

# Evaluation of the 'Freedom to Speak Up Local Guardians' in NHS England Acute and Mental Health Trusts

<b>Submission date</b> 28/08/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/09/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/10/2022	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Employees who "speak-up" or "raise concerns" about problems with healthcare services are often referred to as "whistleblowers". Although "speaking up" makes an important contribution to patient safety in the NHS, whistleblowers have not always been treated well. For example, the Francis Report in 2013 into serious patient care failures at Stafford Hospital identified that whistleblowers were often ignored and mistreated by colleagues. The related Freedom to Speak Up review by Francis in 2015 recommended that raising concerns should become a normal part of the job for anyone working in the NHS. The aim of this study is to better understand the introduction of a new role in NHS England 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 "FTSUG"). The introduction of the new FTSUG role is described as potentially making a huge contribution to improving the way "Speak Up" cases are handled. However, there are some important differences in how the FTSUG role is being introduced by organisations across England. More information is needed to fully understand differences in FTSUG roles and what these differences mean for staff raising concerns and how concerns, when raised, are acted upon. The researchers are interested in finding out how FTSUG roles are being introduced in Acute Trusts and Mental Health Trusts and whether FTSUGs are helping staff to "speak up" about their concerns.

### Who can participate?

Current FTSUGs, employees who have spoken up via FTSUGs, who have raised concerns through other channels (e.g. a Trade Union) but have not been in contact with FTSUGs, or who may not have spoken up about concerns, and stakeholders who are involved in the oversight and delivery of the FTSUG role and any related speak up initiatives

### What does the study involve?

Telephone interviews are carried out with FTSUGs in Acute Hospital and Mental Health Trusts to provide a better understanding of the FTSUG role and what they do within their organisations. Information is also gathered about the number and types of concerns that FTSUGs have dealt with, to show similarities and differences in FTSUG roles and how these influence FTSUGs' work

and how, when and how often staff concerns are raised. The survey results are used to identify case study sites in four Acute Trusts and two Mental Health Trusts. The researchers interview FTSUGs, those working with FTSUGs and employees who have raised concerns and others who have not, and analyse documents (e.g. FTSUG role descriptions, minutes of meetings) and observe the FTSUG working in practice e.g. observe training delivered and meetings attended by the FTSUG.

What are the possible benefits and risks of participating?

Participants will contribute to a better understanding of a new and innovative intervention to enhance patient safety and staff wellbeing. There are no risks of participating.

Where is the study run from?

Cardiff University (UK)

When is the study starting and how long is it expected to run for?

May 2018 to August 2020

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Aled Jones

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**Study website**

<http://speakupsafely.org.uk/>

## Contact information

**Type(s)**

Public

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

v1

## Study information

### Scientific Title

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

### Acronym

FTSUGproject

### Study objectives

The aim of this study is to better understand the introduction of a new role in NHS England 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 "FTSUG"). The trialists are interested in finding out how FTSUG roles are being introduced in Acute Trusts and Mental Health Trusts and whether FTSUGs are helping staff to "speak up" about their concerns.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

School of Healthcare Sciences Research Ethics Committee, Cardiff University, 14/08/2018

### Study design

Mixed methods multicentre case study over 27 months

### Primary study design

Observational

### Secondary study design

Mixed methods multicentre case study

### Study setting(s)

Hospital

### Study type(s)

Other

### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

## **Health condition(s) or problem(s) studied**

Patient safety and employee 'speaking-up'

## **Interventions**

The research study is planned over 27 months in 3 discrete but related work packages:

Work Package (WP) 1: A review of literature that investigates different approaches used to encourage staff to speak up in healthcare and other sectors. This will help us develop our survey questions for WP 2. We will also speak to staff in FTSUG roles to help us develop survey questions and gain NHS research ethics/governance approvals at this time.

WP 2: Telephone interviews with FTSUGs in Acute Hospital and Mental Health Trusts will provide a better understanding of the FTSUG role and what they do within their organisations. We will also gather information about the number and types of concerns that FTSUGs have dealt with. Survey results will show similarities and differences in FTSUG roles and how these influence FTSUG's work and how, when and how often staff concerns are raised.

WP 3: Survey results from WP 2 will help identify case study sites in 4 Acute Trusts and 2 Mental Health Trusts. In these case studies we will interview FTSUGs, those working with FTSUGs and employees who have raised concerns and others who have not. We will also analyse documents (e.g. FTSUG role descriptions, minutes of meetings) and observe the FTSUG working in practice e.g. observe training delivered and meetings attended by the FTSUG. At the end of WP 3 we will better understand whether and how different ways of rolling out the FTSUG role affects staff speaking up.

A respected framework called Normalisation Process Theory (NPT) used by health researchers to collect and analyse data will assist the team to better understand this unique new role in practice. We will analyse the six case study sites separately, before analysing findings across all cases. A project report will then be produced in WP 4, describing differences in the FTSUG role across England and whether these differences have affected staff speaking up. We will also develop training materials and a 'speak up' guide for managers, clinicians, patients and others.

## **Intervention Type**

Other

## **Primary outcome measure**

Phase 2 (Oct 2018 -May 2019) – interviews with guardians and national policy leaders (n=110) including respondent demographics, organisation size and CQC rating, examples of barriers /enablers to operationalizing the role and effective response to concerns, numbers, types and severity of concerns raised since FTSUG post created.

Phase 3 (April 2019-December 2019) – interviews in 6 case study sites with various NHS staff (n=120), observations of practice, documentary analysis e.g. 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. Documentary analysis of relevant organisational policies, internal communications, reports /investigations undertaken by LGs and reports prepared for the Trust Board on concerns raised by staff and the organisation's cultures.

## **Secondary outcome measures**

There are no secondary outcome measures

**Overall study start date**

01/05/2018

**Completion date**

31/08/2020

## Eligibility

**Key inclusion criteria**

In phase 2 (telephone interviews) of the study the participants have to be a current Freedom to Speak Up Guardian (FTSUG). In phase 3 (case studies) 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 LG role, and the culture of speaking up. Therefore, the trialists 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.

**Participant type(s)**

Health professional

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100 for phase 2

**Total final enrolment**

87

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/10/2018

**Date of final enrolment**

31/01/2020

## Locations

**Countries of recruitment**

United Kingdom

Wales

**Study participating centre**

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## **Sponsor information**

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**ROR**

<https://ror.org/03kk7td41>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

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:

1. 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
2. Briefing documents and guidance for managers, commissioners and policy makers on findings and implications for future implementation and sustainability of the LG role. Interim briefing documents to be prepared at the completion of each WP
3. Training for LGs 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
4. 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
5. Accessible public information and ongoing lay summaries about the progress and findings of the research and the LG role via a bi-monthly blog/vlog and a dedicated Twitter account
6. Peer reviewed academic journal articles (e.g. BMJ Quality and Safety; Implementation Science) and Health Services professional Journals (HSJ etc)
7. Presentations at NHS conferences attended by managers e.g. NHS Confederation Conference and key academic national and international conferences
8. The final report

**Intention to publish date**

01/10/2020

**Individual participant data (IPD) sharing plan**

Due to the nature of the study some of the data, even when anonymised, may contain highly sensitive information about whistleblowing and patient safety in the NHS. As a result the dataset will not be made immediately available.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/08/2022	28/10/2022	Yes	No