FULL/LONG TITLE OF THE STUDY

Understanding how frontline staff use patient experience data for service improvement - an exploratory case study evaluation

SHORT TITLE

US-PEx: Understanding how frontline staff use patient experience data

PROTOCOL VERSION NUMBER AND DATE

V1 09.02.16

RESEARCH REFERENCE NUMBERS

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The authors declare there are no potential conflicts of interest.

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

Chief Investigator:

Date: 09.02.16

Signature:

.....

Name: (please print):

Louise Locock

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STUDY SUMMARY

Study Title	Understanding how frontline staff use patient experience data for service improvement - an exploratory case study evaluation
Short title	US-PEx: Understanding how frontline staff use patient experience data
Study Design	Case study evaluation of a quality improvement project, using a baseline and follow-up survey and interviews, and a focused ethnography (including observations, interviews and documentary analysis)
Study Participants	Case studies will be conducted in 6 medical wards in NHS acute Trusts. Baseline and follow-up survey and interviews: all patients discharged from the 6 wards over a 3-month period before and then after the intervention period will be surveyed and a subset will be interviewed Ethnography: frontline staff from various disciplines, and patients and family members involved in the quality improvement project from the 6 wards, will be interviewed and observed. Senior managers in the Trust will also be interviewed.
Planned Size of Sample (if applicable)	Baseline and follow-up survey and interviews: approximately 240 patients per ward expected to be surveyed, of whom up to 8 will be interviewed (total 2880 surveys and 96 interviews) Ethnography: up to 25 interviews in each site (total 150)
Follow up duration (if applicable)	None
Planned Study Period	1st April 2016 to 31st January 2018
Research Question/Aim(s)	Our overarching research question is to understand how frontline staff use different types of patient experience data for quality improvement; what motivates them to get involved in improvement; what helps or hinders; and what can be done to make patient experience data more convincing, credible and practically useful. Aims: To explore and analyse how NHS frontline teams use different types of patient experience data for improvement. To develop a practical toolkit for the NHS on strategies for making patient experience data more convincing, credible and useful for frontline teams and Trusts.

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ROLE OF STUDY SPONSOR

The Sponsor will assume legal responsibility for initiation and management of the study, and provide insurance cover for the study.

PROTOCOL CONTRIBUTORS

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KEY WORDS: Patient experience, ethnography, case study evaluation, NHS staff, quality improvement

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ABBREVIATIONS

CQC	Care Quality Commission
DBS	Demographics Batch Service
GCP	Good Clinical Practice
GMC	General Medical Council
HS&DR	Health Services and Delivery Research
HRA	Health Research Authority
HSRU	Health Services Research Unit
ICU	Intensive Care Unit
NHS	National Health Service
NIHR	National Institute for Health Research
PPI	Patient and Public Involvement
RAMESES II	Realist And Meta-narrative Evidence Syntheses: Evolving Standards
RDS	Research Design Service
REC	Research Ethics Committee

STUDY FLOWCHART

Timetable 14/156/06	**Jun-Nov 2015**	**Nov 2015**	**D**	**Jan 2016**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**Jan 2017**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J 2018**
Phase 1 Survey work MS-IDREC-C1-2015-203																												
Phase 2																												
Ethics and local R&D approval																												
Identification of case study sites																												
Baseline survey of medical ward patients																												
Learning community initial meeting and selection of local interventions																												
Frontline teams work on using patient experience data																												
Ethnographic observations of case study sites																												
Further learning community meetings – mid and post-intervention																												
Repeat survey of medical ward patients																												

Analysis of case study findings																												
Phase 3 Toolkit and dissemination **No ethics required**																												

STUDY PROTOCOL

Use and usefulness of patient experience data: national survey of patient experience leads in NHS acute Trusts

1 BACKGROUND AND RATIONALE

Patient experience - alongside patient safety and clinical effectiveness - is a key component of quality of care. Improving patient experience is thus a priority for the NHS, which has led the way in developing measures of patient experience such as the NHS Inpatient Survey. Patients have a right to expect care that is compassionate, respectful and convenient, as well as safe and effective. Collecting data about patient experience, while important, is not enough: the data need to be used for improvement, and it is arguably unethical to ask patients to comment on their experience if these comments are not acted on (1).

Recent evidence suggests positive associations between patient experience, patient safety and clinical effectiveness for a wide range of disease areas, and between patient experience and self-reported and objectively measured health outcomes (2,3). At a time of global recession, there is a risk that better quality patient experience may be seen as a luxury rather than a top priority. But the apparent conflict between maintaining tight financial control and providing good patient experience may not be as stark as is sometimes supposed.

Firstly, we know that many of the things which matter most to patients are relational, for example paying attention to dignity, courtesy and kindness. These are rarely resource-intensive. Secondly, there is growing evidence linking person-centred care with decreased mortality and lower hospital-acquired infection rates, as well as a range of other organizational goals such as reduced malpractice claims, lower operating costs, increased market share and better staff retention and morale. Hospital organisations where care is person-centred are reported to have shorter lengths of stay and fewer medication errors and adverse events (4-11).

Yet despite these good reasons for paying close attention to experience data, the quality of patient experience remains a concern, and recent problems (for example at Mid Staffordshire NHS Trust and Winterbourne View) have suggested there is a long way to go in developing care which is genuinely and consistently person-centred at all levels of the organisation.

Whilst the NHS Inpatient Survey shows small incremental improvements in some aspects of experience, including information provision, communication with staff, hospital cleanliness, and privacy (12), the pace of change remains slow on some of the most important questions for person-centred care (12-13). Only 54% of patients feel 'definitely' as involved as they want to be in decisions about their care, and only 50% feel doctors and nurses 'definitely' gave their families all the information they needed (12). Furthermore, 79% of patients said they had not been asked during their stay in hospital to comment on the quality of their care. Although this was an improvement on the 86% saying they had not been asked in 2012, it nonetheless indicates a substantial missed opportunity to learn from patients.

Dr Foster Intelligent Board research into how Trust boards use patient experience data found substantial variation in what data were collected but more importantly in the degree to which they were effectively analysed and used to improve services (14). Strikingly, the research found that over 95% of the time, hospital boards' minuted response to patient experience reports was to note the report but take no further action. Examples where patient experience data was used to spark debate and action were rare, as were examples of non-executive directors challenging performance on patient experience measures. Understanding how to use qualitative evidence, including narrative and observational data, as well as numerical evidence can be

challenging (14-16), and this is undoubtedly one of the key areas where Trusts need support and training. Meanwhile, they also face an explosion of online sources of patient experience data and social media (e.g. NHS Choices, Care Connect, Patient Opinion and Twitter) with little guidance on how to use them.

There is already good evidence of what matters most to many patients and how they experience services (17); the gap is how Trusts can respond to available local and national data and use them to improve care (1; 13-14; 17-19). There is a lack of evidence about how organisations can move beyond collecting patient experience data to using it for improvement, and how best to use different types of quantitative and qualitative data. We know remarkably little about how frontline staff make sense of or contest patient experience data, what supports or hinders them in making person-centred improvements and what motivates staff - and patients and families - to get involved in improvement work.

While quality improvement programmes and techniques abound, few are strongly evidence-based and few take seriously the need to involve patients and families throughout the process. A few studies have provided some evidence of promising approaches. For example, Reeves, West and Barron (20) showed that facilitated feedback of survey findings at ward team level has potential to improve patient experience scores. Locock et al. (21) recently reported positive findings on the use of nationally collected narrative data alongside local observational data in experience-based co-design to generate improvements. However, there remains insufficient evidence to say which types of data or quality improvement approaches are more or less likely to be useful with frontline teams in making care more person-centred in different contexts and settings, and how well these are received.

Some studies have identified a mismatch between managerial expectations and how engaged and supported clinicians and other frontline team members feel to make improvements. For example in a survey of hospital clinicians Rozenblum et al (22) found that 90.4% of clinicians believed improving patient satisfaction with their experience of hospitalisation was achievable, but only 9.2% thought their department had a structured plan to do so. Friedberg at al. (23) found physicians' use of patient experience reports was variable, and importantly that little training in communication skills was provided, even though improving communication with patients was thought to be fundamental to the provision of person-centred care. These findings suggest that not enough is being done to make patient experience data available in a useful and credible way to clinical staff, and empower them – with positive organisational support – to see improving patient experience as a priority that they can lead on.

The 'theory of change' underlying this study is that high level organisational support is necessary but not sufficient for person-centred service improvement; that many experiences which matter most to patients happen in frontline encounters; and that bottom-up engagement in person-centred improvement (as opposed to top-down managerially driven initiatives) can be motivating for frontline staff (21), consistent with evidence that patient experience seems to be better in wards with motivated staff (10).

This study will use a formative and exploratory case study approach, drawing on realist evaluation principles and methods, to understand how frontline staff can be supported and encouraged to work with patient experience evidence, and subsequently to develop a practical toolkit for the NHS. It builds on a body of internationally recognised patient experience work to which members of this research team have made a major contribution.

It should of course be noted that the *process* of gathering and analysing data on patient experiences at local level can itself be part of building momentum for their use in improvement; in reality collecting narratives and using them for improvement are closely linked as part of the same process of cultural change in approaches

such as experience-based co-design (24). Frontline teams involved in this study will be invited to engage in local data collection, and comparisons between cases looking at how this is approached and what influence it has will form part of our ethnographic observations. However, given the nature of the research call, our focus is primarily on using rather than collecting experience evidence.

2 RESEARCH QUESTION, AIMS AND OBJECTIVES

Our overarching research question is to understand how frontline staff use different types of patient experience data for quality improvement; what motivates them to get involved in improvement; what helps or hinders; and what can be done to make patient experience data more convincing, credible and practically useful.

Aims:

To explore and analyse how NHS frontline teams use different types of patient experience data for improvement.

To develop a practical toolkit for the NHS on strategies for making patient experience data more convincing, credible and useful for frontline teams and Trusts.

Objectives:

To meet our first aim, we will observe organisational responses to using patient experience data for service improvement in six medical wards case studies. This includes the following steps:Conduct a baseline survey of patients from the six wards, using questions drawn from existing surveys, followed by 8 in-depth interviews per ward.

b. Create a learning community for the six ward teams, including patients and family members. Approaches to learning from and improving patient experience will be presented with facilitated discussion of issues involved. Teams will develop and implement their own interventions and measures
c. Observe what happens in each site using focused ethnographic methods; how staff make sense of (or contest) different types of data; what supports/hinders them in making person-centred improvements; what changes are successfully implemented. Ongoing support will be provided to teams through a 'virtual campus' led by the research team with further feedback and discussion; two further face-to-face meetings; support from an improvement science adviser; and improvement support from NHS England, building on previous experience and learning from the Cancer Patient Experience programme. Emerging findings will be shared formatively with teams to help them identify problems and maximise their chances of effective person-centred service improvement.
d. Repeat local survey of medical ward patients' experiences and interviews, and compare with baseline and with national Trust-level survey findings.

To meet our second aim we will:

a. Produce toolkit for NHS with a range of strategies for using patient experience data, summarising best evidence, likely organisational and cultural conditions for successful implementation, and how to involve patients and families in the process.
b. Disseminate both online and through national seminars co-organised with NHS England; social media; conference presentations; academic publications

3 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

We will conduct ethnographic case study evaluation in six sites. Using a combination of re-analysis of existing survey data and a new survey of NHS Trust patient experience leads currently being conducted, we will group Trusts according to their performance on patient experience, and select three sites performing at a high level and three with a more mixed performance. In each site, a frontline medical ward team will be identified to join the study. We will support them with evidence and practice examples to design their own quality improvement intervention using patient experience data (which may be quantitative, qualitative or both) and we will observe the results.

3.1 Baseline survey of medical patients' experiences

Case studies will begin with a baseline postal experience survey of medical patients discharged from each ward over three months. The questionnaire will focus on experience of four areas of care:

- Referral to service and accessing care, such as route of admission to the hospital and information received on or prior to admission

- Inpatient care, particularly focusing on relational aspects of care, including involvement in decisions and interactions with ward staff

- Discharge, such as information provision, discharge planning and danger signals to watch out for at home

- Support for self-management, such as support and information received for managing health day-to-day

A database of questions has been compiled mapped against the four areas of care. The questions are drawn from extensively tested, reputable sources such as the NHS Adult Inpatient Survey, Oxford Patient Involvement and Experience scale (OxPIE), previously developed questions about self-management and demographic indicators.

The survey will be administered using a postal methodology. Fieldwork will last for 12 weeks with two reminder mailings being sent to non-responders during this period. We propose to survey a census of all discharged patients from each of the six medical wards in a given three month period, with an anticipated sample size of 240 patients per ward. (See also 'sample and recruitment' below).

The pre-and post-intervention surveys should be viewed as part of the overall package of information collected rather than the only source of evidence. The survey will be used alongside the in-depth interviews (see below)

and the ethnographic work to provide an understanding of the changes that have been made within different sites and to gauge the impact of these.

The survey will be accompanied by in-depth interviews with patients and family or carers to gather more detailed information on their experiences. Up to forty-eight interviews will be conducted, with the aim being to carry out eight interviews per ward. Interview participants will be recruited via the patient experience survey. A question will be included in the survey allowing participants to indicate if they would be happy to be contacted to take part in a follow up interview. This method of recruitment is associated with a degree of bias, as survey non-respondents will be excluded from the subsequent interviews. However, this is acceptable because the findings from these interviews are not intended to be representative of the overall patient population; they are to provide further descriptive information helping form a rich overall quantitative and qualitative dataset.

Participants will be offered a choice of telephone or face-to-face interviews, which will be recorded, transcribed, and analysed using NVivo coding software. Thematic framework analysis will be used to identify, analyse and report themes and patterns within the responses from each ward.

Reports showing survey and interview data for each case study site, will be generated. They will detail:

- Response rate information
- The demographic profile of respondents
- Results for each question in the survey. Caveats about interpretation of the data and the limits of significance testing will also be noted.
- Results from the in-depth interviews

The Picker Institute will lead on this aspect of the research with input from the Nuffield Department of Public Health, University of Oxford, and will ensure the survey captures key domains of patient experience and adheres to best practice in survey research.

3.2. Establishing and supporting a learning community and developing frontline interventions

The six frontline teams will join a facilitated learning community to share and discuss findings from the baseline data. The initial meeting will be a two-day event in Oxford. Learning sessions will include presentations on different approaches to learning from and improving patients' experience; different features, uses, strengths and limitations of both quantitative and qualitative data; how to include experiences of 'seldom heard' groups; the evidence base for various quality improvement approaches. Teams will be offered improvement science support through NHS England.

Teams will then develop and implement their own interventions and measures and select priorities for improvement. Although we will not want to constrain ward teams' choice of focus, we will encourage them to consider, for example, the experience of frail elderly people and/or people with dementia. Given the topical importance of this we anticipate it might well be an attractive choice for one or more wards. This would allow for interesting experimentation with collecting and using carer/visitor experience data, and using techniques such as staff- or user-led observation, shadowing and 'in your shoes' exercises. Regardless of whether any of the sites choose to focus specifically on the experiences of a particular 'seldom-heard group', we see this as an important

issue for all of the participating wards. If services are to provide a good experience to all of their users, they must be mindful of issues of diversity and ensure that care and information are tailored, where possible, to meet the needs of different patients and groups. To that end, we envisage encouraging staff to give consideration to issues related to diversity when planning interventions, and to identify areas where these may need adaptation or tailoring to be of greatest benefit to different groups.

Senior Trust managers will be expected to sign up to ensuring internally that frontline staff are given time and support for taking part in the project, as part of the Trusts' general commitment to improving patient experience. It is important not to set a precedent that successful person-centred improvement can only be undertaken with external research funding. All Trusts should be working on this topic and devoting staff resources and expertise to improving quality. However, our research costs include funding for the additional time required for the frontline teams to be involved in the learning community meetings and other additional tasks specifically related to the research, such as being interviewed by the ethnographers.

The exact size and composition of teams will be determined by each site, but we anticipate up to 5 people from both clinical and non-clinical backgrounds, including, for example, ward administration and support staff, and a patient or family member. We will encourage ward teams to think creatively about whom they might involve, whilst recognising that attendance at the learning community events will necessarily be limited to a sub-set of the wider group of people who will get involved in the project at local level, for example ward clerks, healthcare assistants and cleaning staff.

One advantage of whole team attendance is that it fosters continuity and capacity-building regardless of staff turnover (compared to a model where a single facilitator is trained). Teams will be strongly encouraged to include patient and family members in the group attending the learning community meetings. There will also be independent patient advisers present with the research team led by co-applicant Bostock (see also Patient and Public Involvement below).

During the fieldwork phase the teams will have access to a 'virtual campus' facilitated by the improvement science adviser where they can exchange ideas and experiences, a monthly webinar with the research team and ongoing informal support from the improvement adviser. In addition, NHS England has developed an improvement support package for Trusts working to improve care as part of the Cancer Patient Experience programme. NHS England has agreed to extend this package to wards participating in this study.

Two further face-to-face learning community meetings will be organised. The first of these will provide an opportunity for formative feedback of interim findings from the case study ethnographic work, and for reflection on successes and problems so far. Each team will plan its next steps with support from the research team and the improvement adviser, and with input and shared learning from the other teams. The third and final meeting will be a time to report on final outcomes, reflect on learning and help the research team shape the form and content of the guidance to be disseminated across the NHS.

3.3 Ethnographic case study fieldwork and analysis incorporating realist evaluation

Organisational ethnographers will use longitudinal observations, interviews and documentary analysis to assess what happens in each site and record service changes made, with input from the frontline teams.

The case studies will be formative and exploratory; this means that findings will be fed back to the teams on an ongoing basis to help them develop and adapt their approach, and reflect on what has worked well or less well

and why. A 'focused ethnography' approach will underpin the case studies. Focused ethnographies share many characteristics with classic ethnographies i.e. they are exploratory rather than hypothesis-testing; elicit unstructured data in the form of field notes and transcripts; involve a small sample, collect rich data and result in narrative description. Unlike classic ethnography, rather than embedding a sole researcher in a setting for a lengthy continuous period, more targeted observation periods are used.

There will be two main formal interviewing periods at the start and end of the quality improvement work, with a smaller number of interviews with key team leads at the midway point. The exact number of interviews to be conducted will depend to some extent on the composition of the frontline teams (including patients and family members) from each site, but we estimate a maximum of 10 at the beginning and end of the intervention, with 2-3 key improvement leaders on each ward at the mid-point, and 2-3 senior managers at the end of the fieldwork period, totalling approximately 25 in each site. In addition they will observe all the learning community meetings and webinars, and conduct observations for approximately 10 days in each site. The observation periods will include opportunities to record further informal conversations with members of the teams, as well as observing quality improvement meetings and workshops, general staff meetings, and reviewing meeting notes and improvement plans. Formal interviews will be recorded and transcribed verbatim; detailed observational fieldwork notes will be written by the ethnographers. Ward team members will be invited to keep a diary of their experiences and reflections and contribute this to the documentary analysis if they wish.

With the help of the frontline teams, the ethnographers will complete a 'service improvement log', recording planned and implemented changes as a result of the project, and categorising them as small-scale change; process redesign within team; process redesign between services; and process redesign between organisations (the categorisation used previously in HS&DR study 10/1009/14 on accelerated experience-based co-design).

The separation of patient experience evidence from the process of collecting and analysing it at local level is somewhat artificial, as collecting such data can itself be part of building momentum for their use in improvement and generating momentum for cultural change. Frontline teams involved in this study will be invited to engage in local data collection as well as using existing sources such as survey data or patient comments; comparisons between cases looking at how this is approached and what influence it has will form part of our ethnographic observations. However, our focus is primarily on the stage of using rather than collecting experience evidence.

Our analysis of the case studies will draw on realist evaluation methods (25). The aim is to 'make sense' of different patterns of actions and outcomes, understanding why, for whom and in what circumstances particular approaches work or not, rather than developing a predictive model. Realist evaluation produces generalisable findings, but does so by disaggregating interventions into component middle-range theories which we can then reasonably apply in other settings. In practice Trusts are likely to use a mix of complementary data sources and approaches; the toolkit will therefore include advice on how these may be used effectively in different circumstances and for different audiences.

When introducing change in complex systems, there are ideally two 'evaluations'. One is an internally-facing evaluation, usually done by the staff in the organisation, that asks 'how is this project going here?' This typically uses techniques like plan-do-study-act, and the data sources are chosen accordingly. Another kind of evaluation, which may draw on some of the same data, analysed differently and supplemented by other data, asks 'what general conclusions can we draw about the interaction between context, mechanism and outcome?' We will encourage and support staff in the first task and draw on realist methods to achieve the second, using

both the results of the teams' own evaluation and the service improvement logs, and the ethnographic material collected. The analytic process will be supported by NVivo coding software. Coding will be both deductive and inductive, with codes derived both from organisational change theory and existing empirical literature, and from emergent themes in the data collected, focusing on the context-mechanism-outcome formula.

This study will run in parallel with the RAMESES II study to develop methodological standards for realist evaluation (HS&DR 14/19/19). The principal investigator on RAMESES II, co-applicant Prof Trish Greenhalgh, and lead researcher Dr Geoff Wong, are both based at the University of Oxford. Dr Wong will provide methodological and analytic support to this work as part of his (already funded) RAMESES II study.

Whilst realist evaluation will inform and guide elements of the analysis, we recognise that clearly articulating mechanisms of change and distinguishing these from aspects of context can be challenging (26). We will also adopt a wider comparative case study analytic approach as outlined by Fitzgerald and Dopson, taking an interpretive and holistic approach to understanding each case and how it compares with others (27-30). Comparative case study analysis lends itself to 'the exploration of complex "how" and "why" questions' (29:481) and will provide a rich source of information, understanding and pattern detection to inform a toolkit for the NHS. As in any case study design, gathering contextual information about concurrent events such as CQC inspections and changes of leadership will be an important component of data collection. Participants will be invited by the ethnographers to reflect on the significance of such contextual factors.

The face-to-face learning community meetings with frontline teams are very much intended to be two-way discussions rather than simply passive dissemination of research findings. The frontline teams and the patient advisers will contribute formatively to the analysis as well as using it to help them plan their next steps. Their feedback on the issues identified by the ethnographers and their response to the interpretations of the research team will be an important contribution to our understanding of the context and mechanisms at play in each site.

Given the fluid and evolving nature of the interventions we anticipate, we do not propose to conduct a formal cost analysis in each site for this study, though we will ask teams to work with the ethnographers to keep a record of numbers of meetings held and numbers of staff and patients/family members attending, to compare the level of effort and intensity involved with the number and type of changes made in each case. Our priority will be to focus on the process of using experience data of different types and the impact in terms of service improvements and changes in measured patient experience.

3.4 Post-intervention survey

The local baseline patient survey will be repeated a year on with a new set of patients to measure what, if any, change has occurred in measured patient experience following local quality improvement work. This will again be a postal survey with the same anticipated sample size of 240 per ward and will be sent to a census of all discharged patients from the six participating wards.

Results will be compared to data from the pre-intervention survey to see if there are any detectable ward-level changes to question scores. To explore whether ward level changes are observable at a Trust level, results (for those questions that map) will also be compared to Trust level data from the most recent NHS Adult Inpatient Survey.

The main outcome measure (or measures if all wards cannot be evaluated on the same measure) used for evaluating change will be determined through discussions amongst the research team, the project steering

group, and with input from each ward team. This approach has the added benefit of allowing participating Trusts to be involved in the selection of measures, increasing their sense of ownership and 'buy-in' to the study.

Forty-eight in-depth interviews with patients and family or carers will also be carried out to gather more detailed information on the quality of the experience of recently discharged patients.

Reports showing survey and interview data for each case study site will be generated. They will detail:

- Response rate information
- The demographic profile of respondents
- Results for each question in the survey (with historical and Trust-level comparisons where appropriate). Caveats about interpretation of the data and the limits of significance testing will also be noted.
- Free text comments included as part of the survey
- Results from the in-depth interviews

3.5 Synthesising analysis, writing up and preparation of toolkit

Following the completion of the fieldwork, the qualitative and quantitative data from Phase 2 will be brought together by the whole research team to create an overarching understanding of what changes were made and how in each site; what facilitated or hindered the process; how different types of data were received and acted on; what impact (if any) the process had on measured patient experiences; and what we can learn about successful strategies and pitfalls to include in guidance for the NHS. Early explanations will be tested and refined at the final learning community meeting with staff and patient and family advisers. We have scheduled a writing workshop for the research team in month 22 and again in month 25; this is an approach we have used successfully in the past to share out writing tasks and produce and share initial drafts, which will then be refined further in between workshops. From these workshops we will produce both the final NIHR report and the NHS toolkit (see dissemination). We have allowed six months for this process; although analysis will have been ongoing since the start of fieldwork, it is our experience that successful analysis requires repeated revisiting and reflection on the data to develop a nuanced account.

4 STUDY SETTING

The research will take place in six medical wards in NHS acute Trusts in England. Sites will be accessed initially through senior Trust management. As part of a national survey of Trust senior patient experience leads currently being conducted (with separate REC and HRA approvals), Trusts are being invited to express interest in becoming a case study site. Six Trusts will be selected and invited to nominate a medical ward team to take part.

5 SAMPLE AND RECRUITMENT

Because the study involves several components we describe the sampling and recruitment approach for each separately.

5.1 Eligibility criteria

5.1.1 Inclusion criteria

Case study sites: Frontline medical wards in NHS acute hospital Trusts in England.

Baseline and follow up survey of patient experience: All patients discharged from the medical ward within a 3-month period with capacity to consent, or a family member responding on their behalf.

Baseline and follow-up interviews about patient experience: Patients or family members responding to the survey who also express interest in taking part in an interview as well.

Ethnographic case studies: staff members, patients or family members who get involved in quality improvement on one of the six wards; other staff members who work on the ward; members of the senior management team in the six Trusts; members of the research team.

5.1.2 Exclusion criteria

Case study sites: Surgical or other non-medical wards in NHS acute hospital Trusts in England; community and mental health Trusts; Trusts in Scotland, Wales or Northern Ireland.

Baseline and follow up survey of patient experience: Patients discharged from the medical ward outside the relevant 3-month period; those without capacity to consent.

Baseline and follow-up interviews about patient experience: Those without capacity to consent; those unable to take part in an interview in the English language.

Ethnographic case studies: staff and patients from other wards; patients currently receiving care on the ward. (Ethnographic observations will be confined to quality improvement activities and are not designed to observe care being provided).

5.2 Sampling, recruitment and consent

Case study sites

Size of sample: 6

Sampling technique: The sample will be purposive. The sampling frame will be informed by a combination of re-analysis of existing survey data and a new survey of NHS Trust patient experience leads currently being conducted. (This phase of the work is the subject of separate REC and HRA approval already obtained.) We are

combining evidence from these different sources to investigate how Trusts a) perform on these measures and b) organise themselves to work on patient experience and respond to patient experience data. The aim is to gather summary-level data from these sources into a matrix to identify high, average and poor performing Trusts – in other words to see which Trusts consistently demonstrate high performance and strong engagement with patient experience, those which do not, and those where no clear pattern emerges.

Recruitment/sample identification: Using this matrix we will select 3 high performing Trusts and 3 with more mixed performance. Trusts are being invited to express interest in becoming involved when their patient experience lead completes the national survey mentioned above. We will approach potential case studies matching our sampling categories sequentially until we have agreed participation. In each site, a frontline medical ward team will then be identified to join the study.

Consent: Consent to case study participation will be expressed through formal agreement by the Chief Executive or designated officer, and research governance agreement in each Trust. Individual consent will also be sought from staff members, patients and family members involved (see below).

Baseline and follow up survey of patient experience

Size of sample: 240 per ward at baseline, and a further 240 per ward at post-intervention follow-up. Total 2880 across six wards. Expected response rate of 50%.

Response rate data from the NHS Friends and Family Test suggests that on average in acute Trusts approximately 80 people are discharged per ward every month. Using this as a guide, we anticipate an estimated sample size of 240 patients per ward. The average sample of 240 patients per ward should provide 120 responses, assuming a 50% response rate (the response rate for the NHS Inpatient Survey 2013 which uses a similar methodology was 49%). This will allow for a minimum detectable difference of 11 percentage points for wards in the pre and post surveys; a good compromise between sample power and avoiding an excessively long sampling period. This minimum detectable difference of 11 percentage points is calculated based on the number of responses we believe to be achievable from the survey based on typical ward-level activity. Achieving a larger sample and a greater sample power would involve increasing the numbers of patients going through the medical wards in the three month sampling period, and this is out of the research team's control. As such, we will not have access to the kinds of sample sizes required for high precision estimates and detection of small changes. Due to this, the pre-and post-intervention surveys should be viewed as one part of the overall package of information collected rather than the only source of evidence.

Sampling technique: Census of every patient discharged from the ward over a 3-month period at baseline and again at follow-up.

Recruitment/sample identification: The survey will be administered using a postal methodology. Trusts involved in case studies will be asked to undertake the mailout using their patient discharge records, thus avoiding any need for the research team to access personal data. It will be explained that the survey may be completed by the patient or by a family member representative if the patient lacks capacity to complete the survey. Replies will be mailed to the Picker Institute for analysis. Fieldwork will last for 12 weeks with 2 reminder mailings being sent to non-responders during this period. Before each mailing sites will be asked to carry out a DBS (Demographics Batch Service) check to check for any deaths. An opt-out approach will be used with all survey materials stating that participation in the survey is completely voluntary. Materials will provide clear instructions on how people can opt out if they wish. Survey respondents who are interested in taking part in an interview will be invited to

register their interest on the survey. In this case, the research team will send the unique survey ID codes of those selected for interview to the Trust and ask for a list of names and addresses to be supplied.

The methodology (such as the use of reminders and the length of fieldwork) are based on best practice in social research. A sufficiently long fieldwork period and the use of reminders is particularly important for patient experience surveys covering acute care settings as this has been shown to improve the representativeness of results and obtain more feedback from people with poorer experiences.

Consent: Completing and returning the survey will be taken as consent to participate. It will be explained to all participants that if they tick the box registering interest in being interviewed, they will be agreeing for the hospital to pass on their name and address so that the research team can send them more information, but that all answers they provide on the survey will remain entirely anonymous and will not be individually identifiable.

Baseline and follow-up interviews about patient experience

Size of sample: 8 per ward at baseline, and a further 8 per ward at post-intervention follow-up. Total 96 across six wards.

Sampling technique: Purposive sample selected from survey respondents (see previous section), to add qualitative insight to survey responses. Variation will be sought across survey patient experience scores, to include a range of positive, negative and mixed experiences. It is anticipated that the sample will also include some responses from family members/ carers who have completed the survey on behalf of a person who lacks capacity. Responses will be treated the same as patient responses.

Recruitment/sample identification: Survey respondents (see above) will be invited to express interest in taking part in an interview, either face-to-face or by telephone according to their preference. A subset of those volunteering (including family members/carers) will be selected according to scores (see above) and will be sent a participant information sheet in the post.

Consent: Potential participants will be given a week to read the participant information sheet. They will then be contacted by a member of the research team to discuss the study and answer any queries, and to arrange a date for interview. This telephone call will also offer an opportunity for the researcher to assess the person's capacity. Those preferring a telephone interview will be sent a consent form and reply-paid envelope in the post; those preferring a face-to-face interview will sign consent on the day of the interview.

Ethnographic case studies

Size of sample: The nature of ethnographic observational case study work means the sample has to remain flexible and responsive to local circumstances. The exact number of interviews to be conducted will therefore depend to some extent on the composition of the frontline teams (including patients and family members) from each site, but we estimate a maximum of 10 interviews at the beginning and end of the intervention; interviews with 2-3 with key improvement leaders on each ward at the mid-point; and 2-3 senior managers at the end of the fieldwork period, totalling approximately 25 in each site (total 150 across all sites). The two ethnographers will also observe meetings of the research team and incorporate research team reflections on the process into their findings.

Observations will include a wider sample of staff, patients and family members involved in local improvement activities; the exact number cannot be determined in advance. Some may also be invited to take part in an interview.

Staff and patients involved in the project may also be invited to keep a diary of their experiences; again, the number is not known.

Sampling technique: Purposive sample, including core team members (ward staff and patients/family members) involved in running the quality improvement project; other staff, patients and family members who get involved locally; senior managers in the Trust.

Recruitment/sample identification: Once a Trust has agreed to be a case study site, they will nominate a medical ward to get involved. The ward will identify core team members (including patient/family members) to join the study and take responsibility for the project locally, and these team members will form the basis of the sample. The ethnographers will identify further people to observe and interview through their interactions with each local site. A ward poster will inform all staff on the ward that the study is taking place.

Consent: Separate participant information sheets and consent forms have been developed for core team members (staff and patients/family members); other staff and patients/family members who get involved; and senior managers in the Trust. The ethnographers will be responsible for giving information sheets to potential participants, answering any questions they may have about the study, and taking consent. It will be made clear to all participants that the purpose of the ethnographic work is to understand the quality improvement process, not to observe care being provided on the ward.

Consent for the online toolkit

Findings from the study will inform the development of an online toolkit for the NHS (see 'dissemination' below). In order to share good practice, we would like the toolkit to show some real-life cases so that others can see what has worked well and what has not worked so well, and how staff have overcome challenges they encountered. The toolkit may include short videos of participating frontline staff and their patient team members talking about their experiences and the changes they have made. However, we would only include such identifiable material with the additional consent of both the individual and the organisation. Other material in the toolkit will remain anonymised to ensure participating teams can share their learning without identifying the Trust or ward concerned. This is explained in all the participant information sheets for those taking part in the ethnographic case study, and a separate consent form has been prepared for this stage.

6. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

7. ETHICAL AND REGULATORY CONSIDERATIONS

7.1 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

7.2 Assessment and management of risk

This research involves minimal risk to participants. Ethnographic observation in NHS settings raises some potential ethical challenges if patient care is being observed. However, in this case the focus of the observation is on the quality improvement process, and will not include any direct observation of ward care or patients who are currently being cared for. The observations will thus be mainly of meetings and workshops, supplemented by interviews with participants in the frontline ward quality improvement teams (including user and carer team members) and documentary analysis. We have drawn on advice from our lay co-applicant who is a lead reviewer for an NHS ethics committee, an ethics consultant to the Research Design Service and research ethics trainer.

Staff involved in local improvement interventions may conduct their own patient interviews or observations, but these will not form part of the research and will be treated as service improvement work.

In order to measure changes in patient experience as a result of the quality improvement work, we will conduct a baseline survey and interviews with recently discharged medical ward patients, and repeat this after the intervention with another group of recently discharged patients. Patients taking part in the baseline and follow-up survey or interviews may feel some emotional distress as they recall details of their illness or their hospital care experiences. It will be made clear to survey respondents that their participation is voluntary and they can choose to withdraw or not return the survey. If a patient or family member becomes distressed during an interview, the researcher will immediately ask if they would like to pause or stop the interview. The researcher will be trained in how to deal with this situation. Patient information leaflets will stress that further participation in the interviews is voluntary and that consent may be withdrawn at any time without adverse consequences.

In order to fully appreciate the experiences of staff, patients and family members involved in local quality improvement, it may be necessary to explore their views, thoughts and feelings. There is a potential for the participants to disclose information that they may find upsetting or distressing. Again, the ethnographic research team will be fully trained in how to address this should it happen and offer to terminate the observation or interview if the participant prefers. The other burden to the participants is time. The research team will also endeavour to avoid creating any additional work for the staff other than that agreed as part of the study during the observational phase. Trusts will be given funding to backfill staff time needed for research activities.

Staff and patients or family members who are being observed may be concerned about others hearing their views, opinions or practices therefore we will reassure them that all data recorded will be held in the strictest confidence and any output will be anonymised. Time limits for the storage of data are included in the participant information sheets.

In the unlikely event that the researchers observe, or are told about any practice that they may be concerned about this would be raised immediately with their project supervisor and with the lead investigator, Louise Locock. Where necessary the steering committee will be consulted to seek guidance on how to proceed. If the information is considered to be concerning, then this would be addressed by contacting the relevant

safeguarding contact at the Trust and discussing it with them. For situations that may be of a more serious nature then the relevant authorities would be notified, e.g. the GMC, police or social services. The consent forms will make it clear to participants that while the researchers will maintain their duty of research confidentiality to participants as far as possible, that if very poor care or abuse is identified then the researchers will report this.

In order to share good practice, we would like the toolkit we produce for the NHS to show some real-life cases so that others can see what has worked well and what has not worked so well, and how staff have overcome challenges they encountered. The toolkit may include short videos of participating frontline staff and their patient team members talking about their experiences and the changes they have made. However, we would only include such identifiable material with the additional consent of both the individual and the organisation. Other material in the toolkit will remain anonymised to ensure participating teams can share their learning without identifying the Trust or ward concerned.

7.3 Research Ethics Committee (REC) review & reports

The study protocol, data collection tools, participant information sheets and consent forms will be submitted for NHS REC approval, and host institution(s) for written approval. Any amendments requiring REC review will not be implemented until the REC grants a favourable opinion. All correspondence with the REC will be retained

7.4 Peer review and funding

The study was subject to independent, external peer review as part of the competitive funding application (NIHR HS&DR call 14/156).

7.5 Patient & Public Involvement

Our patient research partner Jennifer Bostock is a co-investigator. At outline stage she reviewed the application, edited the lay summary, and made changes in the overall programme of work. She played an equal role in preparing the full proposal, will remain actively involved throughout and contribute to dissemination.

Two lay advisers have been recruited to sit on the Study Steering Committee which will oversee the overall programme of work (one patient and one carer). Jennifer Bostock designed the advertisement used to recruit them. With her input again, we are advertising for up to 8 people with inpatient medical ward experience to act as a patient advisory panel to the study. Having a group of people is important both to ensure they feel that have a strong and equal presence, but also so that people feel they can take time out if need to, for example if they have periods of illness. We will seek a mix of people to be involved, paying attention to demographic diversity as well as people who have different types of experience of healthcare. We will particularly encourage people who have been involved in previous service improvement work to apply as well as people with no improvement experience. Their role will be to advise the research team throughout, and also to contribute to the learning community meetings with ward teams. They will be reimbursed for their time. They will help the ward teams think through what kind of improvements matter to patients and to develop realistic and acceptable improvement

plans. If teams plan to collect any new local data as part of their plans, Bostock and the lay panel will also be able to advise them on involving patients in data collection, for example interviewing and observational work. At subsequent learning community meetings, they will be involved in reflecting on interim findings with the research team and the frontline ward teams, and discussing how to adapt their quality improvement work to overcome any difficulties encountered, thus participating in our formative analysis stages. They will advise on the content of the toolkit and be encouraged and supported to get involved in dissemination (for example through co-presenting and co-authoring).

As noted in the research plan, ward teams will be positively encouraged to bring patients or family members along as part of their team. We appreciate that some teams may involve people better than others in their improvement work, but the ethnographers will be looking out for the nature and extent of patient involvement as one of the factors which may affect outcomes and reporting on this in their analysis.

Jennifer Bostock has also been closely involved in developing the participant information sheets and consent forms, drawing on her experience as a lay ethics committee member, to ensure the study is ethical and acceptable. She has suggested numerous wording changes and text additions (for example explaining what we mean by ‘patient experience data’, and how we should handle consent for being identified in the toolkit).

Given the nature of this study we see PPI as crucial to its success. A strong patient focus will not only aid the research but also encourage frontline NHS teams to involve local patients actively in improvement work now and in future. Bostock will oversee the involvement plan and ensure it continues to meet the needs of the study. As an experienced trainer, she will deliver any training needed, with the support of the research team, and provide ongoing support to less experienced or less confident advisers to ensure they can all contribute effectively. Training will include a 'mini learning set' day for those who would like to advise the learning community. This will take place with members of the research team, before the frontline ward teams are brought in, to familiarise our patient advisers with the kinds of patient experience data available and how these data can be used, and what is known about successful organisational change and service improvement.

7.6 Regulatory compliance

NHS permission and approval for any amendments will be sought through the HRA approvals process.

7.7 Protocol compliance

Accidental protocol deviations can happen at any time. They will be documented and reported to the Principal Investigator and Sponsor. Any deviations from the protocol found to be happening repeatedly will be reported to the independent Study Steering Committee.

7.8 Data protection and confidentiality

All information will be handled in confidence in accordance with the UK Data Protection Act 1998. The Principal Investigator will be responsible for security and access to the data. At the end of the study the research data will be secured for five years in keeping with standard research practice and then destroyed. Any personal identifiers relating to individual participants will be held for less than three months after the end of this 27-month study.

Individual survey respondent data will be held securely, confidentially and anonymously by the Picker Institute and will not be shared with other co-investigators. The Picker Institute has United Kingdom Accreditation Service

(UKAS) accredited certification for its information security management system (ISO27001:2013). Survey respondents who are interested in taking part in an interview will be invited to register their interest on the survey. In this case, the research team will send the unique survey ID codes of those selected for interview to the Trust and ask for a list of names and addresses to be supplied. It will be explained to all participants that if they tick the box registering interest in being interviewed, they will be agreeing for the hospital to pass on their name and address so that the research team can send them more information, but that all answers they provide on the survey will remain entirely anonymous and will not be individually identifiable.

Any recordings, handwritten or typed fieldnotes made during interviews or observation will be stored confidentially on password protected computers. Transcripts of interviews will be anonymised and given a unique ID number. The digital recording and the transcript, identified only by the code number, will be kept in a secure place at the Nuffield Department of Primary Care Health Sciences, University of Oxford (case study interviews), or the Nuffield Department of Population Health, University of Oxford and the Picker Institute (baseline and follow up patient experience interviews). Information linking the names of respondents to ID numbers will be kept separately in hard copy in a locked filing cabinet in the same locations. Quotations used will not be personally identifiable.

Direct access to data will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

7.9 Indemnity

The University of Oxford maintains Public Liability and Professional Liability insurance which will operate in this respect.

7.10 Expenses and Benefits

Staff and patients will be reimbursed for any travel or caring expenses incurred by taking part in the study. Accommodation costs will be covered for those taking part in the core team learning community meetings being held in Oxford in 2016 and 2017.

7.11 Amendments

The Principal Investigator will submit and obtain REC and HRA approval for all amendments to the original approved documents. The sponsor will be notified. The amendment history will be recorded through version numbers of key documents.

7.12 Access to the final study dataset

Individual survey data will be held securely and confidentially by Chris Graham and Jenny King at the Picker Institute and not shared with other co-investigators; aggregated findings will be shared with the rest of the research team and the relevant Trust.

Only the Principal Investigator, Louise Locock, and the researchers responsible for collecting interviews and observations will be able to link the names of participants with anonymised ID numbers. These researchers are: Elizabeth Gibbons and a researcher to be appointed to work with her (Nuffield Department of Population Health; Jenny King (Picker Institute); Stephen Parkin, Catherine Montgomery and Alison Chisholm (Nuffield Department

of Primary Care Health Sciences). Anonymised transcripts and transcript extracts may be shared for analysis with other members of the research team.

8 DISSEMINATION

We will inform participants that the findings of this study will be published in professional journals and presented at conferences and dissemination workshops. They will also be shared with staff working elsewhere in the form of a freely available online toolkit for the NHS on using patient experience data for improvement. The toolkit is likely to include:

- a review of best evidence on using patient experience data
- methodological advice on how to collect, interpret and apply different types of data
- guidance on practical, organisational and cultural factors to consider
- good practice guidance on how best to involve patients and families in the process
- practical real-life examples building on the case studies of difficulties and barriers as well as examples of success.

Authorship of papers submitted to peer review journals will follow guidelines set by the International Committee of Medical Journal Editors and other contributors will be acknowledged. Manuscripts will include acknowledgement and disclaimer statements as required by the funder.

We will offer all participants the opportunity to be sent a summary of findings at the end of the study.

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