Research Protocol

Evaluation of the implementation and normalisation of 'Freedom to Speak Up Guardians' in NHS England Acute and Mental Health Trusts.

Title	**Evaluation of the implementation and normalisation of 'Freedom to Speak Up Guardians' in NHS England Acute and Mental Health Trusts.**			
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Summary of Research

The Freedom to Speak Up (FTSU) Review (Francis, 2015) states that employees who 'speak up' about care failings can save lives. However, although many employees' concerns are dealt with satisfactorily, there is compelling evidence to suggest that in many parts of the NHS staff feel unable to speak up, and when they do speak up there is a prevailing culture 'which not infrequently has negative consequences for those brave enough [to raise concerns]' (Francis, 2015: p.1). As a result, the mistreatment of NHS employees who speak up, or 'raise concerns' (also sometimes referred to as 'whistleblowing'), is a 'serious issue requiring 'urgent attention' (p.4)[1]. This is despite the existence of employment legislation which offers protection for those who speak up and a plethora of initiatives and guidance designed to support employees in raising concerns, and advice to organisations on how best to respond. This is not just a problem within the NHS, as healthcare employees globally experience mistreatment and indifference as a result of raising concerns, for example, in Australia (Lewis et al., 2014), Germany (Fasterling, 2014) and USA (Black, 2011), to name only a few.

To confront this serious issue, the FTSU Review (Francis, 2015) sets out 20 Principles to guide the development of 'a consistent approach to raising concerns throughout the NHS whilst leaving scope for flexibility for organisations to adapt them to their own circumstances' (p.6). A single 'overarching Principle' states that every NHS organisation should 'foster a culture of safety and learning in which all staff feel safe to raise concerns' (p.6). Of specific relevance to this proposal is Principle 11 ('Support'), which outlines the introduction of a new role in all NHS organisations, called Freedom to Speak Up Guardians (FTSUGs), supported by a National Freedom to Speak Up Guardian (NG). The introduction of FTSUGs is founded on three interlinked objectives; to positively influence employees to speak up by creating an environment where

[1] The terms whistleblowing/whistleblower, raising concerns and speaking up are commonly and interchangeably used in literature, policy and the media. This proposal, in the main, refers to speaking up and raising concerns which are frequently used in the NHS and academic literature, and only uses the term whistleblowing and its derivatives where others have referred to this term.

speaking up is ‘part of the normal routine business of any well led NHS organisation’ (p.12); to promote culture change that reverses the woefully long record of NHS employees being professionally and personally victimised for raising concerns and to ensure NHS organisations, both individually and collectively, learn from employees who speak up.

However, the conviction that FTSUGs can make a ‘huge contribution’ (Francis, 2015: p.16) in developing organisational cultures that normalise speaking up requires further scrutiny, given the lack of existing evidence informing the development and implementation of the role. To address some of these significant gaps in knowledge this study will provide a detailed understanding of the different approaches to implementing and normalising the FTSUG role across in Acute Hospital Trusts and Mental Health Trusts in England, whether FTSUGs are helping to foster a culture of safety and learning where staff feel able to speak up about their concerns and how different approaches to implementing the FTSUG role influence, or not, how concerns are raised and responded to. We will undertake a national survey of FTSUGs followed by six in-depth case studies underpinned by Normalisation Process Theory (NPT), which offers a robust conceptual framework to understand how new complex interventions, such as the FTSUG role, and their ensemble of related material and cognitive practices, gradually become normalised, or not, in specific social contexts as the result of people working, individually and collectively, to implement them (May, 2013).

Research questions, aims and objectives

The aim of this study is to better understand the introduction of an innovative new role designed to support staff who wish to raise concerns about the quality of patient care. These roles are called ‘Local Freedom to Speak Up Guardians’ (referred to here as ‘FTSUGs’). We are interested in finding out how FTSUG roles are being introduced and normalised into everyday practice in NHS England and whether FTSUGs are helping NHS staff to speak up about their concerns. The study consists of three separate but interrelated work packages (WP). WP1 comprises a critical synthesis of the national and international research and grey literatures on initiatives which have sought to normalise ‘speaking up’ in healthcare and other industries. WP2 involves telephone interviews with FTSUGs working in Acute Hospital Trusts and Mental Health Trusts and national stakeholders in the FTSUG process, e.g. designers of the system, those regulating and monitoring it, and those able to discuss how it relates in design and implementation to other monitoring systems. WP3 involves 6 in-depth case studies of the implementation of FTSUGs in these areas. A recognized theoretical framework called Normalisation Process Theory (NPT) will be used to structure data generation, analysis and interpretation. We will analyse the six case study sites separately, before integrating and synthesising the emergent findings across all cases. A project report will then be produced describing similarities and differences in the implementation of the FTSUG role across England and whether and how FTSUGs have normalised speaking up by staff and organisational responsiveness to staff concerns. We will also develop induction and training materials and a ‘speak up’ guide for managers, clinicians and others with an interest in this area.

Research Questions

1. How are FTSUGs being variously deployed, managed and held accountable for their work?
2. How is the work of FTSUGs defined and negotiated in relation to the work of others who also deal with employee concerns and patient safety at local and national levels?
3. Do different implementation models for the FTSUG role impact on the ‘freedom to speak up’, both in the ways that employees raise concerns and how these concerns are responded to?

Research Aims

a) To map varying approaches to implementing and configuring FTSUG roles in Acute Trusts and Mental Health Trusts.
b) To generate evidence of the extent to which FTSUG roles have been “normalized” in organisations.
c) To gain insights into benefits and drawbacks of different FTSUG implementation models on staff’s ability to speak up and act upon concerns.

Research Objectives

1. IMPLEMENTATION & USE: Assess the scale and scope of the deployment and work of FTSUGs.
2. IMPLEMENTATION & GOVERNANCE: Assess how the work of FTSUGs is organised and operationalised alongside other relevant local and national roles with responsibilities for employee concerns.
3. EFFECTIVENESS: Evaluate the comparative effectiveness of different types of FTSUG roles in supporting ‘freedom to speak up’.

4. BARRIERS & FACILITATORS: Identify barriers, facilitators and unintended consequences associated with the implementation of FTSUG roles.

We will meet these aims and objective the following work packages (WP):

- **WP1 (months 1-5):** a systematic evidence synthesis of international literature of 'Speak Up' strategies and interventions undertaken in healthcare and other sectors.
- **WP2 (months 6-11):** telephone interviews with (a) FTSUGs working in Acute Hospital and Mental Health Trusts which will provide an understanding of how FTSUGs are selected/recruited, deployed and organised and the numbers and types of concerns raised, and (b) national stakeholders in the FTSUG process, e.g. designers of the system, those regulating and monitoring it, and those able to discuss how FTSUG roles relate in design and implementation to other monitoring systems
- **WP3 (months 12-21):** six case study sites (4 Acute Trusts & 2 Mental Health Trusts) will be selected following analysis of WP2 to provide an in-depth examination of how FTSUG roles are implemented and normalized alongside other local and national roles and initiatives related to developing open reporting cultures in the NHS.
- **WP4 (months 22-27):** integration and final analysis of findings and report writing.
- **Outputs and dissemination events:** publications, workshops, awareness raising and briefings are scheduled throughout the duration of the project.

Research Plan / Methods

Design and theoretical/conceptual framework:

Although the introduction of a new role in the NHS can, in many ways, be seen as a relatively straightforward operation, we theorise that, for the purpose of investigation, it is appropriate to conceptualise the FTSUG role as a complex intervention (Øvretveit, 2011). Complex interventions are widely used in the health service. They are conventionally defined as interventions that are difficult to implement as they consist of several interacting and interlocking components which span a number of organisational levels, from the macro level (national policy organisations and regulators), to the meso level (individual Trusts) and micro level (individual employees, teams, wards/units) (Moore et al., 2015). Hannigan (2013) describes how these complex organisational levels are 'nested', so that each level can be thought of as simultaneously sitting above and below (and inter- acting with) other systems of different scale. For example, FTSUGs responses to concerns will be embedded in micro-level employee relationships and experiences, as well as the characteristics of the concern being raised (type and severity of concern being raised, who raises the concern, how and where etc.). A range of contextual and organisational preconditions will also exist at the meso-level, such as organisational/managerial structures, policies, processes and hierarchies. In addition, public, regulatory and governmental interest in employee concerns adds a social and inter-institutional macro level dimension to the FTSUG role, which may be experienced from an institutional standpoint as external social and regulatory pressure and risk.

Given the complex nature of the FTSUG role and the contexts within which the role is being implemented, Normalisation Process Theory (NPT) offers an appropriate framework to guide the study. At its most basic, NPT seeks to explain how complex interventions work (Murray et al., 2010; May, 2013). NPT assists researchers to identify factors that promote or inhibit the routine incorporation of complex interventions, such as FTSUGs, into everyday practice considering not only early implementation, but also a later point where an intervention 'disappears' from view (i.e., it is normalised) as it becomes completely embedded into routine practices. A recent systematic review of NPT research outlines how the theory has been successfully applied in a wide range of healthcare implementation studies (McEvoy et al., 2014) and provides a practical framework to guide data collection and analysis (www.normalizationprocess.org/). Importantly, given the innovative and relatively newly introduced nature of the FTSUG role, NPT has been shown in numerous studies to be an approach that assists researchers to make clear recommendations for future implementation of healthcare roles and guidelines (McEvoy et al., 2014).

NPT focuses on the work that individuals and groups do to enable an intervention to become normalised. There are four main components, or generative mechanisms, within NPT, which practically help identify the social processes underpinning the implementation of complex interventions (May, 2013); these are described further in Table 1. We will apply NPT throughout the study; during the evidence synthesis, to help map-out the implementation of FTSUGs, in a national telephone survey of FTSUG implementation during more in-depth case studies, which will explore how these components dynamically facilitate, or not, a culture of speaking up

by employees in the workplace. In lay terms, NPT proposes that practices become embedded in social contexts as the result of people working, individually and collectively, to implement them. For example, if those involved in the implementation of FTSUGs can identify coherent arguments for adopting them, are engaged in the process of implementation, are able to adapt their work processes to utilise FTSUGs (or FTSUGs adapt to fit in with existing practices), and judge them to be valuable once they are in use, then FTSUGs are more likely to become embedded in routine practice.

However, making what was once a new intervention a normal part of everyday practice is not a 'one off' process, but requires continuous investment by the parties involved in implementation. Therefore, NPT's generative mechanisms cannot be seen as linear or sequential, but instead interact continuously with each other in emergent and complex ways. Individual experiences of implementation will vary across social time and space, as they are shaped, encouraged and confounded by other endogenous and exogenous factors; for example, through the withdrawal of individuals' shared commitment or through some failure of the intervention's workability. The introduction of FTSUGs cannot, therefore, be considered to be a discrete intervention, which works in the same way regardless of the organisational context. Instead, FTSUG roles are likely to be designed and used in different ways depending on the prevailing institutional arrangements.

NPT generative mechanism	Explanation of the mechanism
Capability	Capability to operationalize the FTSUG role depends on the perceived workability and integration of the various elements of the new role into everyday practice.
Capacity	The incorporation of FTSUGs within the social system of the workplace will depend on relevant individuals' capacity to resource, cooperate and co-ordinate their actions.
Potential	The FTSUG role will be more disposed towards normalization into practice if there is both individual and collective intention and commitment to operationalizing the role in practice.
Contribution	The implementation of the FTSUG role is disposed to normalization into practice if individuals invest in and contribute to operationalizing the role. If contribution cannot be sustained, then the embeddedness of the role may be threatened as individuals' efforts diminish.
Table 1: Normalization Process Theory (NPT) generative mechanisms explained	

A limitation of NPT is that it does not (and cannot) cover all phenomena of interest (May, 2013). Accordingly, we will draw on insights from other theories, concepts and research on initiatives to improve employee speaking up in health care. For example, Westrum's (2004, 2014) model of 'information flow' and workplace culture may provide an useful conceptual heuristic to help explain the variety of ways an organization responds to information from staff who speak up about concerns. The model of information flow considers how concerns may flow from point A to point B and the extent to which the flow of concerns is determined by perceived relevance, timeliness, and appropriateness to the recipient and the organization more generally.

WP1: Evidence synthesis and development of telephone interview – months 1-5; AJ lead with RM, DK & Research Assistant (RA)

WP1a: Evidence synthesis (months 1-4):
Members of the research team have previously published critical reviews of international academic and grey literature on whistleblowing and related concepts within which key theoretical and conceptual frameworks were identified (Kelly and Jones, 2013; Mannion et al., 2017). As well as updating the existing reviews the aim of WP1 is to undertake a narrative evidence synthesis approach (Popay et al., 2006) to identify strategies and interventions used in healthcare, other public services and industries/sectors internationally, that have attempted to promote and/or incentivise speaking up by employees. Narrative' synthesis refers to an approach that relies primarily on the use of words and text to summarise, synthesise and explain research findings and grey literatures. The defining characteristic is that it adopts a textual approach to the process of synthesis to 'tell the story' within the literature, in particular relating to the effectiveness of interventions (Popay et al., 2006). Accordingly, we will seek to identify relevant 'theories of change' (Davidoff et al., 2015), contextual factors and organisational mechanisms that influence (for better or worse) the implementation of employee speaking up policies in healthcare and other industries, that may be useful to subsequent understanding of the implementation of the FTSUG role.

The precise search terms and inclusion and exclusion criteria for the review will be determined by the project team, the advisory group and Cardiff University library specialists. We will conduct an exhaustive literature search of social science, nursing and medical databases, in addition to business and management databases that index relevant research. This will involve: scoping searches to help identify appropriate keywords, synonyms, spelling variations; searches using both free text and database-specific subject headings e.g. MeSH, Thesaurus terms; using advanced Boolean truncation, 'explode' and other search techniques. In systematic reviews of complex and heterogeneous evidence formal protocol-driven search strategies may fail to identify important evidence. Consequently, we will supplement the search of databases with additional 'snowball' search strategies, including reference list checking and 'asking around' through contact with experts, approaches which have proven to substantially increase the yield and efficiency of search efforts in recent NIHR HS&DR evidence reviews undertaken by co-applicants Jones (Simpson et al., 2016, 2017) and Maben (HS&DR 13/07/49). Inclusion and exclusion criteria will be based on relevance to the topic. We will first review abstracts for relevance, followed by full text retrieval and review where appropriate. Methodological quality will be appraised using an appraisal tool such as CASP, which will be used for purposes of moderation rather than for including or excluding papers.

WP1b – Apply for Research Ethics and R&D approvals for telephone survey (months 1-5) – AJ lead with RA – further details below

WP1c – Develop telephone interview topic guide for use in WP2 – MA lead with JM, DK, AJ (months 3-5)
We have allocated time in the work plan to iterate and develop a valid and reliable telephone interview topic guide for the survey being undertaken of FTSUGs and national stakeholders in WP2. For example, a semi structured topic guide, informed by the findings of the evidence synthesis undertaken in WP1a, will be constructed with the assistance of the project advisory group and PPI representatives. The topic guides will then be piloted with the assistance of a small number of FTSUGs. Piloting will ensure that the topic guides are constructed in a way which allows respondents to answer questions candidly, and which consistently address research objectives.

WP2: Survey of FTSUGs and national stakeholders via semi-structured telephone interviews – months 6-11; AJ lead with coapplicants DK, JM, MA, RAsx2
This work package will provide a better understanding of what FTSUGs do within their organisations, by undertaking semi-structured telephone interviews with FTSUGs operating in Acute Trusts and Mental Health Trusts in England (n= 100) and national stakeholders (n=10)in the FTSUG process, e.g. designers of the system, those regulating and monitoring it, and those able to discuss how it relates in design and implementation to other monitoring systems, which will address the following research aims and objectives:

Aim a) To map varying approaches to implementing and configuring FTSUG roles across NHS England.
Aim b) To generate evidence of the extent to which the FTSUG role has been 'normalized' in organisations.
Objective 1. IMPLEMENTATION & USE: Assess the scale and scope of the deployment and work of FTSUGs in NHS England.
Objective 2. IMPLEMENTATION & GOVERNANCE: Assess how the work of FTSUGs is organised and operationalised alongside other relevant local and national roles with responsibilities for managing concerns.
Objective 3. EFFECTIVENESS: Evaluate the comparative effectiveness of different types of FTSUG roles in supporting 'freedom to speak up'.

Following feedback on the outline proposal from the HS&DR panel, we have chosen to undertake WP2 and WP3 with Acute Trusts and Mental Health Trusts. As care delivery organisations, Acute Trusts and Mental Health Trusts face comparable contextual and clinical factors when implementing the FTSUG role. In addition, these Trusts are collectively the most widespread care delivery organisations in England and, since October 2016 at the latest, have at least one FTSUG in post. The FTSUG role is also currently operational in Clinical Commissioning Groups (CCGs), Ambulance Trusts, GP practices and community providers. However, FTSUG implementation is variable, very recent or absent in these organisations, where there are also obvious operational differences to Acute and Mental Health Trusts which would make meaningful comparisons of the FTSUG role difficult to achieve.

WP2 Data collection during months 6 to 9: 110 interviews over 4 months (100 interviews with FTSUGs and 10 interviews with stakeholders, such as regulators, monitors and policy makers).

Telephone interviews are an established and effective way of conducting interview research (Nardi, 2015). In addition to being less costly and time consuming than face-to-face interviews, telephone surveys also have the advantage of face-to-face interviews in being able to probe for information and getting more details through the use of open-ended questions. For some questions respondents may be comfortable in providing information they may not disclose when face-to-face with an interviewer (Nardi, 2015). Importantly, the comparative reliability and quality of answers provided by respondents shows no statistically significant differences between telephone interviews and interviews in person (Rossi et al., 2013). Reflecting this, recent telephone interviews with executive nurses (n=40) across England and Wales, undertaken by co-applicants Jones and Kelly, provided a reliable and efficient method of collecting good quality data, some of which was sensitive by nature (Kelly et al., 2016). Co-applicant Maben has also successfully collected and analysed telephone interviews in two NIHR funded studies, investigating Schwartz rounds (HS&DR 13/07/49) and a training package for health-care assistants (HS&DR 12/129/10).

FTSUGs (n=100) will answer the same set of questions which will help better understand the variable characteristics of the FTSUG such as their age, gender, ethnicity, experience, nature of employment (full or part time, substantive or secondment post), skills and training (both the training received and training needs), as well as the work system within which the FTSUG is embedded. This mapping of characteristics and roles is an important task, given that analysis of data published by NHS Employers and the National Guardian (2017) shows large variation in implementation of FTSUG roles across England. For example, the number of FTSUGs present in Acute Hospital Trusts and Mental Health Trusts range from one to eight. Some FTSUGs were recruited into the role following interview, others were elected by colleagues or personally approached to undertake the role, but not interviewed. There is variation too in staff grades for FTSUGs, which range from Band 3 to 8a, with the majority at Band 7. The amount of protected time to undertake the FTSUG role also shows large variation, ranging from those having less than one day per week for the role (70%), two to three days per week (22%) and more than four days per week (8%), with 81% undertaking the role alongside management, clinical roles or Chaplaincy and voluntary roles. Information about the number, type and experiences of employees disclosing concerns and any contribution made to learning resulting from disclosure will also be collected.

The culture of speaking up within the organisation will be briefly discussed in the final phase of the interview. For example, we will ask FTSUGs about how they communicate their presence to staff and any local speak up initiatives they have implemented and how these have been enacted. Consideration will be given to any factors that have restricted or enabled the normalisation of the FTSUG role within their organisation and whether FTSUGs perceive their role and speaking up as normalised, or not. Unintended consequences, such as the FTSUG role duplicating or inadvertently overturning, for better or worse, existing effective local “speak up” practices within an organisation, will be discussed. We will also explore how concerns are responded to, addressing important concepts and issues identified in the literature, such as the Deaf Effect and Hearer Action/Courage. Candidate items for telephone interview guide (to be further informed by evidence synthesis and NPT) include:

- **Respondent demographics:** Location and role within the organisation. Age, gender, ethnicity, years of service, previous posts, training/education.
- **Organisational descriptors:** Organisation size, type, structure and academic status.
- **Organisational structure, process and policy relating to speaking up:**
  Organisational structures and processes in place for employees to speak up and for hearing and responding to employee concerns.
  Divisional structures, units and roles assigned with responsibility for responding to concerns.
  Overview of actions taken in response to concerns, timescale for response.
  New structures/processes/policies created by FTSUG and resources available to the FTSUG.
- **Evaluation of the local response and commitment to/normalising the FTSUG role:**
  Examples of barriers/enablers to operationalizing the role and effective response to concerns.
  Numbers, types and severity of concerns raised since FTSUG post created.
  Degree to which speaking up activities have led to sustained local positive action.
  Comparison of intended to actual outcomes/changes resulting from implementation of the role
  Self-evaluation of the organisational culture and response to implementation of the FTSUG role.

Relevant Key Findings (KFs – see box 1) from the NHS National Staff Survey 2017 will be analysed to further understand some of the institutional characteristics within which FTSUGs work. NHS Staff Survey data

collection occurs annually between September and October, at which time all the FTSUGs in the relevant Trusts will have been in post for at least 12 months. KFs will be published in March 2018, thus available for use in WP2 starting August 2018. Significant differences (as defined and reported within the survey) in KFs between 2015, 2016 and 2017 for each organisation will be collected and analysed.

Box 1: Examples of key finding (KF) from the NHS National Staff Survey
KF 6 Percentage of staff reporting good communication between senior management and staff; **KF 28** Percentage of staff witnessing potentially harmful errors, near misses or incidents in last month; **KF 24** Percentage of staff reporting most recent experience of physical violence in last 12 months; **KF 27** Percentage of staff reporting most recent experience of harassment, bullying or abuse in last 12 months; **KF 29**. Percentage of staff reporting errors, near misses or incidents witnessed in the last month; **KF 30**. Fairness and effectiveness of procedures for reporting errors, near misses and incidents; **KF 31.**

Publicly available sections of Care Quality Commission (CQC) inspection reports from 2016 onwards will also be collected. For example, the 'responsive', 'safe' and 'effective' sections of the inspection reports will be collected and analysed for evidence of how institutions deal with employee concerns. Importantly, the information from the staff survey and CQC inspection reports will be used to describe the contexts within which FTSUGs operate, rather than drawing direct causal relationships between the staff survey, inspection reports and the extent to which FTSUGs and a speaking up culture have been normalised. However, the total dataset collected in WP2 will be combined to provide a rich and thick description of similarities and differences in FTSUG role implementation, alongside institutional level descriptors of culture, context and speaking up activities by employees, enabling preliminary conclusions to be reached about FTSUGs work and how, when and how often staff concerns are raised.

WP2 Sampling
Telephone interview responses will mostly be obtained at the level of one FTSUG response per Acute Hospital Trust and Mental Health Trust. However, where multiple FTSUGs are in post in the same organisation we may interview additional FTSUGs within the organisation, for example those working at other sites. The NG's office has helpfully agreed to assist with our recruitment of 10 FTSUGs from the 10 regional networks (North East, East of England, South West, Yorks and Humber, East Midlands, London, North West, West Midlands, South East Coast and Thames Valley/Wessex), which are coordinated by 2 National Guardian Engagement Managers. The regional networks meet regularly as sources of support for FTSUGs, where "sharing and learning" best practice is encouraged and facilitated. Details of the study will be disseminated by researchers directly to FTSUGs via attendance at regional network meetings and via FTSUG dedicated email lists. In addition, 10 interviews will be undertaken with national stakeholders in the FTSUG process, e.g. designers of the system, those regulating and monitoring it, and those able to discuss how the implementation of FTSUG roles relates in design and implementation to other monitoring systems. The total sample size will therefore consist of 100 FTSUGs and 10 national stakeholders.

WP2 Data analysis –alongside data collection with months 10 and 11 exclusively for analysis
The telephone interviews will be audio-recorded for two reasons. Firstly, although answers to the structured questions will be noted as the interview progresses, having an audio-recording will be useful where there may be confusion or inaccuracy with answers. Secondly, audio-recording enables transcription of answers to the semi-structured, qualitative sections of the interview. Analysis of the structured questions will initially explore how answers are distributed. For example, descriptive statistics and bar charts will help visualise the 'shape' of the data by describing and summarising categorical variables such as gender and professional background of the FTSUGs. Additionally, continuous data will be explored using frequencies and histograms and described using means and standard deviations if normally distributed and medians and interquartile ranges if non-normally distributed. These steps will help identify interesting or anomalous features within the data and prove useful in then generating cross-tabulations and scattergrams of the relationships between these characteristics and other variables. Thematic analysis is a common technique used in the analysis of qualitative data generated via semi-structured interviews. Specifically, the analytic process will involve:

(i) Data management, using a spreadsheet to preserve respondents with their quantitative and qualitative responses.
(ii) In-depth familiarisation of the interview transcripts followed by thematic analysis, guided by NPT generative mechanisms (see table 1), to identify the range of respondents' views about the extent and their experiences of organisational commitment to the role and resources, barriers to and enablers of

role normalisation.

(iii) Methodological rigour will be ensured through standard procedures of reflexivity, reliability and validity. During analysis, regular meetings will be held within and between the teams in Cardiff and London. Initial coding and emergent themes will be developed within and then across teams, with a sample of transcripts being reviewed by all. Research assistants at each site will then undertake the initial analysis, overseen by a senior researcher who will review a further proportion of all transcripts to ensure consistency. Emerging and final themes will be regularly discussed and agreed across both teams to ensure reliability is maximised across the dataset. Any discrepancies or issues with analysis will be resolved by discussion within a team and if this is not possible, by the wider research team.

(iv) Analytical accounts will establish patterns of similarities and differences across the quantitative and qualitative datasets, with subsequent delineation of why such patterns may be occurring. For example, once data are grouped into qualitative themes, we will draw upon the quantitative findings to establish whether the qualitative theme (and its key dimensions) applies to only a particular group (such as organisations with more than one FTSUG, or an organisation with a part-time or seconded FTSUG) or whether it is a more general theme. Implications for fieldwork in WP3, e.g. the emergence of issues or problems that were not initially anticipated will be discussed, and our field methods modified accordingly.

WP3: Six organisational case studies – months 12-21: 3 months at each site, 1month cross-case consolidation – AJ lead Cardiff, JM lead Surrey & KCL with co-applicants DK, MA, RM, DA and RAsx2

Six in-depth qualitative case studies underpinned by NPT will examine the implementation and normalisation of the FTSUG role and speak up culture within organisations. Building on the findigns of WP1 and WP2, this phase of the study will address the following project aims, objectives and research questions:

Aim b) To generate evidence of the extent to which the FTSUG role has been 'normalized' in organisations.
Aim c) To gain insights into benefits and drawbacks of different FTSUG implementation models on staff's ability to speak up and act upon concerns.
Objective 2. IMPLEMENTATION & GOVERNANCE: Assess how the work of FTSUGs is organised and operationalised alongside other relevant local and national roles with responsibilities for managing concerns.
Objective 3. EFFECTIVENESS: Evaluate the comparative effectiveness of different types of FTSUG roles in supporting 'freedom to speak up'.
Objective 4. BARRIERS & FACILITATORS: Identify barriers, facilitators and unintended consequences associated with the implementation of FTSUG role.
Research question 1. How are FTSUGs being variously deployed, managed and held accountable for their work?
Research question 2. How is the work of FTSUGs defined and negotiated in relation to the work of others who also deal with employee concerns and patient safety at local and national levels?
Research question 3. Do different implementation models for the FTSUG role impact on the 'freedom to speak up', both in the ways that employees raise concerns and how these concerns are responded to?

Qualitative case studies can provide rich detailed data, and are particularly useful when trying to understand and compare the implementation of complex interventions in real life settings (such as workplaces) in which the process cannot be controlled. We see the introduction of FTSUG roles as a 'complex intervention' because the normalisation, or otherwise, of the role and the development of a speaking up culture within an organisation depends on the actions of individuals across a range of different contexts which are dynamic, and where competing demands exist within the system. A qualitative approach consisting of observations, documents and in-depth interviews is therefore required to capture and make sense of this complexity. We have designed the study to have extensive input from stakeholder groups at each of the participating organisations to ensure fieldwork proceeds smoothly and that findings and recommendations reflects stakeholder needs.

WP3 Settings/context and sampling

A total of 6 case studies will be identified from the analysis of the data collected in WP2. Taking into account that there are 152 Acute Trusts and 54 Mental Health Trusts, we will purposefully sample 4 Acute Trusts and 2 Mental Health Trusts for this phase of the study. The Project Advisory Group (PAG) will also be consulted about selection of sites to ensure information rich cases which best address the research aims and objectives. Potential perspectives to consider when selecting sites include:

- Organisational and logistical factors which may influence the implementation and normalisation of the FTSUG role: whether one or more FTSUG is in post; length of time FTSUG has been in post; whether the FTSUG is full-time or part-time and/or role is combined with another role (e.g. lead nurse or human resource manager); the numbers of staff employed; whether FTSUGs cover multiple sites.
- Data from the NHS staff survey will be reviwed e.g. key findings which demonstrate significantly worsening or improving indicators of staff speaking up. CQC inspection reports can similarly provide useful historical or contemporary insights into speaking up cultures within an organisation.

Purposive sampling will be used to identify key informants, documents and stakeholders who are involved in the oversight and delivery of the FTSUG role and any related speak up initiatives. Snowball sampling will be used to include a sample of those employees who have spoken up via the FTSUG. However, interviewing FTSUGs and those that have engaged with FTSUGs offers only a limited perspective about the FTSUG role, and the culture of speaking up. Therefore, we will also recruit, via snowball sampling, those who may have raised concerns through other channels (e.g. a Trade Union), but have not been in contact with the FTSUG, and/or those who may not have spoken up about concerns, thus providing a better understanding why some may not have yet engaged with the FTSUG role. The views of others involved in employee concerns will offer invaluable insights into coordination, cooperation and commitment to the FTSUG role, as well as other insights, such as whether the implementation of the FTSUG role has displaced, for better or worse, historically effective ways of informally or formally raising and responding to concerns.

WP3 Data collection:
Although the data collection phase is presented separately to data analysis for clarity of presentation, it will in practice be inter-twined with data analysis. The focus during the case studies is retrospective rather than longitudinal data collection, with the required data being concurrently collected at two sites at a time within the allotted time. The overall timeline of data collection is therefore sequential, rather than contemporaneous across sites. To provide detailed descriptions of attempts to normalize the FTSUG role and speaking up within their organisational contexts, their relationships with relevant internal and external actors, processes and artefacts will be captured via the following NPT informed data collection methods:

i) An initial period of non-participant observations will allow familiarisation at each site and help researchers build rapport with FTSUGs and other staff. Researchers will observe certain aspects of the FTSUG role e.g. delivering 'speaking up' training and advice to staff, reviewing concerns with colleagues and other FTSUGs within the organisation, attending meetings internally (e.g. patient safety meetings, Board meetings) and externally to the organization (such as the FTSUG regional network meetings). Descriptive free text field notes will be written by researchers as soon after observation periods as possible, with an intention in the early stages of the study to keep the scope of the notes wide on the basis that what previously seemed insignificant may come to take on new meaning in light of subsequent events.
ii) Qualitative interviews (up to 20 per case study) will be electronically recorded at each site with FTSUGs (maximum n=5); employees who have raised concerns (maximum n=5); key stakeholders and those responding to concerns (n=5), such as Director of Patient Safety, Chief Executive and Trade Union representatives. Other 'front-line' employees, who may or may not have spoken up, but who have not been in contact with the FTSUG will also be interviewed (n=5), to better understand those who are yet to engage with the FTSUG role.
iii) Documentary analysis of relevant organisational policies, internal communications, reports/investigations undertaken by FTSUGs and reports prepared for the Trust Board on concerns raised by staff and the organisation's cultures (as recommended by Francis, 2015).

Sensitivity to the demands of the FTSUG role and of the issues surrounding researchers' presence potentially influencing speaking up by employees will be central to our conduct throughout the study. For example, during observations periods the researcher will remove themselves from situations where the FTSUG may be approached in person with a concern, or where the FTSUG or any employee requests the researcher to withdraw (discussed further in ethics section). The main objective during observations will be for the researchers' presence to be unobtrusive and to not alter usual practises in any way.

WP3 Data analysis:
A qualitative data analysis package, NVivo11, will be used to organize and store data ready for analysis. Thematic analysis of qualitative data sources underpinned by methodological rigour will be undertaken, as outlined in WP2. Participants' views will be considered against the range of observational and documentary data collected. NPT will inform each step of the analysis with emerging themes being mapped onto the four

generative mechanisms (capability, capacity, potential and contribution), providing rich understanding of the operational context and implementation of the FTSUG role. Analysis of each case study will be individually undertaken before cross-case triangulation occurs (Yin 2009), where case studies will be aggregated thematically and cross-case similarities and differences drawn out.

WP4: Integration and final analysis of findings, report writing and dissemination events - months 22-27 AJ with co-applicants by JM, DK, MA, RM, DA and RAs x2

It has already been noted that key topics and issues emerging from the data will be analysed with reference to the original NPT informed study objectives. To integrate findings across cases a series of NPT thematic charts will be developed for each case study. Detailed exploration of the charted themes will be undertaken, in order to map and understand the range of views and experiences across each site. Several areas of established research into raising concerns and theory will be invoked as analytic lenses to inform the study data analysis and development of the evaluative framework. We know this literature well and have ourselves contributed substantially. In addition to social sciences research, patient safety, health services management research perspectives and perspectives from PPI team members will contribute to the interpretation of qualitative findings. The analysis will not only feed into the final report, but also (consistent with our view that health services research is only as good as its translation into organisational action) outputs aimed at managers and clinicians in healthcare organisations, as detailed below.

Dissemination and projected outputs

Outputs will focus on service organisation and training. Development will be in close collaboration with the PAG, participating NHS Trusts and national bodies to ensure utility and transferability of materials in different organisational contexts. PPI members will also contribute directly to dissemination; this additional work has been costed adequately. NIHR's principles of good dissemination state that researcher should consider:

Stakeholder engagement

The primary stakeholder audience for this research is the community of FTSUGs and the National Guardian's Office. It is important to engage early with the primary audience, which we have achieved by establishing contact with the National Guardian's Office, a small number of FTSUGs and NHS Improvement. We will also engage with this audience throughout the course of the study, being able to share interim findings at the completion of each work package. Secondary audiences include all NHS employees, including senior hospital managers, trades unions and Board members who are clearly identified in the Francis Review as having a key role to play in helping to normalise a speaking up culture. In addition, we will establish an international profile for our work, drawing on the international work of Public Concern at Work (PAG members) as well as building on our existing contacts with healthcare and other industries globally who have an interest in speak up initiatives. Whether NHS employees feel free to speak up is of obvious relevant and importance to NHS patients and the public, who we will engage with through national groups such Action Against Medical Accidents (PAG members) and local PI groups Finally, we will build on our existing engagement with the community of academic in the UK and internationally who have an ongoing interest in teaching and researching speaking up by healthcare employees.

Format

A range of tailored outputs will be disseminated to decision makers, patients, researchers, clinicians, and the public at national, regional, and/or local levels as appropriate, including:

- Workshops at the end of the study to deliver findings and recommendations and during the study to allow NHS practitioners to input to the research, gain immediate feedback and support further dissemination.
- Briefing documents and guidance for managers, commissioners and policy makers on findings and implications for future implementation and sustainability of the FTSUG role. Interim briefing documents to be prepared at the completion of each WP.
- Training for FTSUGs and other employees on how to facilitate speaking up which builds on training currently being delivered by Public Concern at Work (PAG members) and Health Education England, using latest video lecture capture technology such as Panopto.
- Masterclasses (via video and online factsheets) for all NHS employees about organisational and interactional techniques for speaking up. Also integrated into undergraduate healthcare curricula and disseminated via Royal Colleges, Trades Unions and professional bodies.
- Accessible public information and ongoing lay summaries about the progress and findings of the research

and the FTSUG role via a bi-monthly blog/vlog and a dedicated Twitter account.
- Peer reviewed academic journal articles (e.g. BMJ Quality and Safety; Implementation Science) and Health Services professional Journals (HSJ etc.)
- Presentations at NHS conferences attended by managers e.g. NHS Confederation Conference and key academic national and international conferences
- The Final report

Understanding the service context and timing
To ensure that our research reaches public and professionals in healthcare we will fully utilise the networks and network events of Project Advisory Group members, such as Public Concern at Work, the Royal Colleges and Action Against Medical Accidents. In addition, we will build on our ongoing working partnership with the National Guardian's Office and the FTSUGs Regional Network to ensure direct and timely dissemination of interim and final findings to NHS employees and policy makers. Members of the team will continue to participate in the International Whistleblowing Research Network **-** with a global membership of over 200 people – where study details and findings will be disseminated as the study progresses.

Plan of investigation and timetable
This section provides a concise summary of the project plan of investigation and a quarterly project timetable showing the scheduling of all key stages in the project, their expected durations, and the timing of key milestones throughout the project including the production of outputs.

- **WP1 (months 1-5):** a systematic narrative synthesis of international literature of 'Speak Up' strategies undertaken in healthcare and other sectors.
- **WP2 (months 6-11):** a telephone survey of purposively sampled FTSUGs working in Acute Hospital Trusts and Mental Health Trusts (n=100) which will provide an understanding of how FTSUGs are selected/recruited, deployed and organised and the numbers and types of concerns raised. National stakeholders in the FTSUG process will also be interviewed (n=10), e.g. designers of the system, those regulating and monitoring it, and those able to discuss how FTSUG roles relate in design and implementation to other monitoring systems.
- **WP3 (months 12-21):** based on the findings of the survey, six case study sites (4 Acute Trusts & 2 Mental Health Trusts) will provide an in-depth examination of how FTSUG roles are variously implemented and normalized alongside other local and national roles and initiatives related to developing open reporting cultures in the NHS.
- **WP4 (months 22-27):** integration and final analysis of findings and report writing.
- **Outputs and dissemination events:** publications, workshops, awareness raising and briefings are scheduled throughout the duration of the project

	Quarterly timeline								
Project Stages & Milestones	**1-3**	**4-6**	**7-9**	**10-12**	**13-15**	**16-18**	**19-21**	**22-24**	**25-27**
WP1 Months 1-5 (5 months) Narrative review and synthesis	x	x							
Research ethics and R&D approvals	x	x		x (R&D)	x (R&D)	x (R&D)			
Develop & pilot telephone survey	x	x							
WP2 Months 6-11 (6 months) Telephone survey; sampling and additional R&D approvals for case studies		x	x	x					
WP3 Months 12-21 (10 months) Undertake 6 case studies & consolidation of cases				x	x	x	x		
WP4 Months 22-27 (6 months) Integration of findings, complete analysis								x	x
Project Advisory Group meetings		x		x		x		x	
Outputs: Workshops, publications & other dissemination material/events, blog		x		x	x	x	x	x	x
Outputs: Develop training materials drafting of final report								x	x
Outputs: Progress reports to NIHR				x		x		x	

Table 2 Project timetable

Patient and Public Involvement (PPI)

A group of four PPI members participated in two group discussions of the outline and full application during which they offered constructive direction in the research focus and design of the project and have confirmed the viability and appropriateness of the study. Two of the group will continue contributing directly to the study via the PAG and other research activities listed below. From past experiences, the following are examples of how we anticipate their continued involvement will benefit our research and outputs:

- Ensuring our research processes are in tune with the needs of patients and carers Helping us not lose sight of why the research is important and how the research might positively influence practises from a PPI perspective.
- Contributing to preparation for data collection and data analysis activities, such as reviewing emerging findings and development of later findings through regular discussions with the research team.
- Informing the refinement and accessibility of dissemination materials and participate in workshops and other dissemination events and activities such as authoring blog/vlog content and providing a PPI perspective to training materials for NHS employees, Board members etc.
- Playing a significant role in setting future research priorities.

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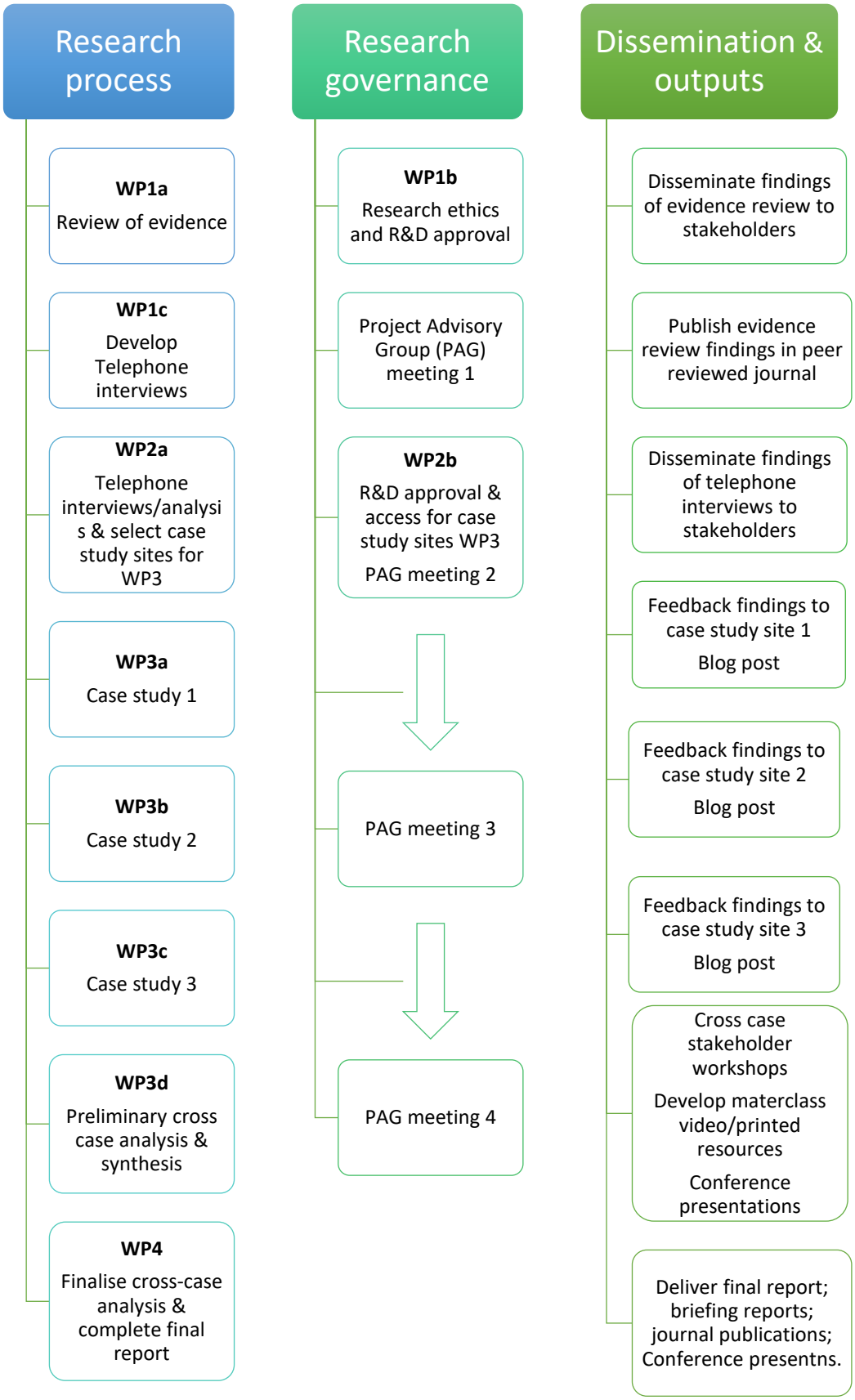
Research process
WP1a
Review of evidence
WP1c
Develop Telephone interviews
WP2a
Telephone interviews/analysis & select case study sites for WP3
WP3a
Case study 1
WP3b
Case study 2
WP3c
Case study 3
WP3d
Preliminary cross case analysis & synthesis
WP4
Finalise cross-case analysis & complete final report
Research governance
WP1b
Research ethics and R&D approval
Project Advisory Group (PAG) meeting 1
WP2b
R&D approval & access for case study sites WP3
PAG meeting 2
PAG meeting 3
PAG meeting 4
Dissemination & outputs
Disseminate findings of evidence review to stakeholders
Publish evidence review findings in peer reviewed journal
Disseminate findings of telephone interviews to stakeholders
Feedback findings to case study site 1
Blog post
Feedback findings to case study site 2
Blog post
Feedback findings to case study site 3
Blog post
Cross case stakeholder workshops
Develop materclass video/printed resources
Conference presentations
Deliver final report; briefing reports; journal publications; Conference presentns.