minimum of two months to maximise participation.

7.3.2 Data analysis

Analysis of documents collected to inform the theory-of-change interviews will use the Framework method (Ritchie and Spencer 1994), assisted by use of Nvivo software, and will provide us with an initial skeletal understanding of the programme and its objectives. We will use this initial understanding to develop topic guides for interviews, focusing both on gaining greater insight into the activities and objectives of the role that are specified in documents, and on filling in the gaps. Data from the interviews will be added to the Nvivo database used for the documentary data and subject to further analysis using the Framework method.

We will use Microsoft Visio to develop accessible graphical representations of our findings from analysis of the documents and interviews (including a logic model that presents the theory of change in a mechanistic, simplified form). We will use these outputs to inform collaborative sense-making of findings at a joint interpretive forum (see also Section 10). This forum will bring a wide range of stakeholders, especially patient safety partners themselves, into interpretation and analysis of the data, to check our emergent understandings, add nuance to our analysis, and ‘stress test’ the developing theory of change and accompanying logic model. Participants in the joint interpretive forum will be recruited through the networks of our expert collaborative group. Following the approach we successfully used for equivalent sense-checking work when developing our earlier theory of change for patient safety specialists, the joint interpretive forum will take the form of up to three two-hour workshops (to maximise opportunities to participate) at which we will review our work to date, ask questions focused on areas of particular uncertainty or ambiguity, share our initial logic model, and discuss its adequacy in break-out groups.

In analysing data from the two surveys, we will use descriptive and analytical statistical approaches, including longitudinal comparisons relating to the characteristics of patient safety partners and changes in their view of the role, the impacts they identify, and their confidence in the potential to achieve change. We will develop our approach with our expert collaborative group and specify the associations for which we will test prospectively.

7.3.3 Data protection and storage

Recordings of interviews, which are likely to contain identifiable data, will be stored on a University of Cambridge safe haven. They will then be transferred via SFTP to the third-party transcription company. The company will anonymise transcripts in the process of transcription, providing a separate anonymisation key. Transcripts will be transferred back to the team via SFTP and stored on the safe haven, pending checking for the removal of any identifying data. Once full anonymisation has been confirmed, they will be transferred to a dedicated folder on THIS Institute's SharePoint storage system. Only the research team and other relevant staff within the institute (e.g. its data manager) will have access to the folder. Anonymisation keys will be kept in a separate folder and password-protected.

Storage of survey data on the Thiscovery platform will involve the same systems and processes as detailed in Section 6.3.3. Following the close of each survey round, anonymised data will be transferred securely from the Thiscovery team to the research team. It will be stored on a dedicated folder on THIS Institute's SharePoint file storage system. Any links between the personal data held in Thiscovery and the data generated by the project will be destroyed 24 months after the end of the study. Personal data used to register for Thiscovery will remain in the Thiscovery personal data stores, as set out in the Thiscovery terms and conditions.

Documentary data sources will be kept in a dedicated folder on THIS Institute's SharePoint storage system.

Names and contact details of participants will be stored for a maximum of two years after completion of the study and then destroyed. Research data will be destroyed seven years after completion of the study.

7.4 Ethical and regulatory considerations

Based on the HRA's criteria and decision tool, Workstream 2 (including the document review, interviews and surveys) constitutes service evaluation. It is therefore not eligible for ethical review as a research project. As outlined above, good-practice approaches including the provision of information on participation in interviews and surveys and the provision of informed consent prior to data collection will be followed. The status of the sub-study as service evaluation will be made clear to participants.

7.4.1 Assessment and management of risk

We consider Workstream 3 to pose low risks to participants and researchers. All participants will be provided with written information prior to data collection and given the opportunity to seek clarification in writing and verbally, will give informed consent, and will have the opportunity to withdraw consent up until the point of anonymisation of data collected. Participants will not be drawn from vulnerable populations and so safeguarding concerns are unlikely.

The data to be collected during interviews are not personal or sensitive in nature, although it is conceivable that participants might raise concerns regarding safety in their organisations or elsewhere. If in the course of an interview, it appears that participants are raising issues that may pose current safety risks, the interviewer will first seek to clarify the nature of these issues. They will encourage the participant to raise concerns within their organisation. If the participant is reluctant to do so, the interviewer will discuss with other colleagues on the research team (including clinically qualified investigator Peerally) whether the concerns are of a nature that requires disclosure by the research team. The participant information sheet will make clear to potential participants that while participant confidentiality will usually be respected and upheld in outputs from the study, if serious and current concerns are raised in the course of interviews, the research team may be obliged to break confidentiality.

7.4.2 Research Ethics Committee (REC) and other regulatory review

As Workstream 3 does not constitute research, it is not eligible for research ethics committee review.

7.4.3 Sponsorship, insurance and indemnity

As Workstream 3 does not constitute research, it does not require sponsorship. Indemnity insurance will be provided through the University of Cambridge's general public liability insurance.

8 Workstream 4: Organisational case studies of the work of patient safety specialists and patient safety partners in action

Led by Professor Martin and Dr Pralat, Workstream 4 will address the fourth set of research questions. It will take place over 24 months from November 2025 to October 2027.

Earlier work in Workstreams 2 and 3 will provide a firm understanding of how the work of patient safety specialists and patient safety partners is 'imagined' in theory and policy, an initial understanding of how they do their work in practice, and a sense of the longitudinal trajectory of the roles in terms of their characteristics, scope and impact. Workstream 4 will build a fuller, richer picture of 'work as done' by specialists and partners, by using ethnographic methods to examine their work towards patient safety, separately and together, in six healthcare organisations. We will follow the activity of patient safety specialists, patient safety partners, and those with whom they interact over extended periods (9–12 months per case study), including observational work, interviews, ethnographic chats, and the collection of relevant documentary materials, focusing on both the 'routine' day-to-day work of specialists

and partners, and on specific projects that they lead and contribute to during the fieldwork period. Through this work we will develop an understanding of the organisational conditions that facilitate delivery of the roles, including the ways in which they interact with one another, with other roles and with the wider context.

8.1 Study setting

Workstream 4 will involve data collection in six healthcare organisations in England, potentially including NHS provider trusts, integrated care boards, and independent-sector organisations providing NHS care.

8.2 Sample and recruitment

8.2.1 Eligibility

At the case level, initial eligibility for inclusion will be based on responses from patient safety specialists and patient safety partners to the first surveys in Workstreams 2 and 3 respectively. Survey respondents will be asked to indicate if they are interested in opportunities for further participation in the study; positive responses will form our initial sampling frame. We will include in our sample organisations that vary in the assessments offered of them by their patient safety specialists and partners, as indicated in data from the surveys, supplemented by follow-up discussions with participants in the surveys who have indicated interest in further participation, and further input from our expert collaborative group. We will also seek variation in our sample in influences that appear, based on empirical and theoretical knowledge developed to date, to enhance or inhibit the ability of patient safety specialists and patient safety partners to deliver their roles (Eisenhardt 1989), at the level of the individual role-holders, the organisation, and the wider system. These might include, for example: variation in organisation function (provider / ICB); different provider types; different configurations of roles in terms of background, selection, positioning; region; personal characteristics of role-holders (including prior relevant experiences of patient safety partners, professional backgrounds of patient safety specialists, and demographic characteristics of both); and demographic characteristics of local populations.

We recognise that, ultimately, a sample that meets these criteria perfectly is likely to be illusory, given the total sample size (Schreier 2017). Careful choices will therefore be needed about which variables to prioritise in sampling, and we will make these decisions in close consultation with our expert collaborative group. Regardless of the final composition of the sample, however, we will ensure that:

- both specialists and partners are covered
- at least one community and/or mental health service provider organisation is included (given the distinctive challenges and opportunities for patient safety in such organisations and their previously neglected status)
- the issue of *equality* is a focus of specialists' and/or partners' activities in at least two of the case study sites.

While a sample of this scale cannot do full justice to the diversity of role-holders or organisational contexts, this theoretical sampling approach, accompanied by a comparative analytical approach of the kind advocated by Eisenhardt (1989), will help to secure transferability to other settings.

Within organisations, eligible participants will include patient safety specialists and patient safety partners themselves, and others working alongside them and in related areas of patient safety. In each case-study organisation, we will identify one or two 'tracer issues' (Rycroft-Malone *et al.* 2015)—key lines of inquiry, such as priority action areas (e.g. 'maternity safety for people from ethnically minoritised backgrounds'), time-limited projects (e.g. 'implementing the Patient Safety Incident Response Framework across all our sites'), enduring priorities (e.g. 'creating a culture in which speaking up by patients and staff is valued and listened to'), or other things used to organise work—that will further guide sampling of individuals, allowing us to investigate the influences on the work of specialists and partners in an empirically grounded way.

8.2.2 Inclusion and exclusion criteria

Within each site, our data collection will encompass observation, accompanying informal chats with staff, formal recorded interviews with patient safety specialists, patient safety partners and others, and collection of relevant, non-confidential documents relating to safety that do not include sensitive information or personal data. For participation in interviews, we will use the following inclusion criteria:

- Working as a patient safety specialist, as a patient safety partner, or in another role within the organisation relating to patient safety and/or the areas of focus within the case study site

Exclusion criteria are as follows:

- Aged under 18
- Unable or unwilling to give consent

8.2.3 Sampling

Sampling criteria at the case study level are given in Section 8.2.1 above.

For activity within case study sites – i.e. observations, informal chats, formal interviews and the collection of documents – we will apply a purposive sampling strategy. Our sampling approach will be driven by the objective of addressing the research questions for this workstream set out in Section 3.3, including developing insight into the form taken by the patient safety specialist and patient safety partner roles in practice, the activities and objectives they are pursuing, the influences on their ability to realise these roles effectively (including the influences of organisational context, relationships with other roles, clinical focus, skills and attributes of the role-holders, and so on), and how these might be optimised. We will therefore seek to ensure that observational data collection includes key activities in the realisation of the roles (for example formal and informal meetings that bring together those

involved in the identified tracer issues), that informal chats and interviews include those with a wide range of perspectives on the roles, their purpose and their impact (including those more and less positive about the roles), and that documents relevant to the roles, the key activities and their impacts are collected.

8.2.4 Size of sample

In each case study site, we will spend between 12 and 15 days undertaking observational data collection, including informal chats as well as ethnographic observation. We will conduct formal interviews with around 15 participants in each case study site. We do not specify a sample size for documents: this will depend on the nature of the focus of data collection in each site, and on the availability of documents.

Our sample size is based on past studies of similar scope led by team members and others in the past. It is informed by the principle of 'information power' (Malterud *et al.* 2016) – the notion that the size of a sample is best determined by the anticipated level of insight likely to be contained in the interviews (or other data sources) to be included, rather than in terms of raw numbers alone. In particular, the specificity of the focus of this study, the profile of those likely to be covered in interviews, informal chats and observational activity, and the insights that can be derived from cross-case comparison (Eisenhardt 1989) mean that a focused sample is likely to offer sufficient information power to address the research question adequately. However, this will also rest on the diversity of views captured through the data collection techniques proposed, including views from those with dissenting views. Accordingly, the size of the sample will be kept under review throughout data collection, and we may vary the degree to which we rely on different methods (e.g. observation versus interviews) and the size of the sample within each site (e.g. focusing greater data collection in one site where the activities of the patient safety specialists and partners are more complex and greater in scope, and so the information power principle demands a larger sample, while reducing data collection in another).

In some cases, individual participants may be interviewed more than once, towards the beginning and the end of the data-collection period in a given site. This is most likely to apply to the patient safety specialists and patient safety partners themselves.

8.2.5 Recruitment

To ensure effective project management and optimise the quality and coverage of the sample of case studies, recruitment of **sites** will be staggered over six months, beginning around month 10 and finishing around month 15. This will allow us to ensure that sampling is informed by findings from the first survey of patient safety partners (as well as the first survey of patient safety specialists), which should be available at around month 12. Data collection in each case-study site will span approximately 12 months, to secure depth of insight and allow an understanding of how the roles, their work and their impacts unfold through time.

In each case study site, recruitment of individual interview participants will take several forms.

First, we will work with our contact point(s) for the site – the patient safety specialist, patient

safety partner or both – to identify opportunities for observation and a potential initial set of interviewees, including the specialists and partners themselves, and a small number of colleagues who work closely with them (circa five per organisation). With a view to securing a diverse initial sample, we will use a social network tool developed in another project led by Professor Waring with a view to identifying individuals with different types of role, at different levels, and in different parts of the organisation. We will also proactively indicate certain roles that we would like to include: for example, executive and non-executive directors with oversight of patient safety; the individuals to whom specialists and partners are accountable. For those known to the team already (the contact point(s) themselves and others involved in securing access to the site), we will provide a written participant information sheet, either in hardcopy or by e-mail, and provide the opportunity to ask further questions. If they are willing to participate, they will give written consent prior to data collection, either using a hardcopy form or a webform. For those not known directly to the team, the contact point(s) will be asked to get in touch with them and provide information about the study, and ask if they are happy to be put in touch with the team (by e-mail or in person). Those who agree will be given further information, including the participant information sheet in hardcopy or e-mail attachment form, and given the opportunity to ask questions of the team. If they are willing to participate, they will give written consent prior to data collection, either using a hardcopy form or a webform.

Second, we are likely to encounter further potential participants in the course of observational data collection, for example in meetings or by being introduced during ad hoc encounters. The researcher will briefly introduce himself and the study at the first opportunity, and will provide participant information sheets where appropriate. Where individuals encountered in this way might be eligible for an interview, the researcher will discuss this opportunity with them either in person or by follow-up e-mail contact, and provide further information about the study including the participant information sheet. If the individual is interested in the possibility of participating, they will be given the opportunity to ask questions and, if they remain interested, will be asked to give written consent prior to data collection, either using a hardcopy form or a webform.

Third, following interviews, participants will be asked if there are other colleagues who may be able to offer relevant insights, a process known as snowball sampling. The individual who has suggested the potential participant will be asked to contact them on behalf of the team with information about the study (either a short summary or the participant information sheet), and to ask if they are happy for their contact information to be shared with the team (either by the individual contacting the potential participant or the potential participant her/himself). Those who agree will be contacted directly by the team (by e-mail or in person) with the participant information sheet (provided either as an e-mail attachment or in hardcopy) and asked to indicate whether they might be interested in participating, as above. They will be given an opportunity to ask questions of the team, and if they remain interested in participating, will be asked to give written consent prior to data collection, either using a hardcopy form or a webform.

Observational data collection will include attending meetings, shadowing specialists and partners, sitting in on their day-to-day work and reflecting on it with them, collecting non-

confidential documents to aid insights, and chatting informally with those encountered.

8.2.6 Consent

For all formal recorded interviews, informed written consent will be obtained prior to the start of data collection. Each participant will be provided with a participant information sheet, and will be given the opportunity to ask questions by e-mail, phone or in person before consenting. Once they have had their questions answered to their satisfaction, they will be asked to provide written consent using either a hardcopy consent form or a link to an online version of the same form where they will be asked to indicate their agreement to data collection, recording and transcription, and use of the data in outputs from the study. The content of the two version of the form will be identical.

After consent has been provided but before the interview starts, the purpose of the interview will be restated verbally by the researcher and the participant will be given the opportunity to ask further questions. Recording and data collection will then commence. The participant will be able to stop the interview and withdraw consent at any point during the interview. Following the interview, the participant will be able to withdraw consent until the point at which data are anonymised (during the transcription process).

For informal contact during observational data collection, the collection of written consent will not be feasible. For example, it would not be reasonable to disrupt a meeting attended by the researcher to allow all those present to provide written consent. However, the purpose of the researcher's presence will be made clear by the researcher at the first opportunity. He will give a brief verbal summary of the study, provide copies of the participant information sheet to all individuals who wish to receive it, and answer questions. He will make it clear that if anyone objects to his presence, he will withdraw from the meeting; if in doubt, he will withdraw from the meeting himself without prompting. The researcher will not attend meetings or other activities where individual patient data might be discussed, and so no personal identifiable data relating to patients will be disclosed without their consent. When chatting informally to those encountered during observational data collection, the researcher will reiterate the reason for their presence, seek verbal assent from others involved in the conversation, and note that they will treat the conversation as a data source unless the individual asks that they do not. No recording will take place of any meetings or other data collection activities that do not involve explicit consent.

8.3 Data

8.3.1 Data collection

Interviews will be conducted in person, via video-conferencing (e.g. Microsoft Teams) or by telephone, and will last on average 45 minutes. All formal interviews will be audio-recorded. Fieldnotes collected during observations (including notes from informal chats) will be recorded initially using an encrypted audio-recording device (Dictaphone) and in handwritten notes. Interviews will be structured around a topic guide informed by our literature review, emergent findings from the other workstreams, and our previous work; interviews will also account for

the particular areas of focus ('tracer issues') in the case study site (see Section 8.2.1). Similarly, observations will be informed by an observation framework covering the same issues.

Interview recordings and audio-recorded notes will be fully professionally transcribed by a third-party transcription company with an existing contract and confidentiality agreement with THIS Institute.

8.3.2 Data analysis

Transcripts of interviews and audio-recorded notes, along with data extracted from documentary materials, will be incorporated into an Nvivo database for analysis, which will take an approach derived from the constant comparative method (Charmaz 2006). Using insights from Workstreams 1, 2 and 3 as sensitising concepts, we will first code data inductively on a case-by-case basis, with coding taking place in parallel with fieldwork to allow insights to feed into the focus of further data-collection activities. We will then move to a comparative analysis approach, comparing data across case-study sites and contrasting data relating to the two roles to refine our coding framework and move towards 'axial' coding: identifying higher-level thematic codes that cut across, refine and rationalise our initial coding framework. We will interact regularly with our expert collaborative group to inform and enrich coding, test out emerging theories, and sharpen our lines of inquiry. Following completion of Workstream 4, in the final six months of the study, we will also undertake a final synthesis of data across all four workstreams, bringing together insights from all data sources and informed by our third joint interpretive forum, which will draw on the insights of a broad range of stakeholders (see Section 10).

8.3.3 Data protection and storage

Interviews undertaken in person, along with oral fieldnotes, will be recorded on a password-protected, encrypted audio recording device held by the researcher. Oral fieldnotes will not contain personal identifiable data, but interview recordings are likely to contain personal identifiable data. As soon as possible (usually on return to the office), they will be transferred to a University of Cambridge safe haven, and the original recordings will be deleted from the device. The files will then be transferred via SFTP to the third-party transcription company. The company will anonymise transcripts in the process of transcription, providing a separate anonymisation key. Transcripts will be transferred back to the team via SFTP and stored on the safe haven, pending checking for the removal of any identifying data. Once full anonymisation has been confirmed, they will be transferred to a dedicated folder on THIS Institute's SharePoint storage system. Only the research team and other relevant staff within the institute (e.g. its data manager) will have access to the folder. Anonymisation keys will be kept in a separate folder and password-protected.

Handwritten fieldnotes will be kept on the person of the researcher at all times during data collection visits. They will not contain any identifying information. Upon the researcher's return to the office, they will be scanned into digital documents which will be kept in a dedicated folder on THIS Institute's SharePoint storage system, and the originals will be destroyed. Similarly, documentary data sources will be scanned into digital documents upon the

researcher's return to the office and kept in a dedicated folder on THIS Institute's SharePoint storage system. They will not contain any personal identifiable information; any information that identifies the organisation from which they are sourced will be removed. The original documents will then be destroyed.

Names and contact details of participants will be stored for a maximum of two years after completion of the study and then destroyed. Research data will be destroyed seven years after completion of the study.

8.4 Ethical and regulatory considerations

Workstream 4 constitutes research according to the definitions provided by the HRA. Therefore ethical review and approval will be required prior to the commencement of recruitment and data collection. Since data collection will involve staff and volunteers only, and not patients, ethical approval will be sought from a University of Cambridge ethics committee (not an NHS REC). Recruitment and data collection will take place through NHS organisations, and therefore in addition to ethical approval, approval from the HRA and from participating organisations' research and development departments will also be required before recruitment commences.

8.4.1 Assessment and management of risk

We consider Workstream 4 to pose low-to-moderate risks to participants and researchers. The greater risks identified than in other workstreams arise from the use of ethnographic data collection, and the risks this poses both to participants (who, in the case of data collected in the course of observations and informal chats, will not be asked to provide written consent) and to the researcher (arising from lone working in a setting other than the usual workplace).

We will mitigate the risk to participants by ensuring that information on the study is readily available to those who might be present during observational data collection in appropriate formats (verbal and written), with the opportunity to ask questions. During informal chats, the researcher will ensure that others involved in the conversation understand the researcher's purpose and that the contents of the conversation will be used as a data source, and will seek verbal assent. In meetings and other group situations where the researcher is present, he will briefly introduce himself at the first opportunity, providing participant information sheets to those who wish to receive them, and explaining that anyone present can request that he withdraw from the situation without giving a reason. If in doubt, he will withdraw from the meeting himself without prompting.

We will mitigate the risks to the researcher by following the University of Cambridge's lone-working policy, including risk assessment ahead of the commencement of fieldwork. This will include specific steps to mitigate any risks identified, including travel to and from the case study site. The locations for fieldwork include public and institutional settings only: data collection will not involve any private settings, such as participants' own homes.

Ahead of formal interviews, participants will be provided with written information prior to data collection and given the opportunity to seek clarification in writing and verbally, will give informed consent, and will have the opportunity to withdraw consent up until the point of anonymisation of data collected. Participants will not be drawn from vulnerable populations and so safeguarding concerns are unlikely.

The data to be collected during interviews, informal chats and conversations are not personal or sensitive in nature. Interviews may include personal identifiable data; Section 8.3.3 sets out our approach to ensuring data security. It is conceivable that participants might raise concerns regarding safety in their organisations. If in the course of an interview or informal chat, it appears that participants are raising issues that may pose current safety risks, the researcher will first seek to clarify the nature of these issues. They will encourage the participant to raise concerns using the usual channels relating to their organisation or industry. If the participant is reluctant to do so, the researcher will discuss with other colleagues on the research team whether the concerns are of a nature that requires disclosure by the research team. The participant information sheet will make clear to potential participants that while participant confidentiality will usually be respected and upheld in outputs from the study, if serious and current concerns are raised in the course of data collection, the research team may be obliged to break confidentiality.

8.4.2 Research Ethics Committee (REC) and other regulatory review

Prior to the start of data collection, an ethical opinion will be sought from a University of Cambridge ethics committee. Research governance review will be sought from the HRA and from participating organisations' research and development departments.

Although the study involves ethnographic data collection, this will not take place in situations where patient-identifiable data will discussed, and therefore no submission to the HRA's Confidentiality Advisory Group will be required.

8.4.3 Sponsorship, insurance and indemnity

The University of Cambridge will act as the sponsor for this sub-study. The university's usual indemnity insurance arrangements for research studies will apply.

9 Peer review

This study is funded by the National Institute for Health and Care Research's Health and Social Care Delivery Research programme, a competitive national funding programme that involves a rigorous two-stage selection process. In addition to review by the programme's selection committee, the proposal also underwent external peer review by four independent expert reviewers.

10 Patient, public and other stakeholder involvement

Patients and the public, along with other affected stakeholders, have been involved in the development of this study and will continue to contribute actively to the study as it takes place. In particular, two forums – an 'expert collaborative group', and a series of 'joint interpretive forums' – will offer the chance for patients, the public and other stakeholders to make an active contribution to the development of the study, including key design decisions, interpretation of findings and dissemination.

The study's **expert collaborative group** is a core group of key stakeholders who will work closely with the investigator and research team throughout the study, guiding key decisions, informing analysis, and using their networks and influence to aid the completion of the project and ensure that its findings reach the right audiences in the optimal formats. An expert collaborative group falls somewhere between the advisory input of consultation-based approaches to stakeholder engagement, and the full accountability for project conduct and delivery that lies with the investigator team. By bringing together relevant experience and expertise from the full range of relevant stakeholder perspectives in spaces that are governed by explicit principles regarding respect, listening and mutual accountability, expert collaborative groups have greatly enriched our past studies, including our existing small-scale evaluation of the patient safety specialist role. We recognise these contributions through payments for people's contributions where appropriate (e.g. for patient, public and lay contributors, whom we pay at a rate at or slightly above current Involve recommendations) or through reimbursement to employing organisations, and – equally importantly – via explicit recognition as members of contributor or author groups for publications.

Membership of the expert collaborative group will be kept under review throughout the study, but will include from the start two public contributors, people with experience of working in patient safety specialist and patient safety partner roles, members of key stakeholder organisations such as NHS England, policy-level stakeholders from across the United Kingdom, and others with academic, clinical or management expertise and experience in patient safety. The first meeting of the expert collaborative group will give explicit consideration to the skills, perspectives and backgrounds provided by its membership, and seek to identify gaps that might be filled, including at the levels of both diversity of thought and experience of individuals, and identifying key organisational stakeholder that might be included in the group to mutual benefit. The expert collaborative group will meet seven times over the course of the study, at roughly six-month intervals.

Joint interpretive forums will play a different but complementary role in the study to that of the expert collaborative group. These are more broad-based and more occasional groups, who will be convened at key points in the study to inform decision-making and/or further enhance our insight and analysis. They will typically involve a *larger* number of people from a

narrower population than expert collaborative groups, and any individual's contribution may be one-off rather than ongoing. We plan to convene three joint interpretive forums over the course of the study:

- **Joint interpretive forum 1** will bring together a group of up to 30 people (predominantly patient safety partners) via the networks of our expert collaborative group. In this forum, people will participate in facilitated breakout group discussions and will be asked for their (verbal and written) feedback and input on a putative theory of change for the patient safety partner role (developed in Workstream 3 – see Section 7). Their insights will help strengthen and refine the theory of change, inform survey development for Workstream 3 and sampling for Workstream 4, and further lines of empirical inquiry. It will take place around month 8 of the study.
- **Joint interpretive forum 2** will convene a group of stakeholders at a policy level via the networks of the expert collaborative group. In this forum, we will present key findings (from Workstream 1 – see Section 5) of our interrogation of similar safety leadership roles in other industries and explore the implications for the design and delivery of patient safety specialist and patient safety partner roles. It will take place around month 11 of the study.
- **Joint interpretive forum 3** will include a wider range of groups, and will be convened towards the end of the study. Those invited to contribute will include members of the expert collaborative group and steering committee, people who participated in the first two joint interpretive forums, stakeholders from the case study organisations included in Workstream 4 (see Section 8), and those who participated in the other three workstreams who consented to further contact. In this forum, we will identify the key implications of the study as a whole, their relevance for policy and practice, how they might best be communicated, and what the next steps will be. It will take place around month 32 of the study.

The first two forums will be hosted online, taking approximately two hours each, and with a view to maximising participation, we will run them two or three times each. The third forum will take place over half a day, in person, likely with a hybrid option for those unable to attend.

11 Dissemination

Our approach to dissemination of findings from the study will be multifaceted, ongoing and dialogical, with a range of outputs intended to provide insights to the full range of audiences in formats that are suited to them. Individual outputs from each workstream are listed in separate sections below, though we anticipate that additional opportunities for dissemination will be identified throughout the course of the study, particularly as we discuss emerging insights with our expert collaborative group. Academic outputs will be produced by each workstream, and together will form a transparent record of the work, following the NIHR's 'threaded publication' model. Research participants at all stages will be given the opportunity to 'sign up' to receive information on the study as it unfolds.

We will secure impact for our study through the links of the investigator team to key organisations in the health and care system, through our collaboration with NHS England as the body overseeing the patient safety specialist and patient safety partner programmes, through our connections with key organisations represented on our expert collaborative group with links to various stakeholder audiences, and through our links with bodies in other nations of the UK besides England, to maximise the reach of our findings.

11.1Workstream 1

The key output of Workstream 1 will be a typology of safety roles focused on common themes across industries, the unique aspects of specialised roles in different sectors, and lessons relevant for healthcare settings. We will pay particular attention to how these roles navigate organisational hierarchies, influence safety culture, and seek to drive improvements in safety practices and outcomes. To sense-check and enrich this typology, and optimise its relevance for the healthcare setting, we will convene a joint interpretive forum (see Section 10) involving stakeholders at policy level, at which we will present the background, the typology, and key potential implications for the delivery of patient safety specialist and partner roles. The forum will run online, for around two hours, with up to three repeat sessions to maximise participation. Findings from Workstream 1 will form an analytical foundation for the other workstreams, providing a theoretically rich and empirically grounded framework.

11.2 Workstream 2

Outputs from Workstream 2 will include an analysis of the first survey that will inform site selection, data collection and analysis in Workstream 4, a full longitudinal analysis of all three surveys (including the one previously completed as part of our earlier study of the patient safety specialist role) together following the completion of the final survey, outputs summarising key findings for practice and policy stakeholders, and a report on the analysis of specialists' work in pursuit of their training that will be used by Jun and Fray to inform future development of the programme, and fed into wider NHS England workforce development planning.

11.3 Workstream 3

Outputs from Workstream 3 will include, first, a theory of change and logic model that will be shared with policymakers, used to inform survey design, presented in an accessible form to patient safety partners and other interested stakeholders following completion of the first survey, and used to inform site selection, data collection and analysis in Workstream 4. Second, we will undertake analyses of the two surveys, including longitudinal comparison, that will again be shared with policy and practice audiences, including patient safety partners themselves. Finally, we will prepare academic outputs from the surveys, potentially combining them with findings from the surveys of patient safety specialists to produce an academic output comparing the experiences of the two groups and deriving implications for their needs

for organisational support.

11.4 Workstream 4

Workstream 4 will give rise to outputs examining the work of patient safety specialists and patient safety partners, including comparisons by role and by context, including a brief summary of findings for each case study that will be fed back via its specialist(s) and partner(s), integrative reports on the influences on the work of each role that will form the basis for peer-reviewed academic papers, outputs oriented towards role-holders and colleagues focusing on practical implications from the whole study, and key implications for policy. Integrative analysis across workstreams may give rise to a further output summarising key findings from the whole programme.

12 IP/IA

Besides academic outputs – which will be published Open Access using an appropriate Creative Commons licence – other key items of intellectual property likely to be produced by the study include:

- Survey instruments for patient safety specialists and patient safety partners: again, these will be made available Open Access with an appropriate Creative Commons licence (e.g. CC BY), with a view to facilitating repeat surveys of the same population (or use with similar populations in other countries, e.g. if similar roles are introduced elsewhere in the UK or in other jurisdictions
- The logic model for the patient safety partner role

We will not seek to exploit financially any intellectual property generated by the study.

13 References

Abbott, A.D. (1988) *The system of professions: an essay on the division of expert labor*. London: University of Chicago Press.

Adra, I., Giga, S., Hardy, C. and Leka, S. (2024) What is safety leadership? A systematic review of definitions, *Journal of Safety Research*.

Allen, D. (2017) From polyformacy to formacology, *BMJ Quality & Safety*. **26**, 9, 695–7.

Anker, S. and Lurie, Y. (2022) On the professional authority of quality engineers and the gaps in their epistemic and organizational authority, *Journal of Professions and Organization*. **9**, 1, 62–76.

Bosk, C.L., Dixon-Woods, M., Goeschel, C.A. and Pronovost, P.J. (2009) Reality check for checklists, *The Lancet*. **374**, 9688, 444–5.

Braithwaite, J., Wears, R.L. and Hollnagel, E. (2015) Resilient health care: turning patient

safety on its head, *International Journal for Quality in Health Care*. **27**, 5, 418–20.
Catchpole, K. and Russ, S. (2015) The problem with checklists, *BMJ Qual Saf*. **24**, 9, 545–9.
Charmaz, K. (2006) *Constructing grounded theory: a practical guide through qualitative analysis*. London: Sage.
Charmaz, K. and Belgrave, L.L. (2007) Grounded theory. In Ritzer, G., Ryan, J.M., and Thorn, B. (eds.) *The Blackwell Encyclopaedia of Sociology*. 2nd edition. Oxford: Blackwell. p.
Clay-Williams, R. and Colligan, L. (2015) Back to basics: checklists in aviation and healthcare, *BMJ Qual Saf*. **24**, 7, 428–31.
Davidoff, F., Dixon-Woods, M., Leviton, L. and Michie, S. (2015) Demystifying theory and its use in improvement, *BMJ Quality & Safety*. **24**, 3, 228–38.
Dixon-Woods, M. (2010) Why is patient safety so hard? A selective review of ethnographic studies, *J Health Serv Res Policy*. **15**, S1, 11–6.
Eisenhardt, K.M. (1989) Building theories from case study research, *Academy of Management Review*. **14**, 4, 532–50.
Friedland, R. and Alford, R.R. (1991) Bringing society back in: symbols, practices and institutional contradictions. In Powell, W.W. and DiMaggio, P.J. (eds.) *The new institutionalism in organizational analysis*. London: University of Chicago Press. pp. 232–63.
Gamble, J.A.A. (2008) *A developmental evaluation primer*. Montréal: McConnell Foundation.
Hale, A. and Booth, R. (2019) The safety professional in the UK: development of a key player in occupational health and safety, *Safety Science*. **118**,76–87.
Hale, A.R. (1995) Occupational health and safety professionals and management: identity, marriage, servitude or supervision?, *Safety Science*. **20**, 2, 233–45.
Hollnagel, E., Wears, R.L. and Braithwaite, J. (2015) *From Safety-I to Safety-II: a white paper*. Middelfart: Center for Kvalitet.
Jubault Krasnopevtseva, N., Guntzburger, Y., Kaminska, R. and Thomas, C. (2024) Building a conceptual framework of organizationally embedded tensions to enhance leadership for safety in high-risk and highly regulated organizations: A complexity leadership perspective, *Safety Science*. **177**,106572.
Lawton, R. (2018) It ain't what you do (but the way that you do it): will Safety II transform the way we do patient safety?, *International Journal of Health Policy and Management*. **0**, 0.
Maguire, K. and Britten, N. (2017) "How can anybody be representative for those kind of people?" Forms of patient representation in health research, and why it is always contestable, *Social Science & Medicine*. **183**,62–9.
Malterud, K., Siersma, V.D. and Guassora, A.D. (2016) Sample size in qualitative interview studies: guided by information power, *Qualitative Health Research*. **26**, 13, 1753–60.
Martin, G., Pralat, R., Waring, J., Peerally, M.F., et al. (2025) Professionalising patient safety? Findings from a mixed-methods formative evaluation of the patient safety specialist role in the English National Health Service, *Journal of Health Services Research & Policy*. **30**, 1, 40–51.
Martin, G.P. (2008) Representativeness, legitimacy and power in public involvement in health-service management, *Social Science & Medicine*. **67**, 11, 1757–65.
Martin, G.P., Currie, G. and Finn, R. (2009a) Leadership, service reform, and public-service networks: the case of cancer-genetics pilots in the English NHS, *Journal of Public*

Administration Research & Theory. **19**, 4, 769–94.
Martin, G.P., Currie, G. and Finn, R. (2009b) Reconfiguring or reproducing intra-professional boundaries? Specialist expertise, generalist knowledge and the 'modernization' of the medical workforce, *Social Science & Medicine*. **68**, 5, 1191–8.
Martin, G.P., Desai, A., Zoccatelli, G., Brearley, S., et al. (2024) Constraining co-creation? An ethnographic study of Healthwatch organizations in England, *Public Management Review*. **0**, 0, 1–21.
Martin, G.P. and Waring, J.J. (2013) Leading from the middle: constrained realities of clinical leadership in healthcare organisations, *Health*. **17**, 4, 358–74.
McKee, L., Charles, K., Willars, J., Dixon-Woods, M., et al. (2013) 'New' and distributed leadership in quality and safety in healthcare, or 'old' and hierarchical? An interview study with strategic stakeholders, *Journal of Health Services Research & Policy*. **18**, S2, 11–9.
Nancarrow, S.A. and Borthwick, A.M. (2005) Dynamic professional boundaries in the healthcare workforce, *Sociology of Health & Illness*. **27**, 7, 897–919.
National Advisory Group on the Safety of Patients in England (2013) *A promise to learn - a commitment to act: improving the safety of patients in England*. London: Department of Health.
NHS England (2021) *Short – medium term priorities for Patient Safety Specialists*. London: NHS England.
NHS England (2023) *Requirements for patient safety specialists*. [Online]. London: NHS England.
NHS England and NHS Improvement (2019) *The NHS patient safety strategy: safer culture, safer systems, safer patients*. London: NHS England.
NHS England and NHS Improvement (2021a) *Framework for involving patients in patient safety*. London: NHS England.
NHS England and NHS Improvement (2021b) *NHS patient safety strategy: 2021 update*. London: NHS England.
NHS Resolution (2023) *Annual report and accounts 2022/23*. London: NHS Resolution.
Ocloo, J. and Matthews, R. (2016) From tokenism to empowerment: progressing patient and public involvement in healthcare improvement, *BMJ Qual Saf*. **25**, 8, 626–32.
O'Hara, J.K., Aase, K. and Waring, J. (2018) Scaffolding our systems? Patients and families 'reaching in' as a source of healthcare resilience., *BMJ Qual Saf*. bmjqs-2018-008216.
Panagioti, M., Khan, K., Keers, R.N., Abuzour, A., et al. (2019) Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis, *BMJ*. **366**,l4185.
Patton, M.Q. (2010) *Developmental evaluation: applying complexity concepts to enhance innovation and use*. New York: Guilford Press.
Pilbeam, C., Doherty, N. and Denyer, D. (2017) Safety leadership: fashion, function, future. In Dingwall, R. and Frost, S. (eds.) *Health and safety in a changing world*. Abingdon: Routledge. pp. 115–37.
Powell, W.W. and DiMaggio, P.J. (1991) *The new institutionalism in organizational analysis*. London: University of Chicago Press.
Ritchie, J. and Spencer, L. (1994) Qualitative data analysis for applied policy research. In Bryman, A. and Burgess, R.G. (eds.) *Analyzing qualitative data*. London: Routledge.

pp. 173–94.
Rycroft-Malone, J., Burton, C.R., Wilkinson, J., Harvey, G., et al. (2015) Collective action for knowledge mobilisation: a realist evaluation of the Collaborations for Leadership in Applied Health Research and Care, *Health Services and Delivery Research*. **3**, 44.
Schreier, M. (2017) Sampling and generalization. In Flick, U. (ed.) *The Sage Handbook of Qualitative Data Collection*. London: Sage. pp. 84–98.
Sheard, L., Marsh, C., O'Hara, J., Armitage, G., et al. (2017) The Patient Feedback Response Framework – understanding why UK hospital staff find it difficult to make improvements based on patient feedback: a qualitative study, *Social Science & Medicine*. **178**,19–27.
Sujan, M.A., Furniss, D., Anderson, J., Braithwaite, J., et al. (2019) Resilient Health Care as the basis for teaching patient safety – A Safety-II critique of the World Health Organisation patient safety curriculum, *Safety Science*. **118**,15–21.
Sutton, E., Eborall, H. and Martin, G. (2015) Patient involvement in patient safety: current experiences, insights from the wider literature, promising opportunities?, *Public Management Review*. **17**, 1, 72–89.
Thornton, P.H. and Ocasio, W. (2008) Institutional logics. In Greenwood, R., Oliver, C., Sahlin-Andersson, K., and Suddaby, R. (eds.) *Sage handbook of organizational institutionalism*. London: Sage. pp. 99–129.
Treadwell, J.R., Lucas, S. and Tsou, A.Y. (2014) Surgical checklists: a systematic review of impacts and implementation, *BMJ Quality & Safety*. **23**, 4, 299–318.
Waring, J., Allen, D., Braithwaite, J. and Sandall, J. (2016) Healthcare quality and safety: a review of policy, practice and research, *Sociology of Health & Illness*. **38**, 2, 198–215.
Waring, J. and Currie, G. (2009) Managing expert knowledge: organizational challenges and managerial futures for the UK medical profession, *Organization Studies*. **30**, 7, 755–78.
Weiss, C.H. (1995) Nothing as practical as good theory: exploring theory-based evaluation for comprehensive community initiatives for children and families. In Connell, J.P., Kubisch, A.C., Schorr, L.B., and Weiss, C.H. (eds.) *New approaches to evaluating community initiatives: concepts, methods, and contexts*. New York: Aspen Institute. pp. 65–92.
Wiig, S., Hibbert, P.D. and Braithwaite, J. (2020) The patient died: what about involvement in the investigation process?, *International Journal for Quality in Health Care*. **32**, 5, 342–6.
Woodward, S. (2019) Moving towards a safety II approach, *Journal of Patient Safety and Risk Management*. **24**, 3, 96–9.
Yau, C.W.H., Leigh, B., Liberati, E., Punch, D., et al. (2020) Clinical negligence costs: taking action to safeguard NHS sustainability, *BMJ*. **368**,m552.

14 Protocol Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
n/a	0.1	2025-02-27	GM	First draft

n/a	0.2	2025-03-28	GM, KD, RP, JW, MFP	Minor changes incorporated into version 0.2 (for funder review)
n/a	0.3	2025-04-06	GM	Addition of NIHR disclaimer
n/a	1	2025-05-21	GM	NIHR approved (no substantive changes from 0.3)