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Complete List of Authors:	Sheard, Laura; Bradford Institute for Health Research, Marsh, Claire; Bradford Institute for Health Research O'Hara, Jane; Bradford Institute for Health Research; University of Leeds, Medical Education Armitage, Gerry; University of Bradford Faculty of Health Studies Wright, John; Bradford Institute for Health Research Lawton, Rebecca; University of Leeds, Institute of Psychological Sciences; Bradford Institute for Health Research, Quality and Safety Research
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Understanding how organisational context affects the implementation of a patient safety intervention: A qualitative process evaluation

Laura Sheard
laura.sheard@bthft.nhs.uk
Bradford Institute for Health Research, England

Claire Marsh
claire.marsh@bthft.nhs.uk
Bradford Institute for Health Research, England

Jane O'Hara
jane.o'hara@bthft.nhs.uk
Bradford Institute for Health Research & University of Leeds, England

Gerry Armitage
g.r.armitage@brad.ac.uk
University of Bradford, England

John Wright
john.wright@bthft.nhs.uk
Bradford Institute for Health Research, England

Rebecca Lawton
r.j.lawton@leeds.ac.uk
Bradford Institute for Health Research & University of Leeds, England

Corresponding author:
Laura Sheard
Bradford Institute for Health Research
Bradford Teaching Hospitals
Bradford Royal Infirmary
Duckworth Lane
Bradford
BD9 6RJ
England

ABSTRACT

Objectives – The PRASE (Patient Reporting and Action for a Safe Environment) intervention elicits patient feedback on safety and then facilitates ward staff to make action plans to improve patient safety. PRASE was tested on acute hospital wards in a large scale randomised controlled trial. No statistically significant difference between intervention and control wards was found. We conducted a process evaluation of the trial and our aim was to understand how PRASE was implemented by staff across the differing contexts of the 17 intervention wards.

Design – Qualitative process evaluation of the implementation of a patient safety intervention, tested in a randomised controlled trial.

Setting and participants – NHS staff based on 17 acute hospital wards located at five hospital sites in the North of England.

Data – We concentrate on three sources here: i) analysis of taped discussion between ward staff during action planning meetings ii) facilitators' field notes iii) follow up telephone interviews with staff focussing on whether action plans had been achieved.

Findings – First, there were palpable differences in the ways that the 17 ward teams engaged with the key components of the intervention. Five main engagement typologies were evident: consistent, partial, upward, downward and disinterested. Second, the intensity of support for the intervention at the level of the hospital management team does not predict the strength of engagement at the level of the individual ward. Third, the standardisation of facilitative processes provided by the research team does not ensure that implementation standardisation of the intervention occurs by ward staff.

Conclusions - A dilution of the intervention occurred during the trial because wards engaged with PRASE in divergent ways, despite the standardisation of key components. Facilitative processes were not sufficiently adequate to enable intervention wards to successfully implement PRASE.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- We devised a process evaluation that had several robust qualitative data collection methods which complemented each other, in order to build a comprehensive and holistic picture of how ward staff implemented the intervention
- Our approach allowed us to reveal how differing organisational contexts can impact on the ability for patient safety changes to be realised at a ward level
- Our novel analytic approach utilised pen portrait methodology in a differing way to how it has previously been used in health services research, in order to document the journey of 17 wards interacting with an intervention over an 18 month period
- Changes in patient safety may have taken longer than the length of the study to come to fruition, but we have little understanding of whether the implementation of PRASE may have gained traction and fuelled subsequent ward based change once the research team left the field
- The qualitative methods we chose were designed to capture a broad understanding of the contexts in which the intervention was implemented but had we known a priori that engagement was such a significant factor, we may have designed the process evaluation to specifically explore its influence.

BACKGROUND

Measurement of patient safety has traditionally relied on information from staff such as incident reports or recording information about harms such as falls or pressure sores. Recently, patients have been emphasised as being an important detector for patient safety and likened to the 'smoke detectors' of safety [1]. There is an increasing recognition that hospitals need to find better ways to capture and respond to the concerns of patients regarding the quality and safety of their care [2-4]. However, patients are rarely asked about structural or procedural aspects of care which may contribute towards failures in patient safety. The Yorkshire Quality and Safety group have developed a patient safety intervention called Patient Reporting and Action for a Safe Environment (PRASE) which firstly elicits patient perceptions on how a ward is performing on a series of issues which are known to contribute towards patient safety incidents and secondly assists staff to interpret patient feedback to aid service improvements. This paper provides an account of a qualitative process evaluation of a randomised controlled trial (RCT) where PRASE was tested. PRASE was designed [5, 6], piloted [7] and trialled [8, 9] between 2010 and 2015. This period has been charted as an era of paradigm shift for patient safety research when the dominant 'measure and manage' orthodoxy has been enriched by approaches sensitive to context, socio-cultural and political influences [10]. It became essential for a process evaluation to capture the nuances involved in the PRASE implementation.

Process evaluations have been used to explain sub-optimum outcome effects, specifically whether there was a 'fault' with the intervention itself, its key components or with delivery [11]. Latterly, they are often not only concerned with adherence to original plans, but also with broader issues such as unintended consequences or the strengths and weaknesses of the intervention itself [12]. Some process evaluations have been able to identify a precise 'pinch point' or problem with an essential component of the intervention that caused it to fail. In a UK trial of peer led HIV prevention for gay men in London, no effect was shown. A qualitative process evaluation [13] revealed that the essential component of 'peer educator' had not played out as intended during the course of the trial due to recruitment problems and the inability of peer educators to confidently communicate harm reduction messages to intended targets. Other process evaluations have been able to point to more general cultural or structural reasons why an intervention may not have succeeded. Dixon-Woods et al [14] evaluated why a U.S. developed patient safety intervention - regarding decreasing central line infections in intensive care units – struggled with implementation after the intervention was transferred to a U.K. setting. A post-hoc qualitative evaluation revealed multiple reasons why, largely the result of cultural differences between the U.S and U.K. settings. It is clear from these examples that process evaluations can support the largely 'experimental' aim of RCTs by identifying specific 'pinch points' within an intervention itself or within the context that will help to predict success or failure.

The methods of the intervention have been reported in detail elsewhere [8], as have the results of the randomised controlled trial which demonstrated no statistically significant effect between the intervention and control wards [9]. Here, we provide a synopsis of the intervention and results of the trial for the reader to be able to view our process evaluation in context. Appendix 1 provides a summary of the intervention. Appendix 2 describes the content of the above in detail. Appendix 3 describes the trial design and results. Briefly, this was a cyclical study with two phases of i) collecting patient feedback about safety from patients at the bedside ii) collation of this data and ward staff interpreting it iii) ward staff action planning to improve patient safety iv) plans then being implemented and monitored.

METHODS

We conducted a robust process evaluation involving differing qualitative and quantitative methods [8] which gathered comprehensive data about all 17 intervention wards. The main research question was: 'where does the intervention work, how and why?' In this paper, we have chosen to focus on the 'how?' and 'why?' and present a detailed picture of how staff engaged with the intervention. Six mixed methods were used in the wider process evaluation but due to the extent and depth of the data collected, we focused intensively on three qualitative methods for the purpose of this paper. The methods described below are those most pertinent to exploring how and why staff engaged with the intervention in the ways they did. Data was collected between August 2013 to November 2014. NHS ethical approval was granted in March 2013.

1. In depth analysis of taped discussion between ward staff

Action planning meetings (APMs) were digitally recorded for all 17 wards at both phases. At phase two, one ward did not meet so we considered the recordings of 33 APMs. These ranged in length from 27 to 80 minutes (average 43 minutes). Our examination focused on which areas of patient feedback staff chose to make action plans on and which areas they chose not to. We wrote detailed notes whilst listening to the voice file.

2. Facilitator's field notes

These notes were written shortly after the action planning meeting had finished and captured: i) implicit dynamics between staff, such as body language, tone of voice and other non-verbal cues ii) environmental factors, such as descriptions of the physical space where the meeting was held iii) facilitator's impressions. Field notes were brief and gave a 'snapshot' of the meeting. There were three facilitators across the 17 intervention wards and each facilitator worked with the same wards across both phases of the study, to ensure continuity.

3. Follow up telephone interviews conducted with the APM lead

The purpose of these short, structured phone interviews was to ascertain whether action plans had been successfully implemented or not and why. They were conducted around six months after the APM, with the 'PRASE lead' for each ward. Each ward was responsible for nominating a named member of ward staff - who was part of the action planning meeting - to be the PRASE lead. This could be any member of the team but was more often than not the person who volunteered for the role was a senior nurse. Questioning mainly centred on asking about implementation of each action plan and the context of this.

For the purpose of this paper, we wanted to understand how wards had engaged (or not) with the PRASE intervention. A synthesis of the above data sources has provided us with a rich account of the '**engagement trajectory'** of each ward and this was realised by creating a pen portrait of engagement. Pen portraits have been used previously in applied health research in fields as diverse as: end of life care [15], vulnerable old people being enabled to keep warm in their homes [16] and sleeping practices amongst homeless drug users [17]. Previously, they have provided a narrative account of a 'typical' participant in qualitative studies or as an analytic aide memoir. We used them in a slightly different manner to document the 'journey' of the wards throughout the trial from the perspective of the researcher who had worked closely with these wards for over 18 months. There is a lack of methodological literature pertaining to the construction of a pen portrait and this has been left to the discretion of individual research teams.

We created a basic structure for the pen portraits which centred on the writing of a linear account of how each ward had engaged with relevant key components of the intervention and the contextual factors which influenced this, ensuring that all data sources were drawn upon. We decided not to adhere to a numerical/scale definition of 'engagement' whereby differing wards attained a binary definition of either 'engaged' or 'disengaged' with the

intervention. Instead we undertook a more nuanced analysis whereby we assessed the following intervention components - which staff were responsible for implementing - in terms of the staff approach taken to: conducting an action planning meeting, creating quality action plans, implementation of these action plans. The pen portrait for Beech ward is shown in Appendix 4 with the prose annotated to show where differing sources of data came from.

Researchers took into account all the information contained within the pen portrait and attributed an overall 'engagement trajectory' label to each ward. Author A wrote all pen portraits for Trusts A and B and Author B for Trust C. We categorised the 17 different ward engagement trajectories into five main 'engagement typologies', which emerged from an analytical session centring mainly on consensus discussion between Author A and Author B. We used techniques derived from 'adaptive theory' [18] which allows for high level frameworks and conceptualisations to emerge from data rather than descriptive themes. Adaptive theory proposes a continual engagement between the arising empirical data and arising theoretical interpretations of the research, working in a continuous cycle with each cycle generating new explorations.

FINDINGS

We now set out to understand context, circumstance and divergence in the ways in which the 17 intervention wards engaged with the intervention. In doing so, we aimed to explore how the intervention may have been interacted with by ward staff in a multiplicity of manners which made an already complex intervention become hyper complicated in its implementation phase. This 'hyper complexity' may have served to dilute key elements of the intervention (which aimed to be standardised across the intervention wards). We explore three high level themes, which emerged from the data. Firstly, we will describe how there were palpable differences in the ways that the differing ward teams engaged with the intervention. Next, we will look at how support for the intervention at the level of the Trust does not indicate ward level support. Lastly, we will demonstrate that standardisation of facilitative processes by the research team does not ensure this filters down to implementation standardisation by ward staff. All quotation extracts are taken from pen portrait notes and all ward names have been ascribed a pseudonym.

1. The same intervention can be interacted with in highly divergent ways

We were able to distinguish the intervention wards into five main 'engagement typologies' (Figure 1). They are:

- Consistently engaged throughout (7 wards)
- Partially engaged throughout (4 wards)
- Upward engagement as trial progressed (2 wards)
- Downward engagement as trial progressed (2 wards)
- Disengaged and disinterested throughout (2 wards)

Consistently engaged – This represents the largest category of how wards chose to participate in the trial with 7 out of the 17 residing here. These wards were fully signed up to the ethos of listening to and acting on patient feedback. They took part in a high proportion of the key components of the cyclical activities and made quality action plans which were largely implemented in both phases. A quality action plan can be defined as one which seeks to address issues which the data from patients had identified and was realistic, relatively timely and more than likely to be achieved. Motivation to take part in the research was high and improving patient safety was even higher.

Partially engaged – These four wards generally did everything asked of them by the research team and largely participated in intervention components but were sometimes lacklustre in their motivation towards improving patient safety. At times, it felt like action planning was just 'going through the motions'. The ability of staff to implement action plans

was mixed although this was sometimes due to external factors rather than inertia on the part of the ward staff themselves.

Upward engagement – These two wards began their involvement with the trial in an ambivalent and – in the case of Maple ward – even hostile manner. However, as the study progressed and the ward staff began to understand what the research team were trying to achieve and engagement with the study solidified. The similarity between these two wards (despite being at different Trusts) is that the turning point for their engagement was attendance at the peer centred Mid-Point Meeting. This is reflected in Maple ward's complete U-turn with implementation of quality action plans at phase two as compared with partial implementation of weak action plans at phase one.

Downward engagement – Conversely, another two wards engaged with the study relatively well at the beginning but, over time, slipped in their level of interest and involvement. Cherry ward is the only ward across all 17 who did not meet in an APM in phase two. The follow up telephone interview revealed that the ward manager for Cherry did not believe the study was a priority. Oak ward had ambitious plans for their phase one action planning but had become dejected by the amount of time their plan was taking to come into effect. Subsequently, they declined to make an action plan in the phase two APM and appeared disinterested in the study.

Disengaged and disinterested – Although these two wards met in APMs for both phases of the trial, they were not interested in using the PRASE data to improve patient safety and viewed the study as a burden. However, the reasons for this response differed. Rowan were a low performing ward whose ward manager preferred to concentrate on the other initiatives rather than our research study. Elm ward were outwardly hostile to the ethos of the study, critical of the comments their patients had made to researchers and defensive of staff members. Despite agreeing to hold an APM, they consistently refused to make action plans.

Through an examination of these differing engagement trajectories, we can unpick where parts of the intervention may have led to divergent strategies for local implementation of the intervention on a ward-by-ward basis. These findings from 'on the ground' implementation by ward teams directly contradict some of the core assumptions held by the research team at the outset of intervention development - namely, that by providing facilitative processes, wards would be able to implement in a uniform manner. It is this aspect of a chasm between implementation expectations and reality which we now turn our attention to.

2. Trust-level support for an intervention does not predict the strength of ward-level engagement

A key assumption was that strong corporate, managerial-level support by the three participating Trusts would facilitate high-level engagement by wards. However an examination of the differing types of engagement trajectories, shown in Figure 1, throw doubt on this assumption and we can find little consistency in engagement style between the wards at the same Trust. For instance, Trust A is a small district general hospital in a semi-rural, affluent area. This Trust prides itself on being a forward thinking, cohesive workplace and senior management support for this intervention was exceptionally strong. However, when reduced down to the level of the ward, we can see that the four intervention wards at Trust A are represented across four distinct engagement trajectories (Consistent = Beech, Upward = Maple, Downward = Oak, Disengaged = Elm). Engagement trajectories for each of the other two Trusts also differed considerably by ward. The implication here is that corporate culture - and receptivity to patient feedback at the level of the organisation - is not a simple predictor of engagement at ward level.

Unpicking these differences further, we find that despite a uniform message about the importance of a multi-disciplinary approach to the study, wards seem to have interpreted this

differently. Oak ward convened a strong first multi-disciplinary APG with representatives from nursing, allied health professionals and support staff. In contrast, on some wards PRASE remained led and implemented by just one or two nursing staff. For example, Maple's first APG consisted of just the ward manager and pen portrait notes illustrate why:

> *A very tense meeting held with just the ward manager who appeared overtly stressed and about to implode. It was clear at this first APM that the ward manager had not understood the purpose of the study and became upset by some of the negative comments which her patients had made in the report. It was a difficult APM to convene as the ward manager thought she had to solve everything by herself and this was partially reinforced by the fact that she had not invited any of her staff to the APM (Maple, Trust A)*

The research team never envisaged that the intervention would be taken on by just one or two members of ward staff and this was actively discouraged throughout but still persisted in five wards at phase one and six wards at phase two, across the 17 intervention wards. It is difficult to suggest a clear reason why this happened but it was often related to:

- Front line context, such as no staff available to be released from direct patient care to attend APG
- A minority of ward managers viewing the study as yet another patient safety initiative that they just needed to 'get on with'
- A misunderstanding of the multi-disciplinary nature of the intervention.

Of most interest is the severe paucity of medical staff involved in the intervention with only four wards (all at Trust C) involving a medic. This was unforeseen at the outset and may have contributed to action plans that were narrower in scope than those generated by a strong MDT. Even those wards who managed to convene a strong multi-disciplinary APG in phase one were often not able to sustain this level of input going into phase two. Towards the end of the study, it was disappointing to see that PRASE had unwittingly become badged as a 'nursing initiative'. Medical and allied health professional input declined over time and the workload was disproportionally being shouldered by individual Ward Managers (managerial nurses) who were for the most part already overloaded in their daily clinical roles.

Furthermore, an assumption was that a tight, coherent and most importantly *consistent* group of staff would engage with the intervention throughout the 14 months of staff involvement. In reality, staff movement around the NHS estate was high. This led to difficulties regarding ownership of action planning with some staff reluctant to proceed with action plans devised by their predecessors and others not believing it was worth the effort to become involved in the study if they were moving on shortly. A few ward teams changed their personnel completely between phase one and two of the study due to managerial reorganisation:

> *A massive change in staffing took place around the latter part of Phase one with a new Ward Manager and 80-85% change in ward staff. The second phone interview revealed that other ward initiatives were taking place…the whole PRASE process was never wholly embraced because of intense ward improvement work, and staff flux, taking place at the same time (Chestnut ward, Trust C)*

It was never anticipated that such wholesale change would take place at the level of the individual ward teams within the lifetime of the trial and the intervention was unprepared for this. There was little formal capacity to continually re-introduce PRASE to new ward staff, despite researchers having to perform this ad hoc and unexpected role. Critically, it points to ownership of the intervention on the ground as a key factor in success. The implementation

of the intervention becomes weak if it is passed around large numbers of different staff or if staff groups change on a dramatic scale.

3. Standardisation of facilitative processes by the research team does not necessarily ensure implementation standardisation by ward staff

A key intention of the facilitative processes was to ensure standardisation of implementation by ward staff. The process evaluation found that, in reality, these uniform training and facilitative processes resulted in little standardisation of approach to action planning regarding a) the issues which staff chose to focus on or b) whether the action plans were successfully implemented (or not). Our pen portraits point to three main issues that appear to underpin why:

- Implementation of action plans were often related to buy in and collegiate working with other departments, some of whom were not willing to spend time, resource and effort on an issue which was not their own
- Existing pan-Trust safety and quality campaigns were prioritised over and above PRASE, to differing degrees which variably helped or hindered PRASE intentions
- Success was often the result of a complex interplay between the personal will of the staff involved in the APG and whether the study fitted into current ward priorities

The following pen portrait excerpt from Apple ward exemplifies the first identified issue regarding buy in from other departments. This ward had several negative comments from patients that pain relief was not being given in a timely manner. To address this, the APG decided they needed assistance from pharmacy but this was not forthcoming and APG members were disappointed. This led to the contradictory position in phase two of engagement still being very present but the act of action planning itself becoming tokenistic:

> *This ward stayed engaged with the project the entire way through despite setbacks with their earliest action plan. The ward manager in particular clearly understood the purpose of the study and was sympathetic to receiving patient feedback. However, inertia may have crept in as their 'outside the box' thinking in phase one did not get any buy in from the pharmacy department. Action planning in phase two then became perfunctory even though engagement was still high (Apple, Trust B)*

The second issue of other safety campaigns being prioritised above this study relates to the capacity with which ward staff have within their normal clinical roles to be able to undertake improvement work. In several of the pen portraits, PRASE was described as "just one of many improvement initiatives which this ward are involved in". Wards were under pressure to take part in hospital wide initiatives that executive teams had deemed to be of most importance. Whilst there was senior support for PRASE, it was not always significant in comparison to other initiatives. In some cases, the existence of other high profile campaigns supported staff in achieving their PRASE action plans. Trust C launched a well-received "Hello my name is…" patient experience campaign tying into a national acknowledgement of the need for staff to introduce themselves and communicate better with patients at the bedside. On the wards where PRASE feedback had also drawn attention to this need, staff were supported to respond (through badges, awareness training and senior-support) to do so.

However, the flip-side of attention on more high-profile campaigns meant that – for some wards – PRASE became sidelined. Associated with this was a feeling of patient safety and quality 'fatigue' with the amount of initiatives in this area felt too numerous and therefore burdensome on staff time:

> *I got the sense that the ward manager saw PRASE as just another audit which she needed to go through the motions of….At one point during phase two, she admitted that in phase one she did not see the value in the study as she thought it just*

replicated other patient experience measures her ward is involved in. However, now she appreciates how it is different from the other measures... Working out where PRASE fitted in with other initiatives seemed to be a big issue for this ward manager (Pine Ward, Trust B)

One strong finding to emerge was the use of PRASE data to reinforce safety or quality issues which the ward staff knew about tacitly but did not have robust data about in order to report to senior management. This finding emerged as a divisive issue. Some wards were pleased that the PRASE study reinforced staff opinion about the ward or validated on a larger scale the results of local audits. However, a minority of staff became irritated and instead chose to view it as duplication.

DISCUSSION

As introduced at the outset, some process evaluations are able to reveal specific 'pinch points' within the intervention itself [13], or within the overall context in which it was applied [14], which help to explain why no effect was seen. Context (internal and external) is said to be one of the most important determining factors in whether interventions are able to show an impact or deliver progress [19]. Our process evaluation found that context was so varied within the intervention group that this led to a general 'dilution' of intervention implementation. We found striking differences in the culture, working arrangements and issues facing individual wards (even within the same Trust), and significantly, changes to these contexts over time. The in-depth analysis of what happened within the intervention group generates useful insights for implementation of patient safety initiatives, to which we will now turn our attention.

The improvement of patient safety is already acknowledged as a cultural issue and the importance of factors such as teamwork, leadership and organizational processes operating at and between multiple levels [20]. Navigating this territory - particularly the link between 'sharp end' ward safety initiatives and 'blunt end' corporate planning - has been documented as a necessary challenge. Initiatives which do not pay adequate attention in this regard are at best destined to fail, and at worst may over-burden already de-motivated staff [21]. The facilitative processes incorporated into PRASE were designed to help address this challenge. The assumption was that by providing these processes – access to senior management at regular intervals and assistance in interpreting patient feedback - staff would be better placed to successfully navigate this complex organizational territory. It was anticipated this would allow some uniformity amongst the intervention group. In actuality, the facilitative processes were not adequate to ensure any such uniformity.

Context inside an organisation is said to have a powerful effect on the delivery and adoption of an intervention [19]. In this study, the relationships between different parts and levels of the organization from senior management to ward teams to individuals were vital in achieving success. When these levels align well, as they appeared to do in one Trust - with respect to a culture shift around introducing and communicating to patients via an external patient experience campaign - it appears that much can be achieved. When they do not – e.g. Apple ward who did not get buy in from the pharmacy department - staff at the ward level can become frustrated and demotivated. We therefore question the capacity of an externally designed intervention, even one with significant resources and facilitative processes, to provide the mechanisms to be continually adaptive to the organisational alignment between the sharp and blunt end at differing institutions. The challenges revealed here are about deeper organizational culture, systems and processes that need longer-term development.

Our findings support the growing understanding that emphasis in patient safety research must continue to shift from the measure and manage orthodoxy of data collection to interpretation and process [10]. In this research, the collection of patient feedback was the

least problematic element. The complexity of what staff are being asked to do in interventions like PRASE (navigating multi-layered organizational systems to implement improvements) requires much more consideration. In the broader but related policy area of patient experience, the overt emphasis and huge resource allocated to collecting patient experience data has not been matched by efforts to utilise and evaluate the impact of feedback on service improvement [22]. There is increasing recognition that using data sources to change practice demands creativity and skills from staff; hence the tendency to present staff with data and expect change to happen as a result [23]. Our intervention considered these issues a priori and hence facilitative processes were built into the trial yet they were not sufficiently robust enough to ensure a standardised implementation across intervention wards.

One interpretation of PRASE could be that it 'failed' due to showing no effect between the intervention and control wards. We believe this a simplistic view which does not take into account the wealth of positive benefits which patients and staff gained. Firstly, it showed that patients are able to give feedback about the safety and quality of care and that they want to do this en masse (our consent rate was 85% of those patients approached by researchers). Secondly, the process evaluation showed that most staff *do* believe the patient voice is important and there is an imperative to listen to, and act on, this voice. Thirdly, despite local struggles, most staff do want to action plan to improve their patients' care. An additional gain which some staff identified was the ability of the patient feedback to allow staff to understand not only the patient perspective but also their priorities and to visualise the ward environment and systems 'through the eyes of the patient'.

Limitations

The qualitative data was collected during the life course of the trial and this raises important points about whether positive attitudes towards patient involvement in patient safety would continue and even strengthen on the intervention wards after the trial was completed. Improvements that staff were working towards may have gained impetus since the research team left. Equally, involvement in the trial may have kick-started ideas which, although did not come to fruition within its life span, may now be fuelling ward level action. Conversely, staff may have felt disempowered to enact improvement to the ward environment if their PRASE action plans had floundered. We have no format for measuring this 'after effect' – either positive or negative – and little scope for knowing at what time point the evidence of a more long lasting effect may be captured.

Our pen portrait methodology is a culmination of all sources of qualitative data collected and has its inherent weaknesses. This methodology is still in its relative infancy in relation to the way in which we have utilised it here. We were careful to draw equally on all sources of data in order to build a comprehensive narrative of the engagement trajectory of each ward. However, a differing analysis paying attention to fewer sources or an unequal weighing of sources may have pulled the narrative account in a slightly different direction. Further, it was difficult to categorise some wards firmly into their allocated engagement typology and arguably some could fit into several. Finally, process evaluation methods were developed a priori to the start of the trial so the design was very open. We devised a loose structure to capture qualitative intelligence on key trial processes. If prior knowledge existed that diversity of engagement within the intervention wards was to be so significant, it may have been possible to target a particular process evaluation framework for analysing outcomes in relation to this diversity, such as the 'diffusion of innovation model' [24]. It is a possibility that utilisation of differing methods may have provided other answers as to where different elements of the intervention worked, for whom and why.

CONCLUSION

Whereas previous process evaluations point towards specific pinch points or broader cultural issues to understand why an intervention showed no effect, this study points to an overall 'dilution effect' of the intervention. This was largely due to wards interacting with the intervention in highly divergent manners despite the standardisation of key components by the research team. Other factors of importance were facilitative processes being inadequate in order to fully embed the intervention in its setting and context. A disconnect existed between senior management support for the study and how ward staff on the ground engaged with it more locally. The above findings assist in explaining why the trial saw no effect between intervention and control wards.

DECLARATIONS

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Competing interests

The authors declare they have no competing interests

Authors' contributions

RL, GA and JW are grant holders of the programme grant. LS devised the methodology of the process evaluation and wrote the qualitative protocol, with assistance from CM. LS, CM and JOH all collected data. LS and CM analysed and interpreted all data, with intellectual input from GA. LS and CM co-wrote the first draft of the paper. All authors edited the first draft of the paper. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by South Yorkshire NHS Research Ethics Committee on 15th March 2013 (Ref: 13/YH/0077). All participants gave informed consent to take part in this study.

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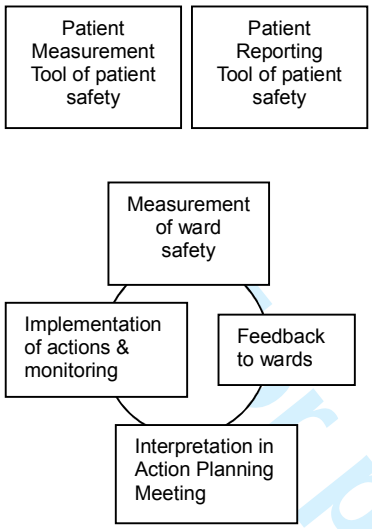
Appendix 1- Intervention summary

Cyclical Activities	***Facilitative Processes***	***Anticipated outcomes***
	Trust-level sign up 'Independent' collection of patient feedback on safety by research team 'Independent' production of feedback reports by research team Ward peer training Facilitated action planning	Improvements in patient safety at a ward level measureable by: Routinely collected data e.g. Patient Safety Thermometer PRASE measures Staff patient safety culture staff survey

Appendix 2: Content of key intervention components

Cyclical Activities	***Facilitative Processes***	***Anticipated Outcomes***
The key activities that comprise PRASE are the measurement of patient feedback using two tools. The first is the Patient Measure of Organisational Safety – PMOS - a 44-item questionnaire which asks patients at the hospital bedside about safety concerns and issues [5, 6]. The second is a reporting proforma for patients to provide detailed safety incidents or positive experiences [7]. The questionnaire items are theoretically-informed from a systems understanding of patient safety whereby experience of care is understood to arise from a complex interaction of factors that include staff team-working and access to resources as well as more traditionally-considered factors such as the physical	The design of PRASE recognises that ward staff need support to implement the intervention. An understanding of the facilitative processes required was derived from a pilot study where the intervention was tested on six wards at a medium-sized Teaching hospital, prior to finalising its design [7]. Specific facilitative processes involved are: - Independent collection of patient feedback by the research team to enable not only objectivity but from a resource and logistics viewpoint as ward staff do not have the capacity to collect this data themselves - Independent production of feedback reports by research team - Negotiation with senior management by the research team to embed the intervention into usual practice - Ward staff training in interpretation of data and role playing of optimum action planning to enable them to tackle systemic issues effectively - Facilitation of the action planning meetings by a senior researcher to i) convene the meeting ii) encourage ward staff to devise action plans which tackle	It was hypothesized that the intervention would lead to safety improvements in terms of both ward culture and ward performance (distal outcomes) alongside a development of a shared, collaborative understanding of the patient's perspective of safety (proximal outcomes). For more detail on this, see Figure 2: Logic Model, which outlines the programme theory of the PRASE

environment. After patient feedback has been collected it is collated and presented in a feedback report to each ward. Ward staff are then asked to interpret this feedback to identify and target areas for improvement. A multi-disciplinary team (MDT) approach is considered essential for enabling the root causes of, often systemic and complex, issues to be effectively addressed. Finally they are asked to implement agreed action plans and monitor progress in a cyclical manner.	systemic issues and discourage concentration only on short-term, simple solutions where this would be inappropriate to do so -Motivation of staff and cross team learning and support via the format of three pan Trust meeting involving representatives from the hospital executive team (Start Up meeting pre-trial, Mid-Point meeting half way through trial, Closing meeting after trial has concluded)	intervention. (see Appendix 5)

Appendix 3: Trial design and results

Trial design	***Trial results***
PRASE was trialled within a multi-centre, cluster, randomised controlled design. The study was undertaken across 33 hospital wards in three NHS Trusts (five hospital sites). Seventeen wards were randomly assigned to an intervention group and 16 wards to a control group. Feedback was collected from approximately 25 patients per ward, collated and fed back to staff for interpretation and action planning. This whole process was then repeated in a second cycle so staff were able to see changes to feedback over time. The study was powered to detect a small to medium difference (0.3) between the intervention and control groups with respect to a Primary Outcome which was the Patient Safety Thermometer (PST). PST data is routinely collected from every ward in England on a monthly basis and reports on harm free care associated with: i) pressure ulcers, ii) venous thromboembolisms, iii) catheter associated urinary tract infections and iv) falls. PMOS was chosen as a secondary outcome. This was obtained twice from the intervention wards within their intervention cycles. It was also taken at the same three time points in the control wards.	No significant effect of the intervention between the allocation groups was found for either of the primary outcomes PST (p=0.98) or PMOS (p=0.09) at 6 or 12 months, nor other secondary outcomes. However, a post hoc analysis on new harms (contained in the PST) found a non-significant increase in harm free care of 1.60 for intervention wards over control wards. All wards were retained throughout the trial. Patient response rate for completing the PMOS tool was 86%. Considerable further detail about the trial results can be found elsewhere [9].

Appendix 4 - Beech ward pen portrait

Facilitator's field notes

Phase one – This ward manager (WM) is exceptionally open to receiving patient feedback, wants to improve patient safety and experience on the ward and convened a small group of staff to discuss the feedback report. However, the other staff had not read the report and had been "pulled off" the ward to attend the meeting. The ward manager was engaged with the process but was very pressed for time and had accidentally double booked himself between the PRASE meeting and an infection control meeting. WM remarked that he had found the PRASE data useful and he listened to the opinion of his staff members when they put forward suggestion for change.

Taped APM discussion

The APG ended up making quite a lot of discussion about what looks on the surface to be not a lot of data i.e. little context to guide PMOS scores. Despite a lively discussion, one of action plans was a quick fix – to put boards up in the bays which showed staff photos with names and to have a board which shows all the different colour tunics.

Follow up phone interviews

The follow up phone interview found that this action plan had been achieved but that was due to a Trust wide initiative being implemented about the same issue rather than any effort on behalf of the ward.

Taped APM discussion

The other action plan was more far reaching and related to noise at night and re-educating staff to be quiet on the night shift. The WM intended to use the PRASE data from patients to let staff know how much noise at night bothered the patients and kept them awake during the night.

Follow up phone interviews

Instead of trying to enact this cultural change, the WM stated in the phone interview that he had found this too difficult and instead had ordered soft closing bins, checked the doors for soft closing and had looked into muting the buzzers (but had not done this as it created another patient safety problem). The WM noted in his phone interview that he found the orientation meeting useful and fully understood the aims and purpose of the study and his role in it as a result of attending this meeting. He also noted that some staff on the ward were aware of the study but it was hard to engage the majority of staff

Facilitator's field notes

Phase two – This APM was with just the WM who remained very enthusiastic towards the study and engaged with it on a personal level. The WM explained that he had wanted other staff to be at this APM but the ward was very short staffed that day. The WM had read the report carefully and thoughtfully and had already come up with several action plans which he wanted to enact as a result of the phase two data. His mood was very positive towards the study and he mentioned several times that he very much valued getting data back from his patients. The WM even said that he had been comparing the comments made in the feedback report with the comments made by patients in the Friends and Family test.

Taped APM discussion

The WM identified that the main issue was still noise at night and he decided to develop a newsletter to go out to all staff about the implications of noise at night for patients.

Follow up phone interviews

In the phone interview, the WM said that other priorities have led to this one sliding and that the Trust is more interested in cannulas and pressure sore prevention at the moment. This WM seems to really want to sort this issue out but is being prevented by external pressure from management to focus on other issues.

Taped APM discussion

The two other substantive action plans made were about contacting estates to see if something can be done about temperature extremities (this was achieved although unsure if estates had been out to rectify it) and to ask people at the senior sisters meeting what other wards were doing about when patients did not known who their consultant was. The latter had not been

Follow up phone interviews

done as the last two senior sisters meetings had been cancelled. The WM further reflected whether it was just down to patients forgetting who their consultant was.

Follow up phone interviews

The WM attended the midpoint meeting and stated in the phone interview that he found it really useful. Part of this was having the Chief Nurse there and being able to discuss some of the problems which had been verified by the study directly with her. It was felt that having such a high level input was really good as it is rare that this happens. When asked about staff engagement with PRASE, the WM said that the study is regularly mentioned at staff briefings and there are numerous posters up. He feels confident that all the sisters know about the study but isn't sure about staff nurses and HCAs. He had a clear understanding of the study and why this was an important issue. He remarked to the phone interviewer that taking part in the study and receiving the patient feedback had been "invaluable" to him and praised the study design, methods, senior research fellows and fieldworkers.

Engagement profile: This ward is led by a nurse who is exceptionally well engaged with the study on a personal level and completely understands the aim and purpose of it. He attended every meeting asked of him and contributed heartily to them. However, the action plans made were – at times – weak and partially unrealised. **Engagement strong throughout, despite setbacks in action planning.** It is useful to state that engagement may have been consistently strong as the ward manager himself had a clear interest in improving patient safety, quality and experience and took part in all study components due to a personal interest.

Appendix 5 - Logic Model: The PRASE Intervention

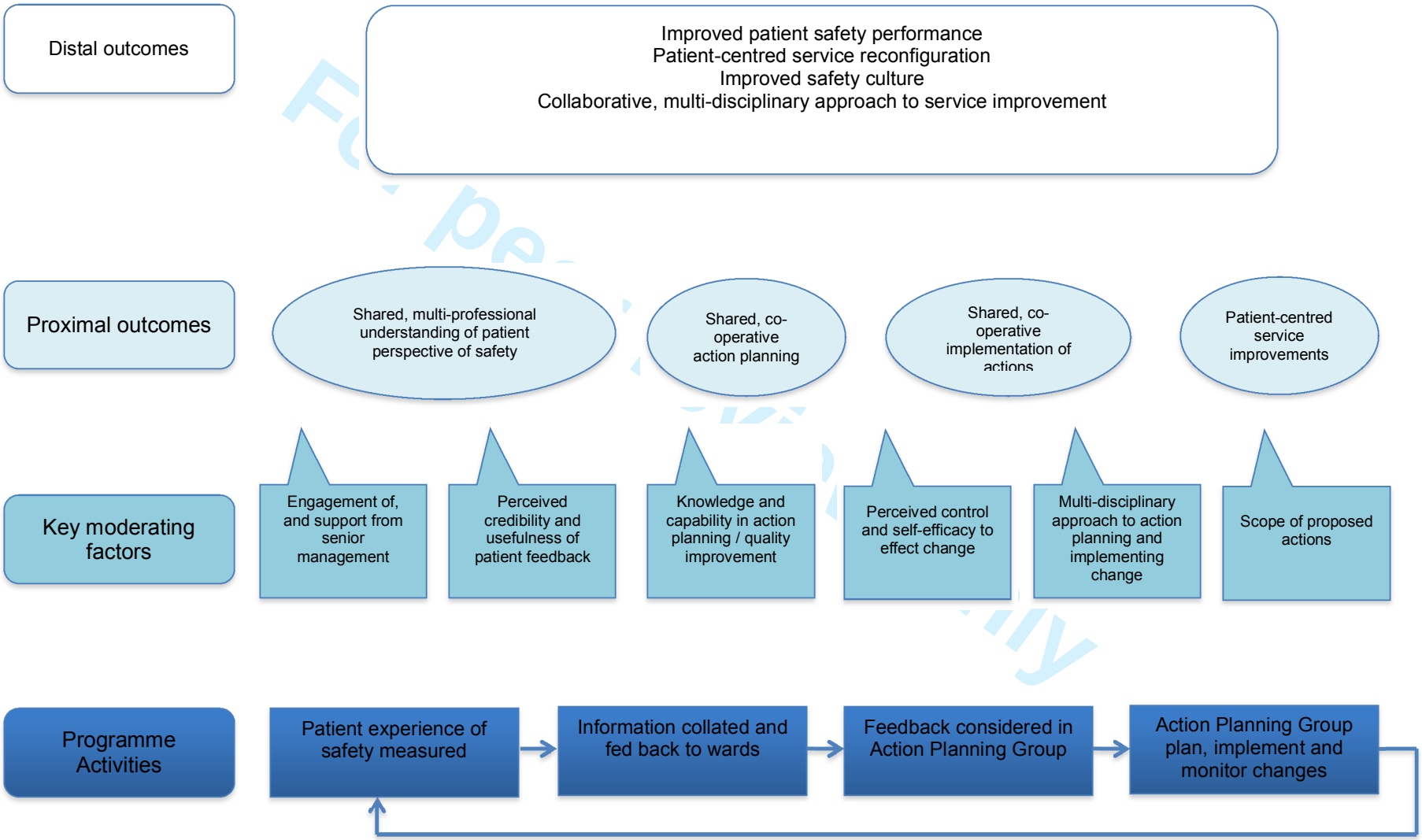
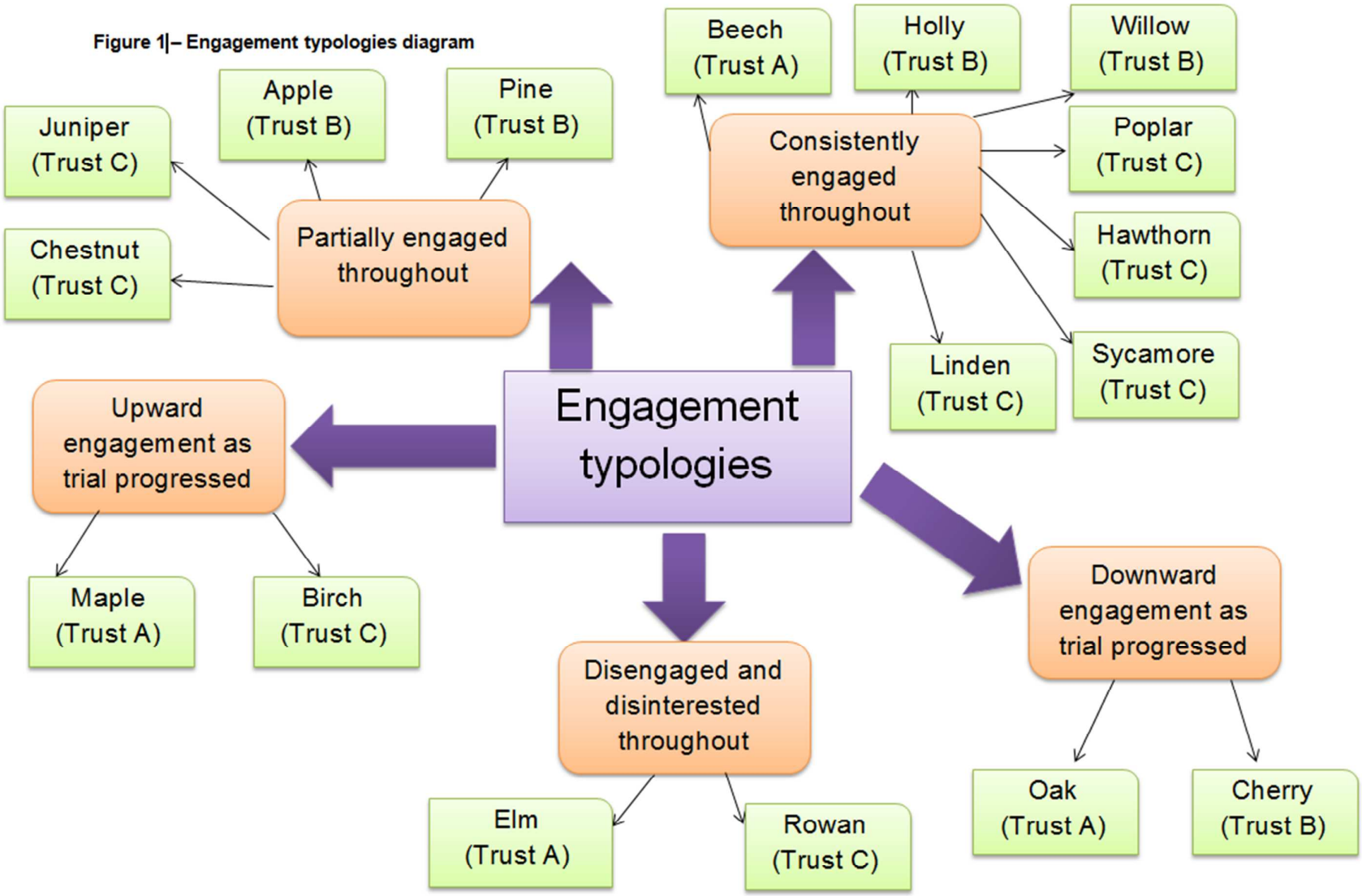


Figure 1|– Engagement typologies diagram



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Exploring how ward staff engage with the implementation of a patient safety intervention: A qualitative process evaluation

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Exploring how ward staff engage with the implementation of a patient safety intervention: A qualitative process evaluation

Laura Sheard
laura.sheard@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Claire Marsh
claire.marsh@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Jane O'Hara
jane.o'hara@bthft.nhs.uk
Bradford Institute for Health Research & University of Leeds, United Kingdom

Gerry Armitage
g.r.armitage@brad.ac.uk
University of Bradford, United Kingdom

John Wright
john.wright@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Rebecca Lawton
r.j.lawton@leeds.ac.uk
Bradford Institute for Health Research & University of Leeds, United Kingdom

Corresponding author:
Laura Sheard
Bradford Institute for Health Research
Bradford Teaching Hospitals
Bradford Royal Infirmary
Duckworth Lane
Bradford
BD9 6RJ
United Kingdom

ABSTRACT

Objectives – A patient safety intervention was tested in a 33 ward randomised controlled trial. No statistically significant difference between intervention and control wards was found. We conducted a process evaluation of the trial and our aim in this paper is to understand staff engagement across the 17 intervention wards.

Design – Large qualitative process evaluation of the implementation of a patient safety intervention.

Setting and participants – NHS staff based on 17 acute hospital wards located at five hospital sites in the North of England.

Data – We concentrate on three sources here: i) analysis of taped discussion between ward staff during action planning meetings ii) facilitators' field notes iii) follow up telephone interviews with staff focussing on whether action plans had been achieved. The analysis involved the use of pen portraits and adaptive theory.

Findings – First, there were palpable differences in the ways that the 17 ward teams engaged with the key components of the intervention. Five main engagement typologies were evident across the life course of the study: consistent, partial, increasing, decreasing and disinterested. Second, the intensity of support for the intervention at the level of the organisation does not predict the strength of engagement at the level of the individual ward team. Third, the standardisation of facilitative processes provided by the research team does not ensure that implementation standardisation of the intervention occurs by ward staff.

Conclusions - A dilution of the intervention occurred during the trial because wards engaged with PRASE in divergent ways, despite the standardisation of key components. Facilitative processes were not sufficiently adequate to enable intervention wards to successfully engage with PRASE components.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- We devised a process evaluation that had several robust qualitative data collection methods which complemented each other, in order to build a comprehensive and holistic picture of how ward staff implemented the intervention
- Our approach allowed us to reveal how the differing ways in which staff teams engage with the intervention may impact on patient safety changes at a ward level
- Our novel analytic approach utilised pen portrait methodology in a differing way to how it has previously been used in health services research, in order to document the journey of 17 wards interacting with an intervention over an 18 month period
- We have little understanding of whether the implementation of PRASE may have gained traction and fuelled subsequent ward based change once the research team left the field
- The qualitative methods we chose were designed to capture a broad understanding of the contexts in which the intervention was implemented but had we known a priori that engagement was such a significant factor, we may have designed the process evaluation to specifically explore its influence.

BACKGROUND

Measurement of patient safety has traditionally relied on information from staff such as incident reports or recording information about harms such as falls or pressure sores. Recently, patients have been emphasised as being an important detector for patient safety and likened to the 'smoke detectors' of safety [1]. There is an increasing recognition that hospitals need to find better ways to capture and respond to the concerns of patients regarding the quality and safety of their care [2-4]. However, patients are rarely asked about structural or procedural aspects of care which may contribute towards failures in patient safety. The Yorkshire Quality and Safety group have developed a patient safety intervention called Patient Reporting and Action for a Safe Environment (PRASE). This intervention firstly elicits patient perceptions on how a ward is performing on a series of issues which are known to contribute towards patient safety incidents and secondly assists staff to interpret patient feedback to aid service improvements. This paper provides an account of a qualitative process evaluation of a randomised controlled trial (RCT) where PRASE was tested. PRASE was designed [5, 6], tested for feasibility [7] and trialled [8, 9] between 2010 and 2015. This period has been charted as an era of paradigm shift for patient safety research when the dominant 'measure and manage' orthodoxy has been enriched by approaches sensitive to setting and socio-cultural/ political influences [10]. It became essential for a process evaluation to capture the nuances involved in the PRASE implementation.

Process evaluations have been used to explain sub-optimum outcome effects, specifically whether there was a 'fault' with the intervention itself, its key components or with delivery [11]. Latterly, they are often not only concerned with adherence to original plans, but also with broader issues such as unintended consequences or the strengths and weaknesses of the intervention itself [12]. Some process evaluations have been able to identify a precise 'pinch point' or problem with an essential component of the intervention that caused it to fail. In a UK trial of peer led HIV prevention for gay men in London, no effect was shown. A qualitative process evaluation [13] revealed that the essential component of 'peer educator' had not played out as intended during the course of the trial due to recruitment problems and the inability of peer educators to confidently communicate harm reduction messages to intended targets. Other process evaluations have been able to point to more general cultural or structural reasons why an intervention may not have succeeded. Dixon-Woods et al [14] evaluated why a U.S. developed patient safety intervention - regarding decreasing central line infections in intensive care units – struggled with implementation after the intervention was transferred to a U.K. setting. A post-hoc qualitative evaluation revealed multiple reasons why, largely the result of cultural differences between the U.S and U.K. settings. It is clear from these examples that process evaluations can support the largely 'experimental' aim of RCTs by identifying specific 'pinch points' within an intervention itself or within the context that will help to explain success or failure.

The components of the intervention have been reported in detail elsewhere [8], and the results of the randomised controlled trial which demonstrated no statistically significant effect between the intervention and control wards [9]. A feasibility study was undertaken prior to commencement of the full RCT and details of our logic model and moderating factors are reported in the feasibility write up [7]. Here, we provide a synopsis of the intervention and results of the trial for the reader to be able to view our process evaluation in context. Appendix 1 provides a detailed summary of the cyclical activities and facilitative processes of the intervention that were trialled, alongside anticipated outcomes. Appendix 2 describes the trial design and results. Briefly, this was a cyclical study with two phases of: i) collecting patient feedback about safety from patients at the bedside ii) collation of this data and ward staff interpreting it iii) ward staff action planning to improve patient safety iv) plans then being implemented and monitored.

METHODS

We conducted a robust process evaluation involving differing qualitative and quantitative methods [8] which gathered comprehensive data about all 17 intervention wards. We drew upon a published framework [12] for designing process evaluations of cluster randomised controlled trials. The main a priori research question was: 'where does the intervention work, how and why?' [8]. In this paper, we have chosen to focus on the 'how?' and 'why?' and present a detailed picture of how staff engaged with the intervention. We now apply our original research question to understand how and why the intervention did *not* work, given the intervention did not have a significant effect on outcomes. Six mixed methods were used in the wider process evaluation but due to the extent and depth of the data collected, we focused intensively on three qualitative methods for the purpose of this paper. The methods described below are those most pertinent to exploring how staff engaged with the intervention in the ways they did, and why. Data was collected between August 2013 to November 2014. NHS ethical approval was granted in March 2013.

1. In depth analysis of taped discussion between ward staff

Action planning meetings (APMs) were digitally recorded for all 17 wards at both phases. At phase two, one ward did not meet so we considered the recordings of 33 APMs. These ranged in length from 27 to 80 minutes (average 43 minutes). Our examination focused on which areas of patient feedback staff chose to make action plans on and which areas they chose not to. We wrote detailed notes whilst listening to the voice file. We structured our notes under the headings: i) Issues seen as important where actions were made (and why) ii) Issues seen as important where no actions were made (and why not) iii) Issues dismissed and reasons for this iv) Comments made by staff about PRASE process/ study/ team v) Comments made by staff about the ward or hospital context.

2. Facilitator's field notes

These notes were written shortly after the APM had finished and captured: i) implicit dynamics between staff, such as body language, tone of voice and other non-verbal cues ii) environmental factors, such as descriptions of the physical space where the meeting was held iii) facilitator's overall impressions. Field notes were brief and gave a 'snapshot' of the meeting. There were three facilitators across the 17 intervention wards and each facilitator worked with the same wards across both phases of the study, to ensure continuity.

3. Follow-up telephone interviews conducted with the APM lead

The purpose of these short, structured phone interviews was to ascertain whether action plans had been successfully implemented or not and why. They were conducted around six months after the APM, with the 'PRASE lead' for each ward. Each ward was responsible for nominating a named member of ward staff - who was part of the action planning meeting - to be the PRASE lead. This could be any member of the team but was more often than not the person who volunteered for the role was a senior nurse. A structured interview guide was used. Researchers had a proforma in front of them which contained details about each action plan per ward and they asked the PRASE lead whether each action plan had been implemented – yes, no or partially. Open questioning then continued to understand the factors surrounding this. Five additional questions were asked which focussed on the PRASE lead's opinion of the facilitative processes embedded in the study.

For the purpose of this paper, we wanted to understand **qualitatively** how wards had engaged (or not) with the PRASE intervention. Implementation fidelity (which captures adherence to specific intervention components) is reported quantitatively elsewhere [9]. Engagement of staff with an intervention can be considered as closely aligned but different from this, referring more to the differing approaches and attitudes that staff take to the task in hand (implementation of different components of the intervention). This is different to whether they have simply delivered the task or not. We decided not to adhere to a numerical/scale definition of 'engagement' whereby differing wards attained a binary

definition of either 'engaged' or 'disengaged' with the intervention. Instead, we undertook a nuanced analysis of staff approaches and attitudes to: conducting an action planning meeting, creating quality action plans and implementation of these action plans. We explored 'engagement' as a concept that we define as the 'depth' and 'nature' of ward teams' approaches and attitudes to the intervention.

Informed by this understanding of engagement, a synthesis of the above data sources has provided us with a rich account of the '**engagement trajectory'** of each ward and this was realised by creating a pen portrait of engagement. Pen portraits have been used previously in applied health research in fields as diverse as: end of life care [15], vulnerable old people being enabled to keep warm in their homes [16] and sleeping practices amongst homeless drug users [17]. Previously, they have provided a narrative account of a 'typical' participant in qualitative studies or as an analytic aide memoir. We used them in a slightly different manner to document the 'journey' of the wards throughout the trial from the perspective of the researcher who had worked closely with these wards for over 18 months. There is a lack of methodological literature pertaining to the construction of a pen portrait and this has been left to the discretion of individual research teams. We created a basic structure for the pen portraits which centred on the writing of a linear, longitudinal account of how each ward had engaged with relevant key components of the intervention and the contextual factors which influenced this, ensuring that all three data sources were drawn upon. We did not use an existing theory or framework on which to extract the data for the pen portraits as we wanted the emergent findings to arise inductively from the data set. As staff engagement was our focus, we included as much material on this as possible (along with explanatory factors and necessary description). We excluded minutiae which did not add to the 'big picture' of the ward team's engagement to maintain a focussed pen portrait. The pen portrait for Holly ward is shown in Appendix 3 with the prose annotated as an illustration of how portraits were constructed from the three data sources outlined above.

Researchers took into account all the information contained within the pen portrait and attributed an overall 'engagement trajectory' label to each ward. Author A wrote all pen portraits for Trusts A and B and Author B for Trust C. We categorised the 17 different ward engagement trajectories into five main 'engagement typologies', which emerged from an analytical session centring mainly on consensus discussion between Author A and Author B. We report three overarching themes in this paper, which are described in detail in the Findings section which follows. The above categorisation of engagement typologies led to the content of the first theme. After we were confident of the findings of this first theme, we then used the differences in engagement detailed in this theme to progress to themes two and three. To achieve this, we looked between and across the engagement trajectories of all 17 wards in order to understand how engagement with the intervention related to components of local implementation. We returned to the detail of the pen portraits to understand commonality and difference and from this we developed the coding framework for themes two and three. We then checked our assumptions by testing the data in the pen portraits against our initial coding framework. After minor adaptions, we then coded the data in all 17 pen portraits. Overall, we used techniques derived from 'adaptive theory' [18] which allows for high level frameworks and conceptualisations to emerge from data rather than descriptive themes. Adaptive theory proposes a continual engagement between the arising empirical data and arising theoretical interpretations of the research, working in a continuous cycle with each cycle generating new explorations.

FINDINGS

We now set out to understand the ways in which the 17 intervention wards engaged with the intervention. We are interested in how a multiplicity of engagement styles could have made an already complex intervention become hyper complicated in its implementation phase. This 'hyper complexity' may have served to dilute key elements of the intervention. By 'dilution' we mean 'non-standardisation' of the intervention group, thereby reducing the potential for this to be meaningfully compared with a control group. We explore three high level themes, which emerged from the data. Firstly, we will describe how there were palpable differences in the ways that ward teams engaged with the intervention. Next, we will look at how support for the intervention at the level of the Trust does not indicate ward level support. Lastly, we will demonstrate that standardisation of facilitative processes by the research team does not ensure this filters down to implementation standardisation by ward staff. All quotation extracts are taken from pen portrait notes and all ward names have been ascribed a pseudonym.

1. The same intervention can be interacted with in highly divergent ways

We were able to distinguish the intervention wards into five main 'engagement typologies' (Appendix 4). They are:

- Consistently engaged throughout (7 wards)
- Partially engaged throughout (4 wards)
- Increasing engagement as trial progressed (2 wards)
- Decreasing engagement as trial progressed (2 wards)
- Disengaged and disinterested throughout (2 wards)

Consistently engaged – This represents the largest category of how wards chose to participate in the trial with 7 out of the 17 residing here. These wards were fully signed up to the ethos of listening to and acting on patient feedback. They took part in a high proportion of the key components of the cyclical activities and made quality action plans which were largely implemented in both phases. A quality action plan can be defined as one which seeks to address issues identified in the patient data and was realistic, relatively timely and more than likely to be achieved. Motivation to take part in the research was high and improving patient safety was even higher.

Partially engaged – These four wards generally did everything asked of them by the research team and largely participated in intervention components but were sometimes lacklustre in their motivation towards improving patient safety. At times, it felt like action planning was just 'going through the motions'. The ability of staff to implement action plans was mixed although this was sometimes due to external factors rather than inertia on the part of the ward staff themselves.

Increasing engagement – These two wards began their involvement with the trial in an ambivalent and – in the case of Maple ward – even hostile manner. However, as the study progressed and the ward staff began to understand what the research team were trying to achieve, engagement with the study solidified. The similarity between these two wards (despite being at different Trusts) is that the turning point for their engagement was attendance at the peer centred Mid-Point Meeting. This is reflected in Maple ward's complete U-turn with implementation of quality action plans at phase two as compared with partial implementation of weak action plans at phase one.

Decreasing engagement – Conversely, another two wards engaged with the study relatively well at the beginning but, over time, slipped in their level of interest and involvement. Cherry ward is the only ward across all 17 who did not meet in an APM in phase two. The follow up telephone interview revealed that the ward manager for Cherry did not believe the study was a priority. Oak ward had ambitious plans for their phase one action planning but had become

dejected by the amount of time their plan was taking to come into effect. Subsequently, they declined to make an action plan in the phase two APM and appeared disinterested in the study.

Disengaged and disinterested – Although these two wards met in APMs for both phases of the trial, they were not interested in using the PRASE data to improve patient safety and viewed the study as a burden. However, the reasons for this response differed. Rowan were a low performing ward whose ward manager preferred to concentrate on the other initiatives rather than our research study. Elm ward were outwardly hostile to the ethos of the study, critical of the comments their patients had made to researchers and defensive of staff members. Despite agreeing to hold an APM, they consistently refused to make action plans.

Through an examination of these differing engagement trajectories, we can unpick where parts of the intervention may have led to divergent strategies for local implementation of the intervention on a ward-by-ward basis. These findings from 'on the ground' implementation by ward teams directly contradict some of the core assumptions held by the research team at the outset of intervention development - namely, that by providing facilitative processes, wards would be able to implement in a uniform manner. It is this aspect of a chasm between implementation expectations and reality which we now turn our attention to.

2. Trust-level support for an intervention does not predict the strength of ward-level engagement

A key assumption was that strong corporate, managerial-level support by the three participating Trusts would facilitate high-level engagement by wards. However an examination of the differing types of engagement trajectories, shown in Figure 1, throw doubt on this assumption and we can find little consistency in engagement style between the wards at the same Trust. For instance, Trust A is a small district general hospital in a semi-rural, affluent area. This Trust prides itself on being a forward thinking, cohesive workplace and senior management support for this intervention was exceptionally strong. However, when reduced down to the level of the ward, we can see that the four intervention wards at Trust A are represented across four distinct engagement trajectories (Consistent = Beech, Increasing = Maple, Decreasing = Oak, Disengaged = Elm). Engagement trajectories for each of the other two Trusts also differed considerably by ward. The implication here is that corporate culture - and receptivity to patient feedback at the level of the organisation - is not a simple predictor of engagement at ward level.

Unpicking these differences further, we find that despite a uniform message about the importance of a multi-disciplinary approach to the study, wards seem to have interpreted this differently. Oak ward convened a strong first multi-disciplinary APG with representatives from nursing, allied health professionals and support staff. In contrast, on some wards PRASE remained led and implemented by just one or two nursing staff. For example, Maple's first APG consisted of just the ward manager and pen portrait notes illustrate why:

> *A very tense meeting held with just the ward manager who appeared overtly stressed and about to implode. It was clear at this first APM that the ward manager had not understood the purpose of the study and became upset by some of the negative comments which her patients had made in the report. It was a difficult APM to convene as the ward manager thought she had to solve everything by herself and this was partially reinforced by the fact that she had not invited any of her staff to the APM (Maple, Trust A)*

The research team never envisaged that the intervention would be taken on by just one or two members of ward staff and this was actively discouraged throughout but still persisted in five wards at phase one and six wards at phase two, across the 17 intervention wards. It is difficult to suggest a clear reason why this happened but it was often related to:

- Front line issues, such as no staff available to be released from direct patient care to attend APG
- A minority of ward managers viewing the study as yet another patient safety initiative that they just needed to 'get on with'
- A misunderstanding of the multi-disciplinary nature of the intervention.

Of most interest is the severe paucity of medical staff involved in the intervention with only four wards (all at Trust C) involving a medic. This was unforeseen at the outset and may have contributed to action plans that were narrower in scope than those generated by a strong MDT. Even those wards who managed to convene a strong multi-disciplinary APG in phase one were often not able to sustain this level of input going into phase two. Towards the end of the study, it was disappointing to see that PRASE had unwittingly become badged as a 'nursing initiative'. Medical and allied health professional input declined over time and the workload was disproportionally being shouldered by individual Ward Managers (managerial nurses) who were for the most part already overloaded in their daily clinical roles.

Furthermore, an assumption was that a tight, coherent and most importantly *consistent* group of staff would engage with the intervention throughout the 14 months of staff involvement. In reality, staff movement around the NHS estate was high. This led to difficulties regarding ownership of action planning with some staff reluctant to proceed with action plans devised by their predecessors and others not believing it was worth the effort to become involved in the study if they were moving on shortly. A few ward teams changed their personnel completely between phase one and two of the study due to managerial reorganisation:

> *A massive change in staffing took place around the latter part of Phase one with a new Ward Manager and 80-85% change in ward staff. The second phone interview revealed that other ward initiatives were taking place…the whole PRASE process was never wholly embraced because of intense ward improvement work, and staff flux, taking place at the same time (Chestnut ward, Trust C)*

It was never anticipated that such wholesale change would take place at the level of the individual ward teams within the lifetime of the trial and the intervention was unprepared for this. There was little formal capacity to continually re-introduce PRASE to new ward staff, despite researchers having to perform this ad hoc and unexpected role. Critically, it points to ownership of the intervention on the ground as a key factor in success. The engagement with the intervention becomes weak if it is passed around large numbers of different staff or if staff groups change on a dramatic scale.

3. Standardisation of facilitative processes by the research team does not necessarily ensure implementation standardisation by ward staff

A key intention of the facilitative processes was to ensure standardisation of implementation by ward staff. The process evaluation found that, in reality, these uniform training and facilitative processes resulted in little standardisation of approach to action planning regarding a) the issues which staff chose to focus on or b) whether the action plans were successfully implemented (or not). Our pen portraits point to three main issues that appear to underpin why:

- Implementation of action plans were often related to buy in and collegiate working with other departments, some of whom were not willing to spend time, resource and effort on an issue which was not their own
- Existing pan-Trust safety and quality campaigns were prioritised over and above PRASE, to differing degrees which variably helped or hindered PRASE intentions
- Success was often the result of a complex interplay between the personal will of the staff involved in the APG and whether the study fitted into current ward priorities

The following pen portrait excerpt from Apple ward exemplifies the first identified issue regarding buy in from other departments. This ward had several negative comments from patients that pain relief was not being given in a timely manner. To address this, the APG decided they needed assistance from pharmacy but this was not forthcoming and APG members were disappointed. This led to the contradictory position in phase two of engagement still being very present but the act of action planning itself becoming tokenistic:

> *This ward stayed engaged with the project the entire way through despite setbacks with their earliest action plan. The ward manager in particular clearly understood the purpose of the study and was sympathetic to receiving patient feedback. However, inertia may have crept in as their 'outside the box' thinking in phase one did not get any buy in from the pharmacy department. Action planning in phase two then became perfunctory even though engagement was still high (Apple, Trust B)*

The second issue of other safety campaigns being prioritised above this study relates to the capacity with which ward staff have within their normal clinical roles to be able to undertake improvement work. In several of the pen portraits, PRASE was described as "just one of many improvement initiatives which this ward are involved in". Wards were under pressure to take part in hospital wide initiatives that executive teams had deemed to be of most importance. Whilst there was senior support for PRASE, it was not always significant in comparison to other initiatives. In some cases, the existence of other high profile campaigns supported staff in achieving their PRASE action plans. Trust C launched a well-received "Hello my name is…" patient experience campaign tying into national acknowledgement of the need for staff to introduce themselves and communicate better with patients at the bedside. On the wards where PRASE feedback had also drawn attention to this need, staff were supported to respond (through badges, awareness training and senior-support) to do so.

However, the flip-side of attention on more high-profile campaigns meant that – for some wards – PRASE became sidelined. Associated with this was a feeling of patient safety and quality 'fatigue' with the amount of initiatives in this area felt too numerous and therefore burdensome on staff time:

> *I got the sense that the ward manager saw PRASE as just another audit which she needed to go through the motions of…At one point during phase two, she admitted that in phase one she did not see the value in the study as she thought it just replicated other patient experience measures her ward is involved in. However, now she appreciates how it is different from the other measures...Working out where PRASE fitted in with other initiatives seemed to be a big issue for this ward manager (Pine Ward, Trust B)*

One strong finding to emerge was the use of PRASE data to reinforce safety or quality issues which the ward staff knew about tacitly but did not have robust data about in order to report to senior management. This finding emerged as a divisive issue. Some wards were pleased that the PRASE study reinforced staff opinion about the ward or validated on a larger scale the results of local audits. However, a minority of staff became irritated and instead viewed it as duplication.

DISCUSSION

As introduced at the outset, some process evaluations are able to reveal specific 'pinch points' within the intervention itself [13], or within the overall setting in which it was applied [14], which help to explain why no effect was seen. The Consolidated Framework for Advancing Implementation Research advocates the 'inner setting' of an organisation as being influential in whether or not implementation can be achieved, where attention must be paid to the domains of: structural characteristics, networks and communications, culture, implementation climate [19]. Our process evaluation found that this inner setting was so varied between wards within the intervention group that this led to a general 'dilution' of intervention implementation. We found striking differences between wards across all the above domains of 'inner setting' – stability of ward teams, quality of relationships between different wards, basic assumptions towards receiving patient feedback and a learning climate (or lack of one). Significantly, we saw changes to the 'inner setting' constructs over time. The in-depth analysis of what happened within the intervention group generates useful insights for implementation of, and staff engagement with, patient safety initiatives to which we will now turn our attention.

The improvement of patient safety is already acknowledged as a cultural issue and the importance of factors such as teamwork, leadership and organisational processes operating at and between multiple levels [20]. Navigating this territory - particularly the link between 'sharp end' ward safety initiatives and 'blunt end' corporate planning - has been documented as a necessary challenge. Initiatives which do not pay adequate attention in this regard are at best destined to fail, and at worst may over-burden already de-motivated staff [21]. The facilitative processes incorporated into PRASE were designed to help address this challenge. These processes arose from the findings of feasibility testing of the intervention [7] where our research team found that, for example, access to senior management at regular intervals and assistance in interpreting patient feedback were important factors which may support action planning. The assumption was that by providing these processes, staff would be better placed to successfully navigate complex organisational territory. It was anticipated this would allow some uniformity amongst the intervention group. In actuality, the facilitative processes were not adequate to ensure any such uniformity.

Dixon-Woods et al (2011) [22] developed a post theorisation of why impressive results were seen in the original Michigan intervention - to decrease central line infections - in the U.S. Six reasons are proposed as to why the program worked. Of particular applicability is the 'creation of a networked community' where ward teams came together to build rapport and support for each other whilst identifying and resolving common barriers. Although part of the facilitative processes within the PRASE intervention aimed to attend to this need, it is likely that the community of wards involved in the study never reached a critical threshold in becoming an organic community who regularly reached out to each other. Further, specific leaders were targeted in the Michigan programme including hospital executives and clinical team leaders. This involvement of leaders at differing levels of the organisation is theorised as being integral to the success of the programme. Conversely, we found that involving senior management and matrons prior to the start of the study and then throughout its entirety had minimal effect on strengthening engagement with the intervention on the ground by frontline ward staff. Questions regarding the ability of senior management to support consistency of intervention adoption throughout an organisation, and the processes required to enable this further, were raised by our study and certainly warrant further exploration.

In this study, the relationships between different parts and levels of the organisation from senior management to ward teams to individuals were vital in achieving success. When these levels align well, as they appeared to do in one Trust - with respect to a culture shift around introducing and communicating to patients via an external patient experience campaign - it appears that much can be achieved. When they do not – e.g. Apple ward who did not get buy in from the pharmacy department - staff at the ward level can become

frustrated and demotivated. We therefore question the capacity of an externally designed intervention, even one with significant resources and facilitative processes, to provide the mechanisms to be continually adaptive to the organisational alignment between the sharp and blunt end at differing institutions. The challenges revealed here are about deeper organisational culture, systems and processes that need longer-term development.

Our findings support the growing understanding that emphasis in patient safety research must continue to shift from the measure and manage orthodoxy of data collection to interpretation and process [10]. In this research, the collection of patient feedback was the least problematic element. The complexity of what staff are being asked to do in interventions like PRASE (navigating multi-layered organisational systems to implement improvements) requires much more consideration. In the broader but related policy area of patient experience, the overt emphasis and huge resource allocated to collecting patient experience data has not been matched by efforts to utilise and evaluate the impact of feedback on service improvement [23]. There is increasing recognition that using data sources to change practice demands creativity and skills from staff; hence the tendency to present staff with data and expect change to happen as a result [24]. Our intervention considered these issues a priori and hence facilitative processes were built into the trial yet they were not sufficiently robust enough to ensure a standardised implementation across intervention wards.

One interpretation of PRASE could be that it 'failed' due to showing no effect between the intervention and control wards. We believe this a simplistic view which does not take into account the wealth of positive benefits which patients and staff gained. Firstly, it showed that patients are able to give feedback about the safety and quality of care and that they want to do this en masse (our consent rate was 85% of those patients approached by researchers and the number of patients recruited to the study was 2400 across five different hospital sites). Secondly, the process evaluation showed that most staff *do* believe the patient voice is important and there is an imperative to listen to, and act on, this voice. Thirdly, despite local struggles, most staff do want to action plan to improve their patients' care. The majority of the wards were receptive to receiving patient feedback – it is when they tried to move improvement work forward that problems arose [25]. An additional gain which some staff identified was the ability of the patient feedback to allow staff to understand not only the patient perspective but also their priorities and to visualise the ward environment and systems 'through the eyes of the patient'.

Limitations

We cannot know whether positive attitudes towards patient involvement in patient safety have continued on the intervention wards after the trial was completed. Improvements that staff were working towards may have gained impetus since the research team left. Equally, involvement in the trial may have kick-started ideas which, although did not come to fruition within its life span, may now be fuelling ward level action. Conversely, staff may have felt disempowered to enact improvement to the ward environment if their PRASE action plans had floundered. We have no format for measuring this 'after effect' – either positive or negative – and little scope for knowing at what time point the evidence of a more long lasting effect may be captured.

Our pen portrait methodology is a culmination of all sources of qualitative data collected and has its inherent weaknesses. This methodology is still in its relative infancy in relation to the way in which we have utilised it here. We were careful to draw equally on all sources of data in order to build a comprehensive narrative of the engagement trajectory of each ward. However, a differing analysis paying attention to fewer sources or an unequal weighing of sources may have pulled the narrative account in a slightly different direction. Further, it was difficult to categorise some wards firmly into their allocated engagement typology and

arguably some could fit into several. Finally, process evaluation methods were developed a priori to the start of the trial so the design was very open. We devised a loose structure to capture qualitative intelligence on key trial processes. If prior knowledge existed that diversity of engagement within the intervention wards was to be so significant, it may have been possible to target a particular process evaluation framework for analysing outcomes in relation to this diversity, such as the 'diffusion of innovation model' [26]. It is a possibility that utilisation of differing methods may have provided other answers as to where different elements of the intervention worked, for whom and why.

CONCLUSION

Whereas previous process evaluations point towards specific pinch points or broader cultural issues to understand why an intervention showed no effect, this study points to an overall 'dilution effect' of the intervention. This was largely due to wards engaging with the intervention in highly divergent manners despite the standardisation of key components by the research team. The facilitative processes were inadequate to ensure full engagement across all wards in the study. A disconnect existed between senior management support for the study and how ward staff on the ground engaged with it more locally. The above findings assist in explaining why the trial saw no effect between intervention and control wards.

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Competing interests

The authors declare they have no competing interests

Authors' contributions

RL, GA and JW are grant holders of the programme grant. LS devised the methodology of the process evaluation and wrote the qualitative protocol, with assistance from CM. LS, CM and JOH all collected data. LS and CM analysed and interpreted all data, with intellectual input from GA. LS and CM co-wrote the first draft of the paper. All authors edited the first draft of the paper. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by South Yorkshire NHS Research Ethics Committee on 15th March 2013 (Ref: 13/YH/0077). All participants gave informed consent to take part in this study.

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Appendix 2 – Trial design and results
Appendix 3 – Holly ward pen portrait
Appendix 4 – diagram of engagement typologies

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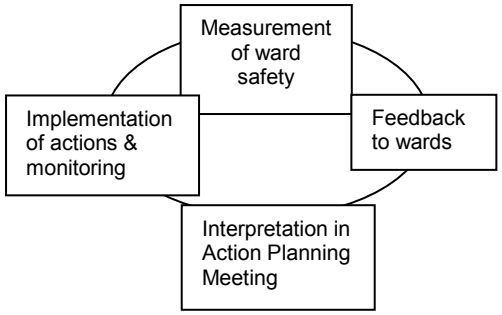
Appendix 1: Key intervention components and anticipated outcomes

Cyclical Activities	***Facilitative Processes***	***Anticipated outcomes***
-Patient Measure of Organisational Safety (PMOS) - a 44 item questionnaire which asks patients at the hospital bedside about safety concerns and issues [5, 6]. -The second is a reporting proforma for patients to provide detailed safety incidents or positive experiences [7]. -The questionnaire items are theoretically-informed from a systems understanding of patient safety whereby experience of care is understood to arise from a complex interaction of factors that include staff team-working and access to resources as well as more traditionally-considered factors such as the physical environment - After patient feedback has been collected it is collated and presented in a feedback report to each ward. Ward staff are then asked to interpret this feedback to identify and target areas for improvement. Finally they are asked to implement agreed action plans and monitor progress in a cyclical manner. - Significant further detail about the cyclical activities is contained in the published protocol of the study [8] and the PRASE RCT results paper [9]  	The design of PRASE recognises that ward staff need support to implement the intervention. An understanding of some of the facilitative processes required was derived from a feasibility study, prior to finalising its design [7]. Specific facilitative processes involved are: - *Independent collection of patient feedback by the research team* to enable not only objectivity but from a resource and logistics viewpoint as ward staff do not have the capacity to collect this data themselves - *Independent production of feedback reports by research team* - *Negotiation with senior management* by the research team to embed the intervention into usual practice - *Ward staff training* in interpretation of data and role playing of optimum action planning to enable them to tackle systemic issues effectively - *Facilitation of the action planning meetings by a senior researcher* to i) convene the meeting ii) encourage ward staff to devise action plans which tackle systemic issues - *Motivation of staff and cross team learning and support* via the format of three pan Trust meeting involving representatives from the hospital senior management (Start Up meeting pre-trial, Mid-Point meeting half way through trial, Closing meeting after trial had concluded)	It was hypothesized that the intervention would lead to safety improvements in terms of both ward culture and ward performance (distal outcomes) alongside a development of a shared, collaborative understanding of the patient's perspective of safety (proximal outcomes). For more detail on this, consult the logic model developed from the feasibility work [7]

Appendix 2: Trial design and results

Trial design	***Trial results***
PRASE was trialled within a multi-centre, cluster, randomised controlled trial. The study was undertaken across 33 hospital wards in three NHS Trusts (five hospital sites). Seventeen wards were randomly assigned to an intervention group and 16 wards to a control group. Feedback was collected from approximately 25 patients per ward, collated and fed back to staff for interpretation and action planning. This whole process was then repeated in a second cycle so staff were able to see changes to feedback over time. The study was powered to detect a small to medium difference (0.3) between the intervention and control groups with respect to a Primary Outcome which was the Patient Safety Thermometer (PST). PST data is routinely collected from every ward in England on a monthly basis and reports on harm free care associated with: i) pressure ulcers, ii) venous thromboembolisms, iii) catheter associated urinary tract infections and iv) falls. PMOS was chosen as a secondary outcome. This was obtained twice from the intervention wards within their intervention cycles. It was also taken at the same three time points in the control wards. For further detail, consult Sheard et al (2014) [8].	No significant effect of the intervention between the allocation groups was found for either of the primary outcomes PST (p=0.98) or PMOS (p=0.09) at 6 or 12 months, nor other secondary outcomes. However, a post hoc analysis on new harms (contained in the PST) found a non-significant increase in harm free care of 1.60 for intervention wards over control wards. All wards were retained throughout the trial. Patient response rate for completing the PMOS tool was 86%. For further detail, consult Lawton et al (2017) [9]

Appendix 3 - Holly ward pen portrait

Facilitator's field notes

Phase one – The action planning meeting (APM) consisted of five staff who had all read the report before the meeting. These were: a sister, a staff nurse, a ward clerk and two HCAs. The ward manager had attended the Trust wide PRASE start-up session but was not able to come to the APM so the facilitator had to give an extensive introduction about the study to the group. The ward clerk did not understand what the term 'patient safety' meant so the facilitator had to go back to basics to make sure that everyone in the room knew what PRASE was about.

Taped APM discussion

Facilitator's field notes

The APM was difficult to convene as discussion tended to jump around. The ward clerk was very vocal and the rest of the group seemed to defer to her opinion, even the sister! Overall, this was a positive meeting and the group seemed engaged with the study by the end of it. The main action plan was to explore whether better systems/communication could be put in place between theatre and the ward to try to reduce the amount of patients who are starved all day only to have their operation cancelled at the last moment. This action plan was challenging in its approach as it sought to redesign well established systems.

Follow up phone interviews

The phone interview found that the action plan about changing the system of communication between theatre and ward was not realised at all because the theatre matron had not responded to the sister about this despite the sister requesting to meet about the issue several times.

Follow up phone interviews

Phase two – The sister attended the Trust wide PRASE midpoint meeting and reported that she found it useful especially to see that many of the problems which patients were reporting on her ward were the same across other wards in the Trust.

Taped APM discussion

Facilitator's field notes

The sister convened another APM although this was smaller in size than the APM in phase one. The failed action plan from phase one about improving communication between theatre and the ward was discussed again. There is acknowledgement that there are not enough qualified staff at night who are able to put a central line in and this is having a knock on effect on the ward.

An action plan was developed to talk to the central line team about this problem of lack of qualified staff.

Follow up phone interviews

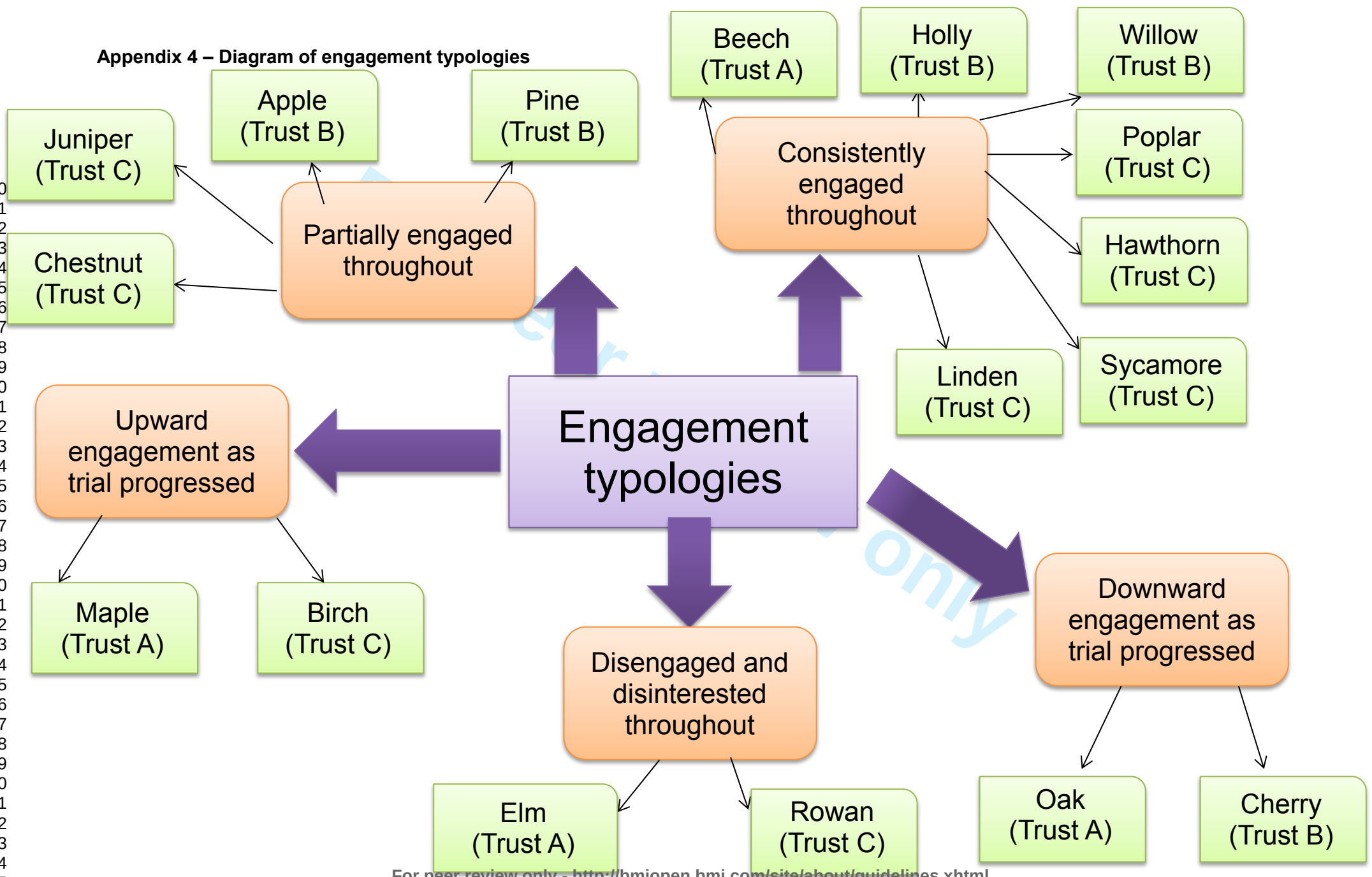
The follow up phone interview for this phase found that implementation had floundered. The APG were far reaching in what they want to happen but were dependent on other departments for buy in and the interest from personnel in other departments was just not there. The sister reported via the phone interview that the Trust are not interested in training more people to be qualified in putting central lines in and the theatre matron is still not interested in rectifying the issue of patients being starved on the ward for days at a time. This ward seemed to be less involved in other safety, quality and experience initiatives than other wards were (even at the same Trust).

Facilitator's field notes

The sister was came in on her day off to attend the Trust wide Closing meeting. She was firmly committed to the study throughout and indeed to improving patient safety.

Engagment profile: This ward team did everything that was asked of them and they were highly engaged as a group with the purpose of PRASE. They made some far reaching action plans which sought to challenge underlying structural barriers but made little progress with these when they tried to implement them as other departments on which they depended for buy in were not interested. **Engaged throughout despite organisational setbacks.**

Appendix 4 – Diagram of engagement typologies



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Exploring how ward staff engage with the implementation of a patient safety intervention: A qualitative process evaluation

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Exploring how ward staff engage with the implementation of a patient safety intervention: A qualitative process evaluation

Laura Sheard
laura.sheard@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Claire Marsh
claire.marsh@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Jane O'Hara
jane.o'hara@bthft.nhs.uk
Bradford Institute for Health Research & University of Leeds, United Kingdom

Gerry Armitage
g.r.armitage@brad.ac.uk
University of Bradford, United Kingdom

John Wright
john.wright@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Rebecca Lawton
r.j.lawton@leeds.ac.uk
Bradford Institute for Health Research & University of Leeds, United Kingdom

Corresponding author:
Laura Sheard
Bradford Institute for Health Research
Bradford Teaching Hospitals
Bradford Royal Infirmary
Duckworth Lane
Bradford
BD9 6RJ
United Kingdom

ABSTRACT

Objectives – A patient safety intervention was tested in a 33 ward randomised controlled trial. No statistically significant difference between intervention and control wards was found. We conducted a process evaluation of the trial and our aim in this paper is to understand staff engagement across the 17 intervention wards.

Design – Large qualitative process evaluation of the implementation of a patient safety intervention.

Setting and participants – NHS staff based on 17 acute hospital wards located at five hospital sites in the North of England.

Data – We concentrate on three sources here: i) analysis of taped discussion between ward staff during action planning meetings ii) facilitators' field notes iii) follow up telephone interviews with staff focussing on whether action plans had been achieved. The analysis involved the use of pen portraits and adaptive theory.

Findings – First, there were palpable differences in the ways that the 17 ward teams engaged with the key components of the intervention. Five main engagement typologies were evident across the life course of the study: consistent, partial, increasing, decreasing and disinterested. Second, the intensity of support for the intervention at the level of the organisation does not predict the strength of engagement at the level of the individual ward team. Third, the standardisation of facilitative processes provided by the research team does not ensure that implementation standardisation of the intervention occurs by ward staff.

Conclusions - A dilution of the intervention occurred during the trial because wards engaged with PRASE in divergent ways, despite the standardisation of key components. Facilitative processes were not sufficiently adequate to enable intervention wards to successfully engage with PRASE components.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- We devised a process evaluation that had several robust qualitative data collection methods which complemented each other, in order to build a comprehensive and holistic picture of how ward staff implemented the intervention
- Our approach allowed us to reveal how the differing ways in which staff teams engage with the intervention may impact on patient safety changes at a ward level
- Our novel analytic approach utilised pen portrait methodology in a differing way to how it has previously been used in health services research, in order to document the journey of 17 wards interacting with an intervention over an 18 month period
- We have little understanding of whether the implementation of PRASE may have gained traction and fuelled subsequent ward based change once the research team left the field
- The qualitative methods we chose were designed to capture a broad understanding of the contexts in which the intervention was implemented but had we known a priori that engagement was such a significant factor, we may have designed the process evaluation to specifically explore its influence.

BACKGROUND

Measurement of patient safety has traditionally relied on information from staff such as incident reports or recording information about harms such as falls or pressure sores. Recently, patients have been emphasised as being an important detector for patient safety and likened to the 'smoke detectors' of safety [1]. There is an increasing recognition that hospitals need to find better ways to capture and respond to the concerns of patients regarding the quality and safety of their care [2-4]. However, patients are rarely asked about structural or procedural aspects of care which may contribute towards failures in patient safety. The Yorkshire Quality and Safety group have developed a patient safety intervention called Patient Reporting and Action for a Safe Environment (PRASE). This intervention firstly elicits patient perceptions on how a ward is performing on a series of issues which are known to contribute towards patient safety incidents and secondly assists staff to interpret patient feedback to aid service improvements. This paper provides an account of a qualitative process evaluation of a randomised controlled trial (RCT) where PRASE was tested. PRASE was designed [5, 6], tested for feasibility [7] and trialled [8, 9] between 2010 and 2015. This period has been charted as an era of paradigm shift for patient safety research when the dominant 'measure and manage' orthodoxy has been enriched by approaches sensitive to setting and socio-cultural/ political influences [10]. It became essential for a process evaluation to capture the nuances involved in the PRASE implementation.

Process evaluations have been used to explain sub-optimum outcome effects, specifically whether there was a 'fault' with the intervention itself, its key components or with delivery [11]. Latterly, they are often not only concerned with adherence to original plans, but also with broader issues such as unintended consequences or the strengths and weaknesses of the intervention itself [12]. Some process evaluations have been able to identify a precise 'pinch point' or problem with an essential component of the intervention that caused it to fail. In a UK trial of peer led HIV prevention for gay men in London, no effect was shown. A qualitative process evaluation [13] revealed that the essential component of 'peer educator' had not played out as intended during the course of the trial due to recruitment problems and the inability of peer educators to confidently communicate harm reduction messages to intended targets. Other process evaluations have been able to point to more general cultural or structural reasons why an intervention may not have succeeded. Dixon-Woods et al [14] evaluated why a U.S. developed patient safety intervention - regarding decreasing central line infections in intensive care units – struggled with implementation after the intervention was transferred to a U.K. setting. A post-hoc qualitative evaluation revealed multiple reasons why, largely the result of cultural differences between the U.S and U.K. settings. It is clear from these examples that process evaluations can support the largely 'experimental' aim of RCTs by identifying specific 'pinch points' within an intervention itself or within the context that will help to explain success or failure.

The components of the intervention have been reported in detail elsewhere [8], and the results of the randomised controlled trial which demonstrated no statistically significant effect between the intervention and control wards [9]. A feasibility study was undertaken prior to commencement of the full RCT and details of our logic model and moderating factors are reported in the feasibility write up [7]. Here, we provide a synopsis of the intervention and results of the trial for the reader to be able to view our process evaluation in context. Appendix 1 provides a detailed summary of the cyclical activities and facilitative processes of the intervention that were trialled, alongside anticipated outcomes. Appendix 2 describes the trial design and results. Briefly, this was a cyclical study with two phases of: i) collecting patient feedback about safety from patients at the bedside ii) collation of this data and ward staff interpreting it iii) ward staff action planning to improve patient safety iv) plans then being implemented and monitored.

METHODS

We conducted a robust process evaluation involving differing qualitative and quantitative methods [8] which gathered comprehensive data about all 17 intervention wards. We drew upon a published framework [12] for designing process evaluations of cluster randomised controlled trials. The main a priori research question was: 'where does the intervention work, how and why?' [8]. In this paper, we have chosen to focus on the 'how?' and 'why?' and present a detailed picture of how staff engaged with the intervention. We now apply our original research question to understand how and why the intervention did *not* work, given the intervention did not have a significant effect on outcomes. Six mixed methods were used in the wider process evaluation but due to the extent and depth of the data collected, we focused intensively on three qualitative methods for the purpose of this paper. The methods described below are those most pertinent to exploring how staff engaged with the intervention in the ways they did, and why. Data was collected between August 2013 to November 2014. NHS ethical approval was granted in March 2013.

1. In depth analysis of taped discussion between ward staff

Action planning meetings (APMs) were digitally recorded for all 17 wards at both phases. At phase two, one ward did not meet so we considered the recordings of 33 APMs. These ranged in length from 27 to 80 minutes (average 43 minutes). Our examination focused on which areas of patient feedback staff chose to make action plans on and which areas they chose not to. We wrote detailed notes whilst listening to the voice file. We structured our notes under the headings: i) Issues seen as important where actions were made (and why) ii) Issues seen as important where no actions were made (and why not) iii) Issues dismissed and reasons for this iv) Comments made by staff about PRASE process/ study/ team v) Comments made by staff about the ward or hospital context.

2. Facilitator's field notes

These notes were written shortly after the APM had finished and captured: i) implicit dynamics between staff, such as body language, tone of voice and other non-verbal cues ii) environmental factors, such as descriptions of the physical space where the meeting was held iii) facilitator's overall impressions. Field notes were brief and gave a 'snapshot' of the meeting. There were three facilitators across the 17 intervention wards and each facilitator worked with the same wards across both phases of the study, to ensure continuity. Field notes were also taken at key meetings and events held with Trust senior management personnel (particularly during set up and roll out of the study). These notes assisted in providing the research team with tacit knowledge of the culture of the site in which the intervention was being implemented.

3. Follow-up telephone interviews conducted with the APM lead

The purpose of these short, structured phone interviews was to ascertain whether action plans had been successfully implemented or not and why. They were conducted around six months after the APM, with the 'PRASE lead' for each ward. Each ward was responsible for nominating a named member of ward staff - who was part of the action planning meeting - to be the PRASE lead. This could be any member of the team but was more often than not the person who volunteered for the role was a senior nurse. A structured interview guide was used. Researchers had a proforma in front of them which contained details about each action plan per ward and they asked the PRASE lead whether each action plan had been implemented – yes, no or partially. Open questioning then continued to understand the factors surrounding this. Five additional questions were asked which focussed on the PRASE lead's opinion of the facilitative processes embedded in the study.

For the purpose of this paper, we wanted to understand **qualitatively** how wards had engaged (or not) with the PRASE intervention. Implementation fidelity (which captures adherence to specific intervention components) is reported quantitatively elsewhere [9]. Engagement of staff with an intervention can be considered as closely aligned but different

from this, referring more to the differing approaches and attitudes that staff take to the task in hand (implementation of different components of the intervention). This is different to whether they have simply delivered the task or not. We decided not to adhere to a numerical/scale definition of 'engagement' whereby differing wards attained a binary definition of either 'engaged' or 'disengaged' with the intervention. Instead, we undertook a nuanced analysis of staff approaches and attitudes to: conducting an action planning meeting, creating quality action plans and implementation of these action plans. We explored 'engagement' as a concept that we define as the 'depth' and 'nature' of ward teams' approaches and attitudes to the intervention.

Informed by this understanding of engagement, a synthesis of the above data sources has provided us with a rich account of the '**engagement trajectory'** of each ward and this was realised by creating a pen portrait of engagement. Pen portraits have been used previously in applied health research in fields as diverse as: end of life care [15], vulnerable old people being enabled to keep warm in their homes [16] and sleeping practices amongst homeless drug users [17]. Previously, they have provided a narrative account of a 'typical' participant in qualitative studies or as an analytic aide memoir. We used them in a slightly different manner to document the 'journey' of the wards throughout the trial from the perspective of the researcher who had worked closely with these wards for over 18 months. There is a lack of methodological literature pertaining to the construction of a pen portrait and this has been left to the discretion of individual research teams. We created a basic structure for the pen portraits which centred on the writing of a linear, longitudinal account of how each ward had engaged with relevant key components of the intervention and the contextual factors which influenced this, ensuring that all three data sources were drawn upon. We did not use an existing theory or framework on which to extract the data for the pen portraits as we wanted the emergent findings to arise inductively from the data set. As staff engagement was our focus, we included as much material on this as possible (along with explanatory factors and necessary description). We excluded minutiae which did not add to the 'big picture' of the ward team's engagement to maintain a focussed pen portrait. The pen portrait for Holly ward is shown in Appendix 3 with the prose annotated as an illustration of how portraits were constructed from the three data sources outlined above.

Researchers took into account all the information contained within the pen portrait and attributed an overall 'engagement trajectory' label to each ward. Author A wrote all pen portraits for Trusts A and B and Author B for Trust C. We categorised the 17 different ward engagement trajectories into five main 'engagement typologies', which emerged from an analytical session centring mainly on consensus discussion between Author A and Author B. We report three overarching themes in this paper, which are described in detail in the Findings section which follows. The above categorisation of engagement typologies led to the content of the first theme. After we were confident of the findings of this first theme, we then used the differences in engagement detailed in this theme to progress to themes two and three. To achieve this, we looked between and across the engagement trajectories of all 17 wards in order to understand how engagement with the intervention related to components of local implementation. We returned to the detail of the pen portraits to understand commonality and difference and from this we developed the coding framework for themes two and three. We then checked our assumptions by testing the data in the pen portraits against our initial coding framework. After minor adaptions, we then coded the data in all 17 pen portraits. Overall, we used techniques derived from 'adaptive theory' [18] which allows for high level frameworks and conceptualisations to emerge from data rather than descriptive themes. Adaptive theory proposes a continual engagement between the arising empirical data and arising theoretical interpretations of the research, working in a continuous cycle with each cycle generating new explorations.

FINDINGS

We now set out to understand the ways in which the 17 intervention wards engaged with the intervention. We are interested in how a multiplicity of engagement styles could have made an already complex intervention become hyper complicated in its implementation phase. This 'hyper complexity' may have served to dilute key elements of the intervention. By 'dilution' we mean 'non-standardisation' of the intervention group, thereby reducing the potential for this to be meaningfully compared with a control group. We explore three high level themes, which emerged from the data. Firstly, we will describe how there were palpable differences in the ways that ward teams engaged with the intervention. Next, we will look at how support for the intervention at the level of the Trust does not indicate ward level support. Lastly, we will demonstrate that standardisation of facilitative processes by the research team does not ensure this filters down to implementation standardisation by ward staff. All quotation extracts are taken from pen portrait notes and all ward names have been ascribed a pseudonym.

1. The same intervention can be interacted with in highly divergent ways

We were able to distinguish the intervention wards into five main 'engagement typologies' (Appendix 4). They are:

- Consistently engaged throughout (7 wards)
- Partially engaged throughout (4 wards)
- Increasing engagement as trial progressed (2 wards)
- Decreasing engagement as trial progressed (2 wards)
- Disengaged and disinterested throughout (2 wards)

Consistently engaged – This represents the largest category of how wards chose to participate in the trial with 7 out of the 17 residing here. These wards were fully signed up to the ethos of listening to and acting on patient feedback. They took part in a high proportion of the key components of the cyclical activities and made quality action plans which were largely implemented in both phases. A quality action plan can be defined as one which seeks to address issues identified in the patient data and was realistic, relatively timely and more than likely to be achieved. Motivation to take part in the research was high and improving patient safety was even higher.

Partially engaged – These four wards generally did everything asked of them by the research team and largely participated in intervention components but were sometimes lacklustre in their motivation towards improving patient safety. At times, it felt like action planning was just 'going through the motions'. The ability of staff to implement action plans was mixed although this was sometimes due to external factors rather than inertia on the part of the ward staff themselves.

Increasing engagement – These two wards began their involvement with the trial in an ambivalent and – in the case of Maple ward – even hostile manner. However, as the study progressed and the ward staff began to understand what the research team were trying to achieve, engagement with the study solidified. The similarity between these two wards (despite being at different Trusts) is that the turning point for their engagement was attendance at the peer centred Mid-Point Meeting. This is reflected in Maple ward's complete U-turn with implementation of quality action plans at phase two as compared with partial implementation of weak action plans at phase one.

Decreasing engagement – Conversely, another two wards engaged with the study relatively well at the beginning but, over time, slipped in their level of interest and involvement. Cherry ward is the only ward across all 17 who did not meet in an APM in phase two. The follow up telephone interview revealed that the ward manager for Cherry did not believe the study was a priority. Oak ward had ambitious plans for their phase one action planning but had become

dejected by the amount of time their plan was taking to come into effect. Subsequently, they declined to make an action plan in the phase two APM and appeared disinterested in the study.

Disengaged and disinterested – Although these two wards met in APMs for both phases of the trial, they were not interested in using the PRASE data to improve patient safety and viewed the study as a burden. However, the reasons for this response differed. Rowan were a low performing ward whose ward manager preferred to concentrate on the other initiatives rather than our research study. Elm ward were outwardly hostile to the ethos of the study, critical of the comments their patients had made to researchers and defensive of staff members. Despite agreeing to hold an APM, they consistently refused to make action plans.

Through an examination of these differing engagement trajectories, we can unpick where parts of the intervention may have led to divergent strategies for local implementation of the intervention on a ward-by-ward basis. These findings from 'on the ground' implementation by ward teams directly contradict some of the core assumptions held by the research team at the outset of intervention development - namely, that by providing facilitative processes, wards would be able to implement in a uniform manner. It is this aspect of a chasm between implementation expectations and reality which we now turn our attention to.

2. Trust-level support for an intervention does not predict the strength of ward-level engagement

A key assumption was that strong corporate, managerial-level support by the three participating Trusts would facilitate high-level engagement by wards. However an examination of the differing types of engagement trajectories, shown in Figure 1, throw doubt on this assumption and we can find little consistency in engagement style between the wards at the same Trust. For instance, Trust A is a small district general hospital in a semi-rural, affluent area. This Trust prides itself on being a forward thinking, cohesive workplace and senior management support for this intervention was exceptionally strong. However, when reduced down to the level of the ward, we can see that the four intervention wards at Trust A are represented across four distinct engagement trajectories (Consistent = Beech, Increasing = Maple, Decreasing = Oak, Disengaged = Elm). Engagement trajectories for each of the other two Trusts also differed considerably by ward. The implication here is that corporate culture - and receptivity to patient feedback at the level of the organisation - is not a simple predictor of engagement at ward level.

Unpicking these differences further, we find that despite a uniform message about the importance of a multi-disciplinary approach to the study, wards seem to have interpreted this differently. Oak ward convened a strong first multi-disciplinary APG with representatives from nursing, allied health professionals and support staff. In contrast, on some wards PRASE remained led and implemented by just one or two nursing staff. For example, Maple's first APG consisted of just the ward manager and pen portrait notes illustrate why:

> *A very tense meeting held with just the ward manager who appeared overtly stressed and about to implode. It was clear at this first APM that the ward manager had not understood the purpose of the study and became upset by some of the negative comments which her patients had made in the report. It was a difficult APM to convene as the ward manager thought she had to solve everything by herself and this was partially reinforced by the fact that she had not invited any of her staff to the APM (Maple, Trust A)*

The research team never envisaged that the intervention would be taken on by just one or two members of ward staff and this was actively discouraged throughout but still persisted in five wards at phase one and six wards at phase two, across the 17 intervention wards. It is difficult to suggest a clear reason why this happened but it was often related to:

- Front line issues, such as no staff available to be released from direct patient care to attend APG
- A minority of ward managers viewing the study as yet another patient safety initiative that they just needed to 'get on with'
- A misunderstanding of the multi-disciplinary nature of the intervention.

Of most interest is the severe paucity of medical staff involved in the intervention with only four wards (all at Trust C) involving a medic. This was unforeseen at the outset and may have contributed to action plans that were narrower in scope than those generated by a strong MDT. Even those wards who managed to convene a strong multi-disciplinary APG in phase one were often not able to sustain this level of input going into phase two. Towards the end of the study, it was disappointing to see that PRASE had unwittingly become badged as a 'nursing initiative'. Medical and allied health professional input declined over time and the workload was disproportionally being shouldered by individual Ward Managers (managerial nurses) who were for the most part already overloaded in their daily clinical roles.

Furthermore, an assumption was that a tight, coherent and most importantly *consistent* group of staff would engage with the intervention throughout the 14 months of staff involvement. In reality, staff movement around the NHS estate was high. This led to difficulties regarding ownership of action planning with some staff reluctant to proceed with action plans devised by their predecessors and others not believing it was worth the effort to become involved in the study if they were moving on shortly. A few ward teams changed their personnel completely between phase one and two of the study due to managerial reorganisation:

> *A massive change in staffing took place around the latter part of Phase one with a new Ward Manager and 80-85% change in ward staff. The second phone interview revealed that other ward initiatives were taking place…the whole PRASE process was never wholly embraced because of intense ward improvement work, and staff flux, taking place at the same time (Chestnut ward, Trust C)*

It was never anticipated that such wholesale change would take place at the level of the individual ward teams within the lifetime of the trial and the intervention was unprepared for this. There was little formal capacity to continually re-introduce PRASE to new ward staff, despite researchers having to perform this ad hoc and unexpected role. Critically, it points to ownership of the intervention on the ground as a key factor in success. The engagement with the intervention becomes weak if it is passed around large numbers of different staff or if staff groups change on a dramatic scale.

3. Standardisation of facilitative processes by the research team does not necessarily ensure implementation standardisation by ward staff

A key intention of the facilitative processes was to ensure standardisation of implementation by ward staff. The process evaluation found that, in reality, these uniform training and facilitative processes resulted in little standardisation of approach to action planning regarding a) the issues which staff chose to focus on or b) whether the action plans were successfully implemented (or not). Our pen portraits point to three main issues that appear to underpin why:

- Implementation of action plans were often related to buy in and collegiate working with other departments, some of whom were not willing to spend time, resource and effort on an issue which was not their own
- Existing pan-Trust safety and quality campaigns were prioritised over and above PRASE, to differing degrees which variably helped or hindered PRASE intentions
- Success was often the result of a complex interplay between the personal will of the staff involved in the APG and whether the study fitted into current ward priorities

The following pen portrait excerpt from Apple ward exemplifies the first identified issue regarding buy in from other departments. This ward had several negative comments from patients that pain relief was not being given in a timely manner. To address this, the APG decided they needed assistance from pharmacy but this was not forthcoming and APG members were disappointed. This led to the contradictory position in phase two of engagement still being very present but the act of action planning itself becoming tokenistic:

> *This ward stayed engaged with the project the entire way through despite setbacks with their earliest action plan. The ward manager in particular clearly understood the purpose of the study and was sympathetic to receiving patient feedback. However, inertia may have crept in as their 'outside the box' thinking in phase one did not get any buy in from the pharmacy department. Action planning in phase two then became perfunctory even though engagement was still high (Apple, Trust B)*

The second issue of other safety campaigns being prioritised above this study relates to the capacity with which ward staff have within their normal clinical roles to be able to undertake improvement work. In several of the pen portraits, PRASE was described as "just one of many improvement initiatives which this ward are involved in". Wards were under pressure to take part in hospital wide initiatives that executive teams had deemed to be of most importance. Whilst there was senior support for PRASE, it was not always significant in comparison to other initiatives. In some cases, the existence of other high profile campaigns supported staff in achieving their PRASE action plans. Trust C launched a well-received "Hello my name is…" patient experience campaign tying into national acknowledgement of the need for staff to introduce themselves and communicate better with patients at the bedside. On the wards where PRASE feedback had also drawn attention to this need, staff were supported to respond (through badges, awareness training and senior-support) to do so.

However, the flip-side of attention on more high-profile campaigns meant that – for some wards – PRASE became sidelined. Associated with this was a feeling of patient safety and quality 'fatigue' with the amount of initiatives in this area felt too numerous and therefore burdensome on staff time:

> *I got the sense that the ward manager saw PRASE as just another audit which she needed to go through the motions of…At one point during phase two, she admitted that in phase one she did not see the value in the study as she thought it just replicated other patient experience measures her ward is involved in. However, now she appreciates how it is different from the other measures...Working out where PRASE fitted in with other initiatives seemed to be a big issue for this ward manager (Pine Ward, Trust B)*

One strong finding to emerge was the use of PRASE data to reinforce safety or quality issues which the ward staff knew about tacitly but did not have robust data about in order to report to senior management. This finding emerged as a divisive issue. Some wards were pleased that the PRASE study reinforced staff opinion about the ward or validated on a larger scale the results of local audits. However, a minority of staff became irritated and instead viewed it as duplication.

DISCUSSION

As introduced at the outset, some process evaluations are able to reveal specific 'pinch points' within the intervention itself [13], or within the overall setting in which it was applied [14], which help to explain why no effect was seen. The Consolidated Framework for Advancing Implementation Research advocates the 'inner setting' of an organisation as being influential in whether or not implementation can be achieved, where attention must be paid to the domains of: structural characteristics, networks and communications, culture, implementation climate [19]. Our process evaluation found that this inner setting was so varied between wards within the intervention group that this led to a general 'dilution' of intervention implementation. We found striking differences between wards across all the above domains of 'inner setting' – stability of ward teams, quality of relationships between different wards, basic assumptions towards receiving patient feedback and a learning climate (or lack of one). Significantly, we saw changes to the 'inner setting' constructs over time. The in-depth analysis of what happened within the intervention group generates useful insights for implementation of, and staff engagement with, patient safety initiatives to which we will now turn our attention.

The improvement of patient safety is already acknowledged as a cultural issue and the importance of factors such as teamwork, leadership and organisational processes operating at and between multiple levels [20]. Navigating this territory - particularly the link between 'sharp end' ward safety initiatives and 'blunt end' corporate planning - has been documented as a necessary challenge. Initiatives which do not pay adequate attention in this regard are at best destined to fail, and at worst may over-burden already de-motivated staff [21]. The facilitative processes incorporated into PRASE were designed to help address this challenge. These processes arose from the findings of feasibility testing of the intervention [7] where our research team found that, for example, access to senior management at regular intervals and assistance in interpreting patient feedback were important factors which may support action planning. The assumption was that by providing these processes, staff would be better placed to successfully navigate complex organisational territory. It was anticipated this would allow some uniformity amongst the intervention group. In actuality, the facilitative processes were not adequate to ensure any such uniformity.

Dixon-Woods et al (2011) [22] developed a post theorisation of why impressive results were seen in the original Michigan intervention - to decrease central line infections - in the U.S. Six reasons are proposed as to why the program worked. Of particular applicability is the 'creation of a networked community' where ward teams came together to build rapport and support for each other whilst identifying and resolving common barriers. Although part of the facilitative processes within the PRASE intervention aimed to attend to this need, it is likely that the community of wards involved in the study never reached a critical threshold in becoming an organic community who regularly reached out to each other. Further, specific leaders were targeted in the Michigan programme including hospital executives and clinical team leaders. This involvement of leaders at differing levels of the organisation is theorised as being integral to the success of the programme. Conversely, we found that involving senior management and matrons prior to the start of the study and then throughout its entirety had minimal effect on strengthening engagement with the intervention on the ground by frontline ward staff. Questions regarding the ability of senior management to support consistency of intervention adoption throughout an organisation, and the processes required to enable this further, were raised by our study and certainly warrant further exploration.

In this study, the relationships between different parts and levels of the organisation from senior management to ward teams to individuals were vital in achieving success. When these levels align well, as they appeared to do in one Trust - with respect to a culture shift around introducing and communicating to patients via an external patient experience campaign - it appears that much can be achieved. When they do not – e.g. Apple ward who did not get buy in from the pharmacy department - staff at the ward level can become

frustrated and demotivated. We therefore question the capacity of an externally designed intervention, even one with significant resources and facilitative processes, to provide the mechanisms to be continually adaptive to the organisational alignment between the sharp and blunt end at differing institutions. The challenges revealed here are about deeper organisational culture, systems and processes that need longer-term development.

Our findings support the growing understanding that emphasis in patient safety research must continue to shift from the measure and manage orthodoxy of data collection to interpretation and process [10]. In this research, the collection of patient feedback was the least problematic element. The complexity of what staff are being asked to do in interventions like PRASE (navigating multi-layered organisational systems to implement improvements) requires much more consideration. In the broader but related policy area of patient experience, the overt emphasis and huge resource allocated to collecting patient experience data has not been matched by efforts to utilise and evaluate the impact of feedback on service improvement [23]. There is increasing recognition that using data sources to change practice demands creativity and skills from staff; hence the tendency to present staff with data and expect change to happen as a result [24]. Our intervention considered these issues a priori and hence facilitative processes were built into the trial yet they were not sufficiently robust enough to ensure a standardised implementation across intervention wards.

One interpretation of PRASE could be that it 'failed' due to showing no effect between the intervention and control wards. We believe this a simplistic view which does not take into account the wealth of positive benefits which patients and staff gained. Firstly, it showed that patients are able to give feedback about the safety and quality of care and that they want to do this en masse (our consent rate was 85% of those patients approached by researchers and the number of patients recruited to the study was 2400 across five different hospital sites). Secondly, the process evaluation showed that most staff *do* believe the patient voice is important and there is an imperative to listen to, and act on, this voice. Thirdly, despite local struggles, most staff do want to action plan to improve their patients' care. The majority of the wards were receptive to receiving patient feedback – it is when they tried to move improvement work forward that problems arose [25]. An additional gain which some staff identified was the ability of the patient feedback to allow staff to understand not only the patient perspective but also their priorities and to visualise the ward environment and systems 'through the eyes of the patient'.

Limitations

We cannot know whether positive attitudes towards patient involvement in patient safety have continued on the intervention wards after the trial was completed. Improvements that staff were working towards may have gained impetus since the research team left. Equally, involvement in the trial may have kick-started ideas which, although did not come to fruition within its life span, may now be fuelling ward level action. Conversely, staff may have felt disempowered to enact improvement to the ward environment if their PRASE action plans had floundered. We have no format for measuring this 'after effect' – either positive or negative – and little scope for knowing at what time point the evidence of a more long lasting effect may be captured.

Our pen portrait methodology is a culmination of all sources of qualitative data collected and has its inherent weaknesses. This methodology is still in its relative infancy in relation to the way in which we have utilised it here. We were careful to draw equally on all sources of data in order to build a comprehensive narrative of the engagement trajectory of each ward. However, a differing analysis paying attention to fewer sources or an unequal weighing of sources may have pulled the narrative account in a slightly different direction. Further, it was difficult to categorise some wards firmly into their allocated engagement typology and

arguably some could fit into several. Finally, process evaluation methods were developed a priori to the start of the trial so the design was very open. We devised a loose structure to capture qualitative intelligence on key trial processes. If prior knowledge existed that diversity of engagement within the intervention wards was to be so significant, it may have been possible to target a particular process evaluation framework for analysing outcomes in relation to this diversity, such as the 'diffusion of innovation model' [26]. It is a possibility that utilisation of differing methods may have provided other answers as to where different elements of the intervention worked, for whom and why.

CONCLUSION

Whereas previous process evaluations point towards specific pinch points or broader cultural issues to understand why an intervention showed no effect, this study points to an overall 'dilution effect' of the intervention. This was largely due to wards engaging with the intervention in highly divergent manners despite the standardisation of key components by the research team. The facilitative processes were inadequate to ensure full engagement across all wards in the study. A disconnect existed between senior management support for the study and how ward staff on the ground engaged with it more locally. The above findings assist in explaining why the trial saw no effect between intervention and control wards.

DECLARATIONS

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Competing interests

The authors declare they have no competing interests

Authors' contributions

RL, GA and JW are grant holders of the programme grant. LS devised the methodology of the process evaluation and wrote the qualitative protocol, with assistance from CM. LS, CM and JOH all collected data. LS and CM analysed and interpreted all data, with intellectual input from GA. LS and CM co-wrote the first draft of the paper. All authors edited the first draft of the paper. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by South Yorkshire NHS Research Ethics Committee on 15th March 2013 (Ref: 13/YH/0077). All participants gave informed consent to take part in this study.

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Data sharing statement

Unpublished data is not available

FIGURE HEADINGS

Appendix 1 – Key intervention components and anticipated outcomes
Appendix 2 – Trial design and results
Appendix 3 – Holly ward pen portrait
Appendix 4 – diagram of engagement typologies

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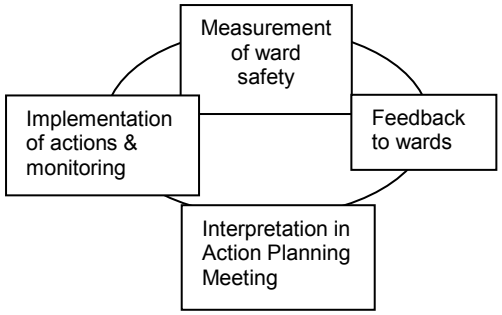
Appendix 1: Key intervention components and anticipated outcomes

Cyclical Activities	***Facilitative Processes***	***Anticipated outcomes***
-Patient Measure of Organisational Safety (PMOS) - a 44 item questionnaire which asks patients at the hospital bedside about safety concerns and issues [5, 6]. -The second is a reporting proforma for patients to provide detailed safety incidents or positive experiences [7]. -The questionnaire items are theoretically-informed from a systems understanding of patient safety whereby experience of care is understood to arise from a complex interaction of factors that include staff team-working and access to resources as well as more traditionally-considered factors such as the physical environment - After patient feedback has been collected it is collated and presented in a feedback report to each ward. Ward staff are then asked to interpret this feedback to identify and target areas for improvement. Finally they are asked to implement agreed action plans and monitor progress in a cyclical manner. - Significant further detail about the cyclical activities is contained in the published protocol of the study [8] and the PRASE RCT results paper [9]  	The design of PRASE recognises that ward staff need support to implement the intervention. An understanding of some of the facilitative processes required was derived from a feasibility study, prior to finalising its design [7]. Specific facilitative processes involved are: - *Independent collection of patient feedback by the research team* to enable not only objectivity but from a resource and logistics viewpoint as ward staff do not have the capacity to collect this data themselves - *Independent production of feedback reports by research team* - *Negotiation with senior management* by the research team to embed the intervention into usual practice - *Ward staff training* in interpretation of data and role playing of optimum action planning to enable them to tackle systemic issues effectively - *Facilitation of the action planning meetings by a senior researcher* to i) convene the meeting ii) encourage ward staff to devise action plans which tackle systemic issues - *Motivation of staff and cross team learning and support* via the format of three pan Trust meeting involving representatives from the hospital senior management (Start Up meeting pre-trial, Mid-Point meeting half way through trial, Closing meeting after trial had concluded)	It was hypothesized that the intervention would lead to safety improvements in terms of both ward culture and ward performance (distal outcomes) alongside a development of a shared, collaborative understanding of the patient's perspective of safety (proximal outcomes). For more detail on this, consult the logic model developed from the feasibility work [7]

Appendix 2: Trial design and results

Trial design	***Trial results***
PRASE was trialled within a multi-centre, cluster, randomised controlled trial. The study was undertaken across 33 hospital wards in three NHS Trusts (five hospital sites). Seventeen wards were randomly assigned to an intervention group and 16 wards to a control group. Feedback was collected from approximately 25 patients per ward, collated and fed back to staff for interpretation and action planning. This whole process was then repeated in a second cycle so staff were able to see changes to feedback over time. The study was powered to detect a small to medium difference (0.3) between the intervention and control groups with respect to a Primary Outcome which was the Patient Safety Thermometer (PST). PST data is routinely collected from every ward in England on a monthly basis and reports on harm free care associated with: i) pressure ulcers, ii) venous thromboembolisms, iii) catheter associated urinary tract infections and iv) falls. PMOS was chosen as a secondary outcome. This was obtained twice from the intervention wards within their intervention cycles. It was also taken at the same three time points in the control wards. For further detail, consult Sheard et al (2014) [8].	No significant effect of the intervention between the allocation groups was found for either of the primary outcomes PST (p=0.98) or PMOS (p=0.09) at 6 or 12 months, nor other secondary outcomes. However, a post hoc analysis on new harms (contained in the PST) found a non-significant increase in harm free care of 1.60 for intervention wards over control wards. All wards were retained throughout the trial. Patient response rate for completing the PMOS tool was 86%. For further detail, consult Lawton et al (2017) [9]

Appendix 3 - Holly ward pen portrait

Facilitator's field notes

Phase one – The action planning meeting (APM) consisted of five staff who had all read the report before the meeting. These were: a sister, a staff nurse, a ward clerk and two HCAs. The ward manager had attended the Trust wide PRASE start-up session but was not able to come to the APM so the facilitator had to give an extensive introduction about the study to the group. The ward clerk did not understand what the term 'patient safety' meant so the facilitator had to go back to basics to make sure that everyone in the room knew what PRASE was about.

Taped APM discussion

Facilitator's field notes

The APM was difficult to convene as discussion tended to jump around. The ward clerk was very vocal and the rest of the group seemed to defer to her opinion. Overall, this was a positive meeting and the group seemed engaged with the study by the end of it. The main action plan was to explore whether better systems/communication could be put in place between theatre and the ward to try to reduce the amount of patients who are starved all day only to have their operation cancelled at the last moment. This action plan was challenging in its approach as it sought to redesign well established systems.

Follow up phone interviews

The phone interview found that the action plan about changing the system of communication between theatre and ward was not realised at all because the theatre matron had not responded to the sister about this despite the sister requesting to meet about the issue several times.

Follow up phone interviews

Phase two – The sister attended the Trust wide PRASE midpoint meeting and reported that she found it useful especially to see that many of the problems which patients were reporting on her ward were the same across other wards in the Trust.

Taped APM discussion

Facilitator's field notes

The sister convened another APM although this was smaller in size than the APM in phase one. The failed action plan from phase one about improving communication between theatre and the ward was discussed again. There is acknowledgement that there are not enough qualified staff at night who are able to put a central line in and this is having a knock on effect on the ward. An action plan was developed to talk to the central line team about this problem of lack of qualified staff.

Follow up phone interviews

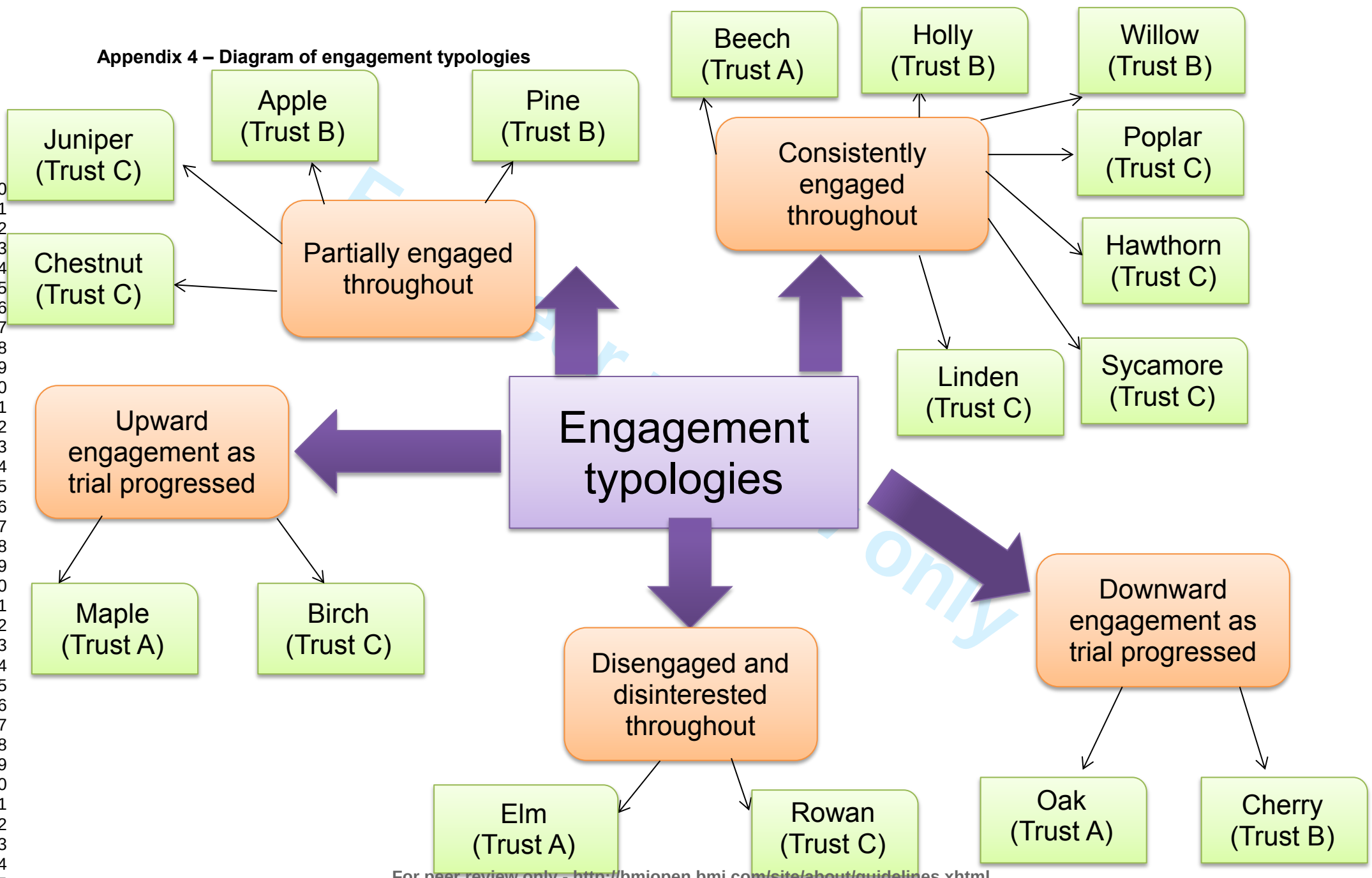
The follow up phone interview for this phase found that implementation had floundered. The APG were far reaching in what they want to happen but were dependent on other departments for buy in and the interest from personnel in other departments was just not there. The sister reported via the phone interview that the Trust are not interested in training more people to be qualified in putting central lines in and the theatre matron is still not interested in rectifying the issue of patients being starved on the ward for days at a time. This ward seemed to be less involved in other safety, quality and experience initiatives than other wards were (even at the same Trust).

Facilitator's field notes

The sister came in on her day off to attend the Trust wide Closing meeting. She was firmly committed to the study throughout and indeed to improving patient safety.

Engagment profile: This ward team did everything that was asked of them and they were highly engaged as a group with the purpose of PRASE. They made some far reaching action plans which sought to challenge underlying structural barriers but made little progress with these when they tried to implement them as other departments on which they depended for buy in were not interested. **Engaged throughout despite organisational setbacks.**

Appendix 4 – Diagram of engagement typologies



Exploring how ward staff engage with the implementation of a patient safety intervention: A qualitative process evaluation

Laura Sheard
laura.sheard@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Claire Marsh
claire.marsh@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Jane O'Hara
jane.o'hara@bthft.nhs.uk
Bradford Institute for Health Research & University of Leeds, United Kingdom

Gerry Armitage
g.r.armitage@brad.ac.uk
University of Bradford, United Kingdom

John Wright
john.wright@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Rebecca Lawton
r.j.lawton@leeds.ac.uk
Bradford Institute for Health Research & University of Leeds, United Kingdom

Corresponding author:
Laura Sheard
Bradford Institute for Health Research
Bradford Teaching Hospitals
Bradford Royal Infirmary
Duckworth Lane
Bradford
BD9 6RJ
United Kingdom

ABSTRACT

Objectives – A patient safety intervention was tested in a 33 ward randomised controlled trial. No statistically significant difference between intervention and control wards was found. We conducted a process evaluation of the trial and our aim in this paper is to understand staff engagement across the 17 intervention wards.

Design – Large qualitative process evaluation of the implementation of a patient safety intervention.

Setting and participants – NHS staff based on 17 acute hospital wards located at five hospital sites in the North of England.

Data – We concentrate on three sources here: i) analysis of taped discussion between ward staff during action planning meetings ii) facilitators' field notes iii) follow up telephone interviews with staff focussing on whether action plans had been achieved. The analysis involved the use of pen portraits and adaptive theory.

Findings – First, there were palpable differences in the ways that the 17 ward teams engaged with the key components of the intervention. Five main engagement typologies were evident across the life course of the study: consistent, partial, increasing, decreasing and disinterested. Second, the intensity of support for the intervention at the level of the organisation does not predict the strength of engagement at the level of the individual ward team. Third, the standardisation of facilitative processes provided by the research team does not ensure that implementation standardisation of the intervention occurs by ward staff.

Conclusions - A dilution of the intervention occurred during the trial because wards engaged with PRASE in divergent ways, despite the standardisation of key components. Facilitative processes were not sufficiently adequate to enable intervention wards to successfully engage with PRASE components.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- We devised a process evaluation that had several robust qualitative data collection methods which complemented each other, in order to build a comprehensive and holistic picture of how ward staff implemented the intervention
- Our approach allowed us to reveal how the differing ways in which staff teams engage with the intervention may impact on patient safety changes at a ward level
- Our novel analytic approach utilised pen portrait methodology in a differing way to how it has previously been used in health services research, in order to document the journey of 17 wards interacting with an intervention over an 18 month period
- We have little understanding of whether the implementation of PRASE may have gained traction and fuelled subsequent ward based change once the research team left the field
- The qualitative methods we chose were designed to capture a broad understanding of the contexts in which the intervention was implemented but had we known a priori that engagement was such a significant factor, we may have designed the process evaluation to specifically explore its influence.

BACKGROUND

Measurement of patient safety has traditionally relied on information from staff such as incident reports or recording information about harms such as falls or pressure sores. Recently, patients have been emphasised as being an important detector for patient safety and likened to the 'smoke detectors' of safety [1]. There is an increasing recognition that hospitals need to find better ways to capture and respond to the concerns of patients regarding the quality and safety of their care [2-4]. However, patients are rarely asked about structural or procedural aspects of care which may contribute towards failures in patient safety. The Yorkshire Quality and Safety group have developed a patient safety intervention called Patient Reporting and Action for a Safe Environment (PRASE). This intervention firstly elicits patient perceptions on how a ward is performing on a series of issues which are known to contribute towards patient safety incidents and secondly assists staff to interpret patient feedback to aid service improvements. This paper provides an account of a qualitative process evaluation of a randomised controlled trial (RCT) where PRASE was tested. PRASE was designed [5, 6], tested for feasibility [7] and trialled [8, 9] between 2010 and 2015. This period has been charted as an era of paradigm shift for patient safety research when the dominant 'measure and manage' orthodoxy has been enriched by approaches sensitive to setting and socio-cultural/ political influences [10]. It became essential for a process evaluation to capture the nuances involved in the PRASE implementation.

Process evaluations have been used to explain sub-optimum outcome effects, specifically whether there was a 'fault' with the intervention itself, its key components or with delivery [11]. Latterly, they are often not only concerned with adherence to original plans, but also with broader issues such as unintended consequences or the strengths and weaknesses of the intervention itself [12]. Some process evaluations have been able to identify a precise 'pinch point' or problem with an essential component of the intervention that caused it to fail. In a UK trial of peer led HIV prevention for gay men in London, no effect was shown. A qualitative process evaluation [13] revealed that the essential component of 'peer educator' had not played out as intended during the course of the trial due to recruitment problems and the inability of peer educators to confidently communicate harm reduction messages to intended targets. Other process evaluations have been able to point to more general cultural or structural reasons why an intervention may not have succeeded. Dixon-Woods et al [14] evaluated why a U.S. developed patient safety intervention - regarding decreasing central line infections in intensive care units – struggled with implementation after the intervention was transferred to a U.K. setting. A post-hoc qualitative evaluation revealed multiple reasons why, largely the result of cultural differences between the U.S and U.K. settings. It is clear from these examples that process evaluations can support the largely 'experimental' aim of RCTs by identifying specific 'pinch points' within an intervention itself or within the context that will help to explain success or failure.

The components of the intervention have been reported in detail elsewhere [8], and the results of the randomised controlled trial which demonstrated no statistically significant effect between the intervention and control wards [9]. A feasibility study was undertaken prior to commencement of the full RCT and details of our logic model and moderating factors are reported in the feasibility write up [7]. Here, we provide a synopsis of the intervention and results of the trial for the reader to be able to view our process evaluation in context. Appendix 1 provides a detailed summary of the cyclical activities and facilitative processes of the intervention that were trialled, alongside anticipated outcomes. Appendix 2 describes the trial design and results. Briefly, this was a cyclical study with two phases of: i) collecting patient feedback about safety from patients at the bedside ii) collation of this data and ward staff interpreting it iii) ward staff action planning to improve patient safety iv) plans then being implemented and monitored.

METHODS

We conducted a robust process evaluation involving differing qualitative and quantitative methods [8] which gathered comprehensive data about all 17 intervention wards. We drew upon a published framework [12] for designing process evaluations of cluster randomised controlled trials. The main a priori research question was: 'where does the intervention work, how and why?' [8]. In this paper, we have chosen to focus on the 'how?' and 'why?' and present a detailed picture of how staff engaged with the intervention. We now apply our original research question to understand how and why the intervention did *not* work, given the intervention did not have a significant effect on outcomes. Six mixed methods were used in the wider process evaluation but due to the extent and depth of the data collected, we focused intensively on three qualitative methods for the purpose of this paper. The methods described below are those most pertinent to exploring how staff engaged with the intervention in the ways they did, and why. Data was collected between August 2013 to November 2014. NHS ethical approval was granted in March 2013.

1. In depth analysis of taped discussion between ward staff

Action planning meetings (APMs) were digitally recorded for all 17 wards at both phases. At phase two, one ward did not meet so we considered the recordings of 33 APMs. These ranged in length from 27 to 80 minutes (average 43 minutes). Our examination focused on which areas of patient feedback staff chose to make action plans on and which areas they chose not to. We wrote detailed notes whilst listening to the voice file. We structured our notes under the headings: i) Issues seen as important where actions were made (and why) ii) Issues seen as important where no actions were made (and why not) iii) Issues dismissed and reasons for this iv) Comments made by staff about PRASE process/ study/ team v) Comments made by staff about the ward or hospital context.

2. Facilitator's field notes

These notes were written shortly after the APM had finished and captured: i) implicit dynamics between staff, such as body language, tone of voice and other non-verbal cues ii) environmental factors, such as descriptions of the physical space where the meeting was held iii) facilitator's overall impressions. Field notes were brief and gave a 'snapshot' of the meeting. There were three facilitators across the 17 intervention wards and each facilitator worked with the same wards across both phases of the study, to ensure continuity. Field notes were also taken at key meetings and events held with Trust senior management personnel (particularly during set up and roll out of the study). These notes assisted in providing the research team with tacit knowledge of the culture of the site in which the intervention was being implemented.

3. Follow-up telephone interviews conducted with the APM lead

The purpose of these short, structured phone interviews was to ascertain whether action plans had been successfully implemented or not and why. They were conducted around six months after the APM, with the 'PRASE lead' for each ward. Each ward was responsible for nominating a named member of ward staff - who was part of the action planning meeting - to be the PRASE lead. This could be any member of the team but was more often than not the person who volunteered for the role was a senior nurse. A structured interview guide was used. Researchers had a proforma in front of them which contained details about each action plan per ward and they asked the PRASE lead whether each action plan had been implemented – yes, no or partially. Open questioning then continued to understand the factors surrounding this. Five additional questions were asked which focussed on the PRASE lead's opinion of the facilitative processes embedded in the study.

For the purpose of this paper, we wanted to understand **qualitatively** how wards had engaged (or not) with the PRASE intervention. Implementation fidelity (which captures adherence to specific intervention components) is reported quantitatively elsewhere [9]. Engagement of staff with an intervention can be considered as closely aligned but different

from this, referring more to the differing approaches and attitudes that staff take to the task in hand (implementation of different components of the intervention). This is different to whether they have simply delivered the task or not. We decided not to adhere to a numerical/scale definition of 'engagement' whereby differing wards attained a binary definition of either 'engaged' or 'disengaged' with the intervention. Instead, we undertook a nuanced analysis of staff approaches and attitudes to: conducting an action planning meeting, creating quality action plans and implementation of these action plans. We explored 'engagement' as a concept that we define as the 'depth' and 'nature' of ward teams' approaches and attitudes to the intervention.

Informed by this understanding of engagement, a synthesis of the above data sources has provided us with a rich account of the '**engagement trajectory'** of each ward and this was realised by creating a pen portrait of engagement. Pen portraits have been used previously in applied health research in fields as diverse as: end of life care [15], vulnerable old people being enabled to keep warm in their homes [16] and sleeping practices amongst homeless drug users [17]. Previously, they have provided a narrative account of a 'typical' participant in qualitative studies or as an analytic aide memoir. We used them in a slightly different manner to document the 'journey' of the wards throughout the trial from the perspective of the researcher who had worked closely with these wards for over 18 months. There is a lack of methodological literature pertaining to the construction of a pen portrait and this has been left to the discretion of individual research teams. We created a basic structure for the pen portraits which centred on the writing of a linear, longitudinal account of how each ward had engaged with relevant key components of the intervention and the contextual factors which influenced this, ensuring that all three data sources were drawn upon. We did not use an existing theory or framework on which to extract the data for the pen portraits as we wanted the emergent findings to arise inductively from the data set. As staff engagement was our focus, we included as much material on this as possible (along with explanatory factors and necessary description). We excluded minutiae which did not add to the 'big picture' of the ward team's engagement to maintain a focussed pen portrait. The pen portrait for Holly ward is shown in Appendix 3 with the prose annotated as an illustration of how portraits were constructed from the three data sources outlined above.

Researchers took into account all the information contained within the pen portrait and attributed an overall 'engagement trajectory' label to each ward. Author A wrote all pen portraits for Trusts A and B and Author B for Trust C. We categorised the 17 different ward engagement trajectories into five main 'engagement typologies', which emerged from an analytical session centring mainly on consensus discussion between Author A and Author B. We report three overarching themes in this paper, which are described in detail in the Findings section which follows. The above categorisation of engagement typologies led to the content of the first theme. After we were confident of the findings of this first theme, we then used the differences in engagement detailed in this theme to progress to themes two and three. To achieve this, we looked between and across the engagement trajectories of all 17 wards in order to understand how engagement with the intervention related to components of local implementation. We returned to the detail of the pen portraits to understand commonality and difference and from this we developed the coding framework for themes two and three. We then checked our assumptions by testing the data in the pen portraits against our initial coding framework. After minor adaptions, we then coded the data in all 17 pen portraits. Overall, we used techniques derived from 'adaptive theory' [18] which allows for high level frameworks and conceptualisations to emerge from data rather than descriptive themes. Adaptive theory proposes a continual engagement between the arising empirical data and arising theoretical interpretations of the research, working in a continuous cycle with each cycle generating new explorations.

FINDINGS

We now set out to understand the ways in which the 17 intervention wards engaged with the intervention. We are interested in how a multiplicity of engagement styles could have made an already complex intervention become hyper complicated in its implementation phase. This 'hyper complexity' may have served to dilute key elements of the intervention. By 'dilution' we mean 'non-standardisation' of the intervention group, thereby reducing the potential for this to be meaningfully compared with a control group. We explore three high level themes, which emerged from the data. Firstly, we will describe how there were palpable differences in the ways that ward teams engaged with the intervention. Next, we will look at how support for the intervention at the level of the Trust does not indicate ward level support. Lastly, we will demonstrate that standardisation of facilitative processes by the research team does not ensure this filters down to implementation standardisation by ward staff. All quotation extracts are taken from pen portrait notes and all ward names have been ascribed a pseudonym.

1. The same intervention can be interacted with in highly divergent ways

We were able to distinguish the intervention wards into five main 'engagement typologies' (Appendix 4). They are:

- Consistently engaged throughout (7 wards)
- Partially engaged throughout (4 wards)
- Increasing engagement as trial progressed (2 wards)
- Decreasing engagement as trial progressed (2 wards)
- Disengaged and disinterested throughout (2 wards)

Consistently engaged – This represents the largest category of how wards chose to participate in the trial with 7 out of the 17 residing here. These wards were fully signed up to the ethos of listening to and acting on patient feedback. They took part in a high proportion of the key components of the cyclical activities and made quality action plans which were largely implemented in both phases. A quality action plan can be defined as one which seeks to address issues identified in the patient data and was realistic, relatively timely and more than likely to be achieved. Motivation to take part in the research was high and improving patient safety was even higher.

Partially engaged – These four wards generally did everything asked of them by the research team and largely participated in intervention components but were sometimes lacklustre in their motivation towards improving patient safety. At times, it felt like action planning was just 'going through the motions'. The ability of staff to implement action plans was mixed although this was sometimes due to external factors rather than inertia on the part of the ward staff themselves.

Increasing engagement – These two wards began their involvement with the trial in an ambivalent and – in the case of Maple ward – even hostile manner. However, as the study progressed and the ward staff began to understand what the research team were trying to achieve, engagement with the study solidified. The similarity between these two wards (despite being at different Trusts) is that the turning point for their engagement was attendance at the peer centred Mid-Point Meeting. This is reflected in Maple ward's complete U-turn with implementation of quality action plans at phase two as compared with partial implementation of weak action plans at phase one.

Decreasing engagement – Conversely, another two wards engaged with the study relatively well at the beginning but, over time, slipped in their level of interest and involvement. Cherry ward is the only ward across all 17 who did not meet in an APM in phase two. The follow up telephone interview revealed that the ward manager for Cherry did not believe the study was a priority. Oak ward had ambitious plans for their phase one action planning but had become

dejected by the amount of time their plan was taking to come into effect. Subsequently, they declined to make an action plan in the phase two APM and appeared disinterested in the study.

Disengaged and disinterested – Although these two wards met in APMs for both phases of the trial, they were not interested in using the PRASE data to improve patient safety and viewed the study as a burden. However, the reasons for this response differed. Rowan were a low performing ward whose ward manager preferred to concentrate on the other initiatives rather than our research study. Elm ward were outwardly hostile to the ethos of the study, critical of the comments their patients had made to researchers and defensive of staff members. Despite agreeing to hold an APM, they consistently refused to make action plans.

Through an examination of these differing engagement trajectories, we can unpick where parts of the intervention may have led to divergent strategies for local implementation of the intervention on a ward-by-ward basis. These findings from 'on the ground' implementation by ward teams directly contradict some of the core assumptions held by the research team at the outset of intervention development - namely, that by providing facilitative processes, wards would be able to implement in a uniform manner. It is this aspect of a chasm between implementation expectations and reality which we now turn our attention to.

2. Trust-level support for an intervention does not predict the strength of ward-level engagement

A key assumption was that strong corporate, managerial-level support by the three participating Trusts would facilitate high-level engagement by wards. However an examination of the differing types of engagement trajectories, shown in Figure 1, throw doubt on this assumption and we can find little consistency in engagement style between the wards at the same Trust. For instance, Trust A is a small district general hospital in a semi-rural, affluent area. This Trust prides itself on being a forward thinking, cohesive workplace and senior management support for this intervention was exceptionally strong. However, when reduced down to the level of the ward, we can see that the four intervention wards at Trust A are represented across four distinct engagement trajectories (Consistent = Beech, Increasing = Maple, Decreasing = Oak, Disengaged = Elm). Engagement trajectories for each of the other two Trusts also differed considerably by ward. The implication here is that corporate culture - and receptivity to patient feedback at the level of the organisation - is not a simple predictor of engagement at ward level.

Unpicking these differences further, we find that despite a uniform message about the importance of a multi-disciplinary approach to the study, wards seem to have interpreted this differently. Oak ward convened a strong first multi-disciplinary APG with representatives from nursing, allied health professionals and support staff. In contrast, on some wards PRASE remained led and implemented by just one or two nursing staff. For example, Maple's first APG consisted of just the ward manager and pen portrait notes illustrate why:

> *A very tense meeting held with just the ward manager who appeared overtly stressed and about to implode. It was clear at this first APM that the ward manager had not understood the purpose of the study and became upset by some of the negative comments which her patients had made in the report. It was a difficult APM to convene as the ward manager thought she had to solve everything by herself and this was partially reinforced by the fact that she had not invited any of her staff to the APM (Maple, Trust A)*

The research team never envisaged that the intervention would be taken on by just one or two members of ward staff and this was actively discouraged throughout but still persisted in five wards at phase one and six wards at phase two, across the 17 intervention wards. It is difficult to suggest a clear reason why this happened but it was often related to:

- Front line issues, such as no staff available to be released from direct patient care to attend APG
- A minority of ward managers viewing the study as yet another patient safety initiative that they just needed to 'get on with'
- A misunderstanding of the multi-disciplinary nature of the intervention.

Of most interest is the severe paucity of medical staff involved in the intervention with only four wards (all at Trust C) involving a medic. This was unforeseen at the outset and may have contributed to action plans that were narrower in scope than those generated by a strong MDT. Even those wards who managed to convene a strong multi-disciplinary APG in phase one were often not able to sustain this level of input going into phase two. Towards the end of the study, it was disappointing to see that PRASE had unwittingly become badged as a 'nursing initiative'. Medical and allied health professional input declined over time and the workload was disproportionally being shouldered by individual Ward Managers (managerial nurses) who were for the most part already overloaded in their daily clinical roles.

Furthermore, an assumption was that a tight, coherent and most importantly *consistent* group of staff would engage with the intervention throughout the 14 months of staff involvement. In reality, staff movement around the NHS estate was high. This led to difficulties regarding ownership of action planning with some staff reluctant to proceed with action plans devised by their predecessors and others not believing it was worth the effort to become involved in the study if they were moving on shortly. A few ward teams changed their personnel completely between phase one and two of the study due to managerial reorganisation:

> *A massive change in staffing took place around the latter part of Phase one with a new Ward Manager and 80-85% change in ward staff. The second phone interview revealed that other ward initiatives were taking place…the whole PRASE process was never wholly embraced because of intense ward improvement work, and staff flux, taking place at the same time (Chestnut ward, Trust C)*

It was never anticipated that such wholesale change would take place at the level of the individual ward teams within the lifetime of the trial and the intervention was unprepared for this. There was little formal capacity to continually re-introduce PRASE to new ward staff, despite researchers having to perform this ad hoc and unexpected role. Critically, it points to ownership of the intervention on the ground as a key factor in success. The engagement with the intervention becomes weak if it is passed around large numbers of different staff or if staff groups change on a dramatic scale.

3. Standardisation of facilitative processes by the research team does not necessarily ensure implementation standardisation by ward staff

A key intention of the facilitative processes was to ensure standardisation of implementation by ward staff. The process evaluation found that, in reality, these uniform training and facilitative processes resulted in little standardisation of approach to action planning regarding a) the issues which staff chose to focus on or b) whether the action plans were successfully implemented (or not). Our pen portraits point to three main issues that appear to underpin why:

- Implementation of action plans were often related to buy in and collegiate working with other departments, some of whom were not willing to spend time, resource and effort on an issue which was not their own
- Existing pan-Trust safety and quality campaigns were prioritised over and above PRASE, to differing degrees which variably helped or hindered PRASE intentions
- Success was often the result of a complex interplay between the personal will of the staff involved in the APG and whether the study fitted into current ward priorities

The following pen portrait excerpt from Apple ward exemplifies the first identified issue regarding buy in from other departments. This ward had several negative comments from patients that pain relief was not being given in a timely manner. To address this, the APG decided they needed assistance from pharmacy but this was not forthcoming and APG members were disappointed. This led to the contradictory position in phase two of engagement still being very present but the act of action planning itself becoming tokenistic:

> *This ward stayed engaged with the project the entire way through despite setbacks with their earliest action plan. The ward manager in particular clearly understood the purpose of the study and was sympathetic to receiving patient feedback. However, inertia may have crept in as their 'outside the box' thinking in phase one did not get any buy in from the pharmacy department. Action planning in phase two then became perfunctory even though engagement was still high (Apple, Trust B)*

The second issue of other safety campaigns being prioritised above this study relates to the capacity with which ward staff have within their normal clinical roles to be able to undertake improvement work. In several of the pen portraits, PRASE was described as "just one of many improvement initiatives which this ward are involved in". Wards were under pressure to take part in hospital wide initiatives that executive teams had deemed to be of most importance. Whilst there was senior support for PRASE, it was not always significant in comparison to other initiatives. In some cases, the existence of other high profile campaigns supported staff in achieving their PRASE action plans. Trust C launched a well-received "Hello my name is…" patient experience campaign tying into national acknowledgement of the need for staff to introduce themselves and communicate better with patients at the bedside. On the wards where PRASE feedback had also drawn attention to this need, staff were supported to respond (through badges, awareness training and senior-support) to do so.

However, the flip-side of attention on more high-profile campaigns meant that – for some wards – PRASE became sidelined. Associated with this was a feeling of patient safety and quality 'fatigue' with the amount of initiatives in this area felt too numerous and therefore burdensome on staff time:

> *I got the sense that the ward manager saw PRASE as just another audit which she needed to go through the motions of…At one point during phase two, she admitted that in phase one she did not see the value in the study as she thought it just replicated other patient experience measures her ward is involved in. However, now she appreciates how it is different from the other measures...Working out where PRASE fitted in with other initiatives seemed to be a big issue for this ward manager (Pine Ward, Trust B)*

One strong finding to emerge was the use of PRASE data to reinforce safety or quality issues which the ward staff knew about tacitly but did not have robust data about in order to report to senior management. This finding emerged as a divisive issue. Some wards were pleased that the PRASE study reinforced staff opinion about the ward or validated on a larger scale the results of local audits. However, a minority of staff became irritated and instead viewed it as duplication.

DISCUSSION

As introduced at the outset, some process evaluations are able to reveal specific 'pinch points' within the intervention itself [13], or within the overall setting in which it was applied [14], which help to explain why no effect was seen. The Consolidated Framework for Advancing Implementation Research advocates the 'inner setting' of an organisation as being influential in whether or not implementation can be achieved, where attention must be paid to the domains of: structural characteristics, networks and communications, culture, implementation climate [19]. Our process evaluation found that this inner setting was so varied between wards within the intervention group that this led to a general 'dilution' of intervention implementation. We found striking differences between wards across all the above domains of 'inner setting' – stability of ward teams, quality of relationships between different wards, basic assumptions towards receiving patient feedback and a learning climate (or lack of one). Significantly, we saw changes to the 'inner setting' constructs over time. The in-depth analysis of what happened within the intervention group generates useful insights for implementation of, and staff engagement with, patient safety initiatives to which we will now turn our attention.

The improvement of patient safety is already acknowledged as a cultural issue and the importance of factors such as teamwork, leadership and organisational processes operating at and between multiple levels [20]. Navigating this territory - particularly the link between 'sharp end' ward safety initiatives and 'blunt end' corporate planning - has been documented as a necessary challenge. Initiatives which do not pay adequate attention in this regard are at best destined to fail, and at worst may over-burden already de-motivated staff [21]. The facilitative processes incorporated into PRASE were designed to help address this challenge. These processes arose from the findings of feasibility testing of the intervention [7] where our research team found that, for example, access to senior management at regular intervals and assistance in interpreting patient feedback were important factors which may support action planning. The assumption was that by providing these processes, staff would be better placed to successfully navigate complex organisational territory. It was anticipated this would allow some uniformity amongst the intervention group. In actuality, the facilitative processes were not adequate to ensure any such uniformity.

Dixon-Woods et al (2011) [22] developed a post theorisation of why impressive results were seen in the original Michigan intervention - to decrease central line infections - in the U.S. Six reasons are proposed as to why the program worked. Of particular applicability is the 'creation of a networked community' where ward teams came together to build rapport and support for each other whilst identifying and resolving common barriers. Although part of the facilitative processes within the PRASE intervention aimed to attend to this need, it is likely that the community of wards involved in the study never reached a critical threshold in becoming an organic community who regularly reached out to each other. Further, specific leaders were targeted in the Michigan programme including hospital executives and clinical team leaders. This involvement of leaders at differing levels of the organisation is theorised as being integral to the success of the programme. Conversely, we found that involving senior management and matrons prior to the start of the study and then throughout its entirety had minimal effect on strengthening engagement with the intervention on the ground by frontline ward staff. Questions regarding the ability of senior management to support consistency of intervention adoption throughout an organisation, and the processes required to enable this further, were raised by our study and certainly warrant further exploration.

In this study, the relationships between different parts and levels of the organisation from senior management to ward teams to individuals were vital in achieving success. When these levels align well, as they appeared to do in one Trust - with respect to a culture shift around introducing and communicating to patients via an external patient experience campaign - it appears that much can be achieved. When they do not – e.g. Apple ward who did not get buy in from the pharmacy department - staff at the ward level can become

frustrated and demotivated. We therefore question the capacity of an externally designed intervention, even one with significant resources and facilitative processes, to provide the mechanisms to be continually adaptive to the organisational alignment between the sharp and blunt end at differing institutions. The challenges revealed here are about deeper organisational culture, systems and processes that need longer-term development.

Our findings support the growing understanding that emphasis in patient safety research must continue to shift from the measure and manage orthodoxy of data collection to interpretation and process [10]. In this research, the collection of patient feedback was the least problematic element. The complexity of what staff are being asked to do in interventions like PRASE (navigating multi-layered organisational systems to implement improvements) requires much more consideration. In the broader but related policy area of patient experience, the overt emphasis and huge resource allocated to collecting patient experience data has not been matched by efforts to utilise and evaluate the impact of feedback on service improvement [23]. There is increasing recognition that using data sources to change practice demands creativity and skills from staff; hence the tendency to present staff with data and expect change to happen as a result [24]. Our intervention considered these issues a priori and hence facilitative processes were built into the trial yet they were not sufficiently robust enough to ensure a standardised implementation across intervention wards.

One interpretation of PRASE could be that it 'failed' due to showing no effect between the intervention and control wards. We believe this a simplistic view which does not take into account the wealth of positive benefits which patients and staff gained. Firstly, it showed that patients are able to give feedback about the safety and quality of care and that they want to do this en masse (our consent rate was 85% of those patients approached by researchers and the number of patients recruited to the study was 2400 across five different hospital sites). Secondly, the process evaluation showed that most staff *do* believe the patient voice is important and there is an imperative to listen to, and act on, this voice. Thirdly, despite local struggles, most staff do want to action plan to improve their patients' care. The majority of the wards were receptive to receiving patient feedback – it is when they tried to move improvement work forward that problems arose [25]. An additional gain which some staff identified was the ability of the patient feedback to allow staff to understand not only the patient perspective but also their priorities and to visualise the ward environment and systems 'through the eyes of the patient'.

Limitations

We cannot know whether positive attitudes towards patient involvement in patient safety have continued on the intervention wards after the trial was completed. Improvements that staff were working towards may have gained impetus since the research team left. Equally, involvement in the trial may have kick-started ideas which, although did not come to fruition within its life span, may now be fuelling ward level action. Conversely, staff may have felt disempowered to enact improvement to the ward environment if their PRASE action plans had floundered. We have no format for measuring this 'after effect' – either positive or negative – and little scope for knowing at what time point the evidence of a more long lasting effect may be captured.

Our pen portrait methodology is a culmination of all sources of qualitative data collected and has its inherent weaknesses. This methodology is still in its relative infancy in relation to the way in which we have utilised it here. We were careful to draw equally on all sources of data in order to build a comprehensive narrative of the engagement trajectory of each ward. However, a differing analysis paying attention to fewer sources or an unequal weighing of sources may have pulled the narrative account in a slightly different direction. Further, it was difficult to categorise some wards firmly into their allocated engagement typology and

arguably some could fit into several. Finally, process evaluation methods were developed a priori to the start of the trial so the design was very open. We devised a loose structure to capture qualitative intelligence on key trial processes. If prior knowledge existed that diversity of engagement within the intervention wards was to be so significant, it may have been possible to target a particular process evaluation framework for analysing outcomes in relation to this diversity, such as the 'diffusion of innovation model' [26]. It is a possibility that utilisation of differing methods may have provided other answers as to where different elements of the intervention worked, for whom and why.

CONCLUSION

Whereas previous process evaluations point towards specific pinch points or broader cultural issues to understand why an intervention showed no effect, this study points to an overall 'dilution effect' of the intervention. This was largely due to wards engaging with the intervention in highly divergent manners despite the standardisation of key components by the research team. The facilitative processes were inadequate to ensure full engagement across all wards in the study. A disconnect existed between senior management support for the study and how ward staff on the ground engaged with it more locally. The above findings assist in explaining why the trial saw no effect between intervention and control wards.

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Competing interests

The authors declare they have no competing interests

Authors' contributions

RL, GA and JW are grant holders of the programme grant. LS devised the methodology of the process evaluation and wrote the qualitative protocol, with assistance from CM. LS, CM and JOH all collected data. LS and CM analysed and interpreted all data, with intellectual input from GA. LS and CM co-wrote the first draft of the paper. All authors edited the first draft of the paper. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by South Yorkshire NHS Research Ethics Committee on 15th March 2013 (Ref: 13/YH/0077). All participants gave informed consent to take part in this study.

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Data sharing statement

Unpublished data is not available

FIGURE HEADINGS

Appendix 1 – Key intervention components and anticipated outcomes
Appendix 2 – Trial design and results
Appendix 3 – Holly ward pen portrait
Appendix 4 – diagram of engagement typologies

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Exploring how ward staff engage with the implementation of a patient safety intervention: A UK based qualitative process evaluation

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Exploring how ward staff engage with the implementation of a patient safety intervention: A UK based qualitative process evaluation

Laura Sheard
laura.sheard@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Claire Marsh
claire.marsh@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Jane O'Hara
jane.o'hara@bthft.nhs.uk
Bradford Institute for Health Research & University of Leeds, United Kingdom

Gerry Armitage
g.r.armitage@brad.ac.uk
University of Bradford, United Kingdom

John Wright
john.wright@bthft.nhs.uk
Bradford Institute for Health Research, United Kingdom

Rebecca Lawton
r.j.lawton@leeds.ac.uk
Bradford Institute for Health Research & University of Leeds, United Kingdom

Corresponding author:
Laura Sheard
Bradford Institute for Health Research
Bradford Teaching Hospitals
Bradford Royal Infirmary
Duckworth Lane
Bradford
BD9 6RJ
United Kingdom

ABSTRACT

Objectives – A patient safety intervention was tested in a 33 ward randomised controlled trial. No statistically significant difference between intervention and control wards was found. We conducted a process evaluation of the trial and our aim in this paper is to understand staff engagement across the 17 intervention wards.

Design – Large qualitative process evaluation of the implementation of a patient safety intervention.

Setting and participants – NHS staff based on 17 acute hospital wards located at five hospital sites in the North of England.

Data – We concentrate on three sources here: i) analysis of taped discussion between ward staff during action planning meetings ii) facilitators' field notes iii) follow up telephone interviews with staff focussing on whether action plans had been achieved. The analysis involved the use of pen portraits and adaptive theory.

Findings – First, there were palpable differences in the ways that the 17 ward teams engaged with the key components of the intervention. Five main engagement typologies were evident across the life course of the study: consistent, partial, increasing, decreasing and disengaged. Second, the intensity of support for the intervention at the level of the organisation does not predict the strength of engagement at the level of the individual ward team. Third, the standardisation of facilitative processes provided by the research team does not ensure that implementation standardisation of the intervention occurs by ward staff.

Conclusions - A dilution of the intervention occurred during the trial because wards engaged with PRASE in divergent ways, despite the standardisation of key components. Facilitative processes were not sufficiently adequate to enable intervention wards to successfully engage with PRASE components.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- We devised a process evaluation that had several robust qualitative data collection methods which complemented each other, in order to build a comprehensive and holistic picture of how ward staff implemented the intervention
- Our approach allowed us to reveal how the differing ways in which staff teams engage with the intervention may impact on patient safety changes at a ward level
- Our novel analytic approach utilised pen portrait methodology in a differing way to how it has previously been used in health services research, in order to document the journey of 17 wards interacting with an intervention over an 18 month period
- We have little understanding of whether the implementation of PRASE may have gained traction and fuelled subsequent ward based change once the research team left the field
- The qualitative methods we chose were designed to capture a broad understanding of the contexts in which the intervention was implemented but had we known a priori that engagement was such a significant factor, we may have designed the process evaluation to specifically explore its influence.

BACKGROUND

Measurement of patient safety has traditionally relied on information from staff such as incident reports or recording information about harms such as falls or pressure sores. Recently, patients have been emphasised as being an important detector for patient safety and likened to the 'smoke detectors' of safety [1]. There is an increasing recognition that hospitals need to find better ways to capture and respond to the concerns of patients regarding the quality and safety of their care [2-4]. However, patients are rarely asked about structural or procedural aspects of care which may contribute towards failures in patient safety. The Yorkshire Quality and Safety group have developed a patient safety intervention called Patient Reporting and Action for a Safe Environment (PRASE). This intervention firstly elicits patient perceptions on how a ward is performing on a series of issues which are known to contribute towards patient safety incidents and secondly assists staff to interpret patient feedback to aid service improvements. This paper provides an account of a qualitative process evaluation of a randomised controlled trial (RCT) where PRASE was tested. PRASE was designed [5, 6], tested for feasibility [7] and trialled [8, 9] between 2010 and 2015. This period has been charted as an era of paradigm shift for patient safety research when the dominant 'measure and manage' orthodoxy has been enriched by approaches sensitive to setting and socio-cultural/ political influences [10]. It became essential for a process evaluation to capture the nuances involved in the PRASE implementation.

Process evaluations have been used to explain sub-optimum outcome effects, specifically whether there was a 'fault' with the intervention itself, its key components or with delivery [11]. Latterly, they are often not only concerned with adherence to original plans, but also with broader issues such as unintended consequences or the strengths and weaknesses of the intervention itself [12]. Some process evaluations have been able to identify a precise 'pinch point' or problem with an essential component of the intervention that caused it to fail. In a UK trial of peer led HIV prevention for gay men in London, no effect was shown. A qualitative process evaluation [13] revealed that the essential component of 'peer educator' had not played out as intended during the course of the trial due to recruitment problems and the inability of peer educators to confidently communicate harm reduction messages to intended targets. Other process evaluations have been able to point to more general cultural or structural reasons why an intervention may not have succeeded. Dixon-Woods et al [14] evaluated why a U.S. developed patient safety intervention - regarding decreasing central line infections in intensive care units – struggled with implementation after the intervention was transferred to a U.K. setting. A post-hoc qualitative evaluation revealed multiple reasons why, largely the result of cultural differences between the U.S and U.K. settings. It is clear from these examples that process evaluations can support the largely 'experimental' aim of RCTs by identifying specific 'pinch points' within an intervention itself or within the context that will help to explain success or failure.

The components of the intervention have been reported in detail elsewhere [8], and the results of the randomised controlled trial which demonstrated no statistically significant effect between the intervention and control wards [9]. A feasibility study was undertaken prior to commencement of the full RCT and details of our logic model and moderating factors are reported in the feasibility write up [7]. Here, we provide a synopsis of the intervention and results of the trial for the reader to be able to view our process evaluation in context. Appendix 1 provides a detailed summary of the cyclical activities and facilitative processes of the intervention that were trialled, alongside anticipated outcomes. Appendix 2 describes the trial design and results. Briefly, this was a cyclical study with two phases of: i) collecting patient feedback about safety from patients at the bedside ii) collation of this data and ward staff interpreting it iii) ward staff action planning to improve patient safety iv) plans then being implemented and monitored.

METHODS

We conducted a robust process evaluation involving differing qualitative and quantitative methods [8] which gathered comprehensive data about all 17 intervention wards. We drew upon a published framework [12] for designing process evaluations of cluster randomised controlled trials. The main a priori research question was: 'where does the intervention work, how and why?' [8]. In this paper, we have chosen to focus on the 'how?' and 'why?' and present a detailed picture of how staff engaged with the intervention. We now apply our original research question to understand how and why the intervention did *not* work, given the intervention did not have a significant effect on outcomes. Six mixed methods were used in the wider process evaluation but due to the extent and depth of the data collected, we focused intensively on three qualitative methods for the purpose of this paper. The methods described below are those most pertinent to exploring how staff engaged with the intervention in the ways they did, and why. Data was collected between August 2013 to November 2014. NHS ethical approval was granted in March 2013. LS, CM and JOH undertook method one and two. LS and CM conducted method three. LS is a sociologist, JOH is a psychologist and CM has a background in sustainability. All were working as researchers on this study and educated to doctorate level in their respective fields.

1. In depth analysis of taped discussion between ward staff

Action planning meetings (APMs) were digitally recorded for all 17 wards at both phases. At phase two, one ward did not meet so we considered the recordings of 33 APMs. These ranged in length from 27 to 80 minutes (average 43 minutes). Our examination focused on which areas of patient feedback staff chose to make action plans on and which areas they chose not to. We wrote detailed notes whilst listening to the voice file. We structured our notes under the headings: i) Issues seen as important where actions were made (and why) ii) Issues seen as important where no actions were made (and why not) iii) Issues dismissed and reasons for this iv) Comments made by staff about PRASE process/ study/ team v) Comments made by staff about the ward or hospital context.

2. Facilitator's field notes

These notes were written shortly after the APM had finished and captured: i) implicit dynamics between staff, such as body language, tone of voice and other non-verbal cues ii) environmental factors, such as descriptions of the physical space where the meeting was held iii) facilitator's overall impressions. Field notes were brief and gave a 'snapshot' of the meeting. There were three facilitators (LS, CM and JOH) across the 17 intervention wards and each facilitator worked with the same wards across both phases of the study, to ensure continuity. Field notes were also taken at key meetings and events held with Trust senior management personnel (particularly during set up and roll out of the study). These notes assisted in providing the research team with tacit knowledge of the culture of the site in which the intervention was being implemented.

3. Follow-up telephone interviews conducted with the APM lead

The purpose of these short, structured phone interviews was to ascertain whether action plans had been successfully implemented or not and why. They were conducted around six months after the APM, with the 'PRASE lead' for each ward. Each ward was responsible for nominating a named member of ward staff - who was part of the action planning meeting - to be the PRASE lead. This could be any member of the team but was more often than not the person who volunteered for the role was a senior nurse. A structured interview guide was used. Researchers had a proforma in front of them which contained details about each action plan per ward and they asked the PRASE lead whether each action plan had been implemented – yes, no or partially. Open questioning then continued to understand the factors surrounding this. Five additional questions were asked which focussed on the PRASE lead's opinion of the facilitative processes embedded in the study.

For the purpose of this paper, we wanted to understand **qualitatively** how wards had engaged (or not) with the PRASE intervention. Implementation fidelity (which captures adherence to specific intervention components) is reported quantitatively elsewhere [9]. Engagement of staff with an intervention can be considered as closely aligned but different from this, referring more to the differing approaches and attitudes that staff take to the task in hand (implementation of different components of the intervention). This is different to whether they have simply delivered the task or not. We decided not to adhere to a numerical/scale definition of 'engagement' whereby differing wards attained a binary definition of either 'engaged' or 'disengaged' with the intervention. Instead, we undertook a nuanced analysis of staff approaches and attitudes to: conducting an action planning meeting, creating quality action plans and implementation of these action plans. We explored 'engagement' as a concept that we define as the 'depth' and 'nature' of ward teams' approaches and attitudes to the intervention.

Informed by this understanding of engagement, a synthesis of the above data sources has provided us with a rich account of the '**engagement trajectory'** of each ward and this was realised by creating a pen portrait of engagement. Pen portraits have been used previously in applied health research in fields as diverse as: end of life care [15], vulnerable old people being enabled to keep warm in their homes [16] and sleeping practices amongst homeless drug users [17]. Previously, they have provided a narrative account of a 'typical' participant in qualitative studies or as an analytic aide memoir. We used them in a slightly different manner to document the 'journey' of the wards throughout the trial from the perspective of the researcher who had worked closely with these wards for over 18 months. There is a lack of methodological literature pertaining to the construction of a pen portrait and this has been left to the discretion of individual research teams. We created a basic structure for the pen portraits which centred on the writing of a linear, longitudinal account of how each ward had engaged with relevant key components of the intervention and the contextual factors which influenced this, ensuring that all three data sources were drawn upon. We did not use an existing theory or framework on which to extract the data for the pen portraits as we wanted the emergent findings to arise inductively from the data set. As staff engagement was our focus, we included as much material on this as possible (along with explanatory factors and necessary description). We excluded minutiae which did not add to the 'big picture' of the ward team's engagement to maintain a focussed pen portrait. The pen portrait for Holly ward is shown in Appendix 3 with the prose annotated as an illustration of how portraits were constructed from the three data sources outlined above.

Researchers took into account all the information contained within the pen portrait and attributed an overall 'engagement trajectory' label to each ward. Author A wrote all pen portraits for Trusts A and B and Author B for Trust C. We categorised the 17 different ward engagement trajectories into five main 'engagement typologies', which emerged from an analytical session centring mainly on consensus discussion between Author A and Author B. We report three overarching themes in this paper, which are described in detail in the Findings section which follows. The above categorisation of engagement typologies led to the content of the first theme. After we were confident of the findings of this first theme, we then used the differences in engagement detailed in this theme to progress to themes two and three. To achieve this, we looked between and across the engagement trajectories of all 17 wards in order to understand how engagement with the intervention related to components of local implementation. We returned to the detail of the pen portraits to understand commonality and difference and from this we developed the coding framework for themes two and three. We then checked our assumptions by testing the data in the pen portraits against our initial coding framework. After minor adaptions, we then coded the data in all 17 pen portraits. Overall, we used techniques derived from 'adaptive theory' [18] which allows for high level frameworks and conceptualisations to emerge from data rather than descriptive themes. Adaptive theory proposes a continual engagement between the arising

empirical data and arising theoretical interpretations of the research, working in a continuous cycle with each cycle generating new explorations.

FINDINGS

We now set out to understand the ways in which the 17 intervention wards engaged with the intervention. We are interested in how a multiplicity of engagement styles could have made an already complex intervention become hyper complicated in its implementation phase. This 'hyper complexity' may have served to dilute key elements of the intervention. By 'dilution' we mean 'non-standardisation' of the intervention group, thereby reducing the potential for this to be meaningfully compared with a control group. We explore three high level themes, which emerged from the data. Firstly, we will describe how there were palpable differences in the ways that ward teams engaged with the intervention. Next, we will look at how support for the intervention at the level of the Trust does not indicate ward level support. Lastly, we will demonstrate that standardisation of facilitative processes by the research team does not ensure this filters down to implementation standardisation by ward staff. All quotation extracts are taken from pen portrait notes and all ward names have been ascribed a pseudonym.

1. The same intervention can be interacted with in highly divergent ways

We were able to distinguish the intervention wards into five main 'engagement typologies' (Appendix 4). They are:

- Consistently engaged throughout (7 wards)
- Partially engaged throughout (4 wards)
- Increasing engagement as trial progressed (2 wards)
- Decreasing engagement as trial progressed (2 wards)
- Disengaged throughout (2 wards)

Consistently engaged – This represents the largest category of how wards chose to participate in the trial with 7 out of the 17 residing here. These wards were fully signed up to the ethos of listening to and acting on patient feedback. They took part in a high proportion of the key components of the cyclical activities and made quality action plans which were largely implemented in both phases. A quality action plan can be defined as one which seeks to address issues identified in the patient data and was realistic, relatively timely and more than likely to be achieved. Motivation to take part in the research was high and improving patient safety was even higher.

Partially engaged – These four wards generally did everything asked of them by the research team and largely participated in intervention components but were sometimes lacklustre in their motivation towards improving patient safety. At times, it felt like action planning was just 'going through the motions'. The ability of staff to implement action plans was mixed although this was sometimes due to external factors rather than inertia on the part of the ward staff themselves.

Increasing engagement – These two wards began their involvement with the trial in an ambivalent and – in the case of Maple ward – even hostile manner. However, as the study progressed and the ward staff began to understand what the research team were trying to achieve, engagement with the study solidified. The similarity between these two wards (despite being at different Trusts) is that the turning point for their engagement was attendance at the peer centred Mid-Point Meeting. This is reflected in Maple ward's complete U-turn with implementation of quality action plans at phase two as compared with partial implementation of weak action plans at phase one.

Decreasing engagement – Conversely, another two wards engaged with the study relatively well at the beginning but, over time, slipped in their level of interest and involvement. Cherry ward is the only ward across all 17 who did not meet in an APM in phase two. The follow up telephone interview revealed that the ward manager for Cherry did not believe the study was a priority. Oak ward had ambitious plans for their phase one action planning but had become dejected by the amount of time their plan was taking to come into effect. Subsequently, they declined to make an action plan in the phase two APM and appeared disengaged in the study.

Disengaged throughout – Although these two wards met in APMs for both phases of the trial, they were not interested in using the PRASE data to improve patient safety and viewed the study as a burden. However, the reasons for this response differed. Rowan were a low performing ward whose ward manager preferred to concentrate on the other initiatives rather than our research study. Elm ward were outwardly hostile to the ethos of the study, critical of the comments their patients had made to researchers and defensive of staff members. Despite agreeing to hold an APM, they consistently refused to make action plans.

Through an examination of these differing engagement trajectories, we can unpick where parts of the intervention may have led to divergent strategies for local implementation of the intervention on a ward-by-ward basis. These findings from 'on the ground' implementation by ward teams directly contradict some of the core assumptions held by the research team at the outset of intervention development - namely, that by providing facilitative processes, wards would be able to implement in a uniform manner. It is this aspect of a chasm between implementation expectations and reality which we now turn our attention to.

2. Trust-level support for an intervention does not predict the strength of ward-level engagement

A key assumption was that strong corporate, managerial-level support by the three participating Trusts would facilitate high-level engagement by wards. However an examination of the differing types of engagement trajectories, shown in Appendix 4, throw doubt on this assumption and we can find little consistency in engagement style between the wards at the same Trust. For instance, Trust A is a small district general hospital in a semi-rural, affluent area. This Trust prides itself on being a forward thinking, cohesive workplace and senior management support for this intervention was exceptionally strong. However, when reduced down to the level of the ward, we can see that the four intervention wards at Trust A are represented across four distinct engagement trajectories (Consistent = Beech, Increasing = Maple, Decreasing = Oak, Disengaged = Elm). Engagement trajectories for each of the other two Trusts also differed considerably by ward. The implication here is that corporate culture - and receptivity to patient feedback at the level of the organisation - is not a simple predictor of engagement at ward level.

Unpicking these differences further, we find that despite a uniform message about the importance of a multi-disciplinary approach to the study, wards seem to have interpreted this differently. Oak ward convened a strong first multi-disciplinary APG with representatives from nursing, allied health professionals and support staff. In contrast, on some wards PRASE remained led and implemented by just one or two nursing staff. For example, Maple's first APG consisted of just the ward manager and pen portrait notes illustrate why:

> *A very tense meeting held with just the ward manager who appeared overtly stressed and about to implode. It was clear at this first APM that the ward manager had not understood the purpose of the study and became upset by some of the negative comments which her patients had made in the report. It was a difficult APM to convene as the ward manager thought she had to solve everything by herself and this was partially reinforced by the fact that she had not invited any of her staff to the APM (Maple, Trust A)*

The research team never envisaged that the intervention would be taken on by just one or two members of ward staff and this was actively discouraged throughout but still persisted in five wards at phase one and six wards at phase two, across the 17 intervention wards. It is difficult to suggest a clear reason why this happened but it was often related to:

- Front line issues, such as no staff available to be released from direct patient care to attend APG
- A minority of ward managers viewing the study as yet another patient safety initiative that they just needed to 'get on with'
- A misunderstanding of the multi-disciplinary nature of the intervention.

Of most interest is the severe paucity of medical staff involved in the intervention with only four wards (all at Trust C) involving a medic. This was unforeseen at the outset and may have contributed to action plans that were narrower in scope than those generated by a strong MDT. Even those wards who managed to convene a strong multi-disciplinary APG in phase one were often not able to sustain this level of input going into phase two. Towards the end of the study, it was disappointing to see that PRASE had unwittingly become badged as a 'nursing initiative'. Medical and allied health professional input declined over time and the workload was disproportionally being shouldered by individual Ward Managers (managerial nurses) who were for the most part already overloaded in their daily clinical roles.

Furthermore, an assumption was that a tight, coherent and most importantly *consistent* group of staff would engage with the intervention throughout the 14 months of staff involvement. In reality, staff movement around the NHS estate was high. This led to difficulties regarding ownership of action planning with some staff reluctant to proceed with action plans devised by their predecessors and others not believing it was worth the effort to become involved in the study if they were moving on shortly. A few ward teams changed their personnel completely between phase one and two of the study due to managerial reorganisation:

> *A massive change in staffing took place around the latter part of Phase one with a new Ward Manager and 80-85% change in ward staff. The second phone interview revealed that other ward initiatives were taking place…the whole PRASE process was never wholly embraced because of intense ward improvement work, and staff flux, taking place at the same time (Chestnut ward, Trust C)*

It was never anticipated that such wholesale change would take place at the level of the individual ward teams within the lifetime of the trial and the intervention was unprepared for this. There was little formal capacity to continually re-introduce PRASE to new ward staff, despite researchers having to perform this ad hoc and unexpected role. Critically, it points to ownership of the intervention on the ground as a key factor in success. The engagement with the intervention becomes weak if it is passed around large numbers of different staff or if staff groups change on a dramatic scale.

3. Standardisation of facilitative processes by the research team does not necessarily ensure implementation standardisation by ward staff

A key intention of the facilitative processes was to ensure standardisation of implementation by ward staff. The process evaluation found that, in reality, these uniform training and facilitative processes resulted in little standardisation of approach to action planning regarding a) the issues which staff chose to focus on or b) whether the action plans were successfully implemented (or not). Our pen portraits point to three main issues that appear to underpin why:

- Implementation of action plans were often related to buy in and collegiate working with other departments, some of whom were not willing to spend time, resource and effort on an issue which was not their own
- Existing pan-Trust safety and quality campaigns were prioritised over and above PRASE, to differing degrees which variably helped or hindered PRASE intentions
- Success was often the result of a complex interplay between the personal will of the staff involved in the APG and whether the study fitted into current ward priorities

The following pen portrait excerpt from Apple ward exemplifies the first identified issue regarding buy in from other departments. This ward had several negative comments from patients that pain relief was not being given in a timely manner. To address this, the APG decided they needed assistance from pharmacy but this was not forthcoming and APG members were disappointed. This led to the contradictory position in phase two of engagement still being very present but the act of action planning itself becoming tokenistic:

> *This ward stayed engaged with the project the entire way through despite setbacks with their earliest action plan. The ward manager in particular clearly understood the purpose of the study and was sympathetic to receiving patient feedback. However, inertia may have crept in as their 'outside the box' thinking in phase one did not get any buy in from the pharmacy department. Action planning in phase two then became perfunctory even though engagement was still high (Apple, Trust B)*

The second issue of other safety campaigns being prioritised above this study relates to the capacity with which ward staff have within their normal clinical roles to be able to undertake improvement work. In several of the pen portraits, PRASE was described as "just one of many improvement initiatives which this ward are involved in". Wards were under pressure to take part in hospital wide initiatives that executive teams had deemed to be of most importance. Whilst there was senior support for PRASE, it was not always significant in comparison to other initiatives. In some cases, the existence of other high profile campaigns supported staff in achieving their PRASE action plans. Trust C launched a well-received "Hello my name is…" patient experience campaign tying into national acknowledgement of the need for staff to introduce themselves and communicate better with patients at the bedside. On the wards where PRASE feedback had also drawn attention to this need, staff were supported to respond (through badges, awareness training and senior-support) to do so.

However, the flip-side of attention on more high-profile campaigns meant that – for some wards – PRASE became sidelined. Associated with this was a feeling of patient safety and quality 'fatigue' with the amount of initiatives in this area felt too numerous and therefore burdensome on staff time:

> *I got the sense that the ward manager saw PRASE as just another audit which she needed to go through the motions of…At one point during phase two, she admitted that in phase one she did not see the value in the study as she thought it just replicated other patient experience measures her ward is involved in. However, now she appreciates how it is different from the other measures...Working out where PRASE fitted in with other initiatives seemed to be a big issue for this ward manager (Pine Ward, Trust B)*

One strong finding to emerge was the use of PRASE data to reinforce safety or quality issues which the ward staff knew about tacitly but did not have robust data about in order to report to senior management. This finding emerged as a divisive issue. Some wards were pleased that the PRASE study reinforced staff opinion about the ward or validated on a larger scale the results of local audits. However, a minority of staff became irritated and instead viewed it as duplication.

DISCUSSION

As introduced at the outset, some process evaluations are able to reveal specific 'pinch points' within the intervention itself [13], or within the overall setting in which it was applied [14], which help to explain why no effect was seen. The Consolidated Framework for Advancing Implementation Research advocates the 'inner setting' of an organisation as being influential in whether or not implementation can be achieved, where attention must be paid to the domains of: structural characteristics, networks and communications, culture, implementation climate [19]. Our process evaluation found that this inner setting was so varied between wards within the intervention group that this led to a general 'dilution' of intervention implementation. We found striking differences between wards across all the above domains of 'inner setting' – stability of ward teams, quality of relationships between different wards, basic assumptions towards receiving patient feedback and a learning climate (or lack of one). Significantly, we saw changes to the 'inner setting' constructs over time. The in-depth analysis of what happened within the intervention group generates useful insights for implementation of, and staff engagement with, patient safety initiatives to which we will now turn our attention.

The improvement of patient safety is already acknowledged as a cultural issue and the importance of factors such as teamwork, leadership and organisational processes operating at and between multiple levels [20]. Navigating this territory - particularly the link between 'sharp end' ward safety initiatives and 'blunt end' corporate planning - has been documented as a necessary challenge. Initiatives which do not pay adequate attention in this regard are at best destined to fail, and at worst may over-burden already de-motivated staff [21]. The facilitative processes incorporated into PRASE were designed to help address this challenge. These processes arose from the findings of feasibility testing of the intervention [7] where our research team found that, for example, access to senior management at regular intervals and assistance in interpreting patient feedback were important factors which may support action planning. The assumption was that by providing these processes, staff would be better placed to successfully navigate complex organisational territory. It was anticipated this would allow some uniformity amongst the intervention group. In actuality, the facilitative processes were not adequate to ensure any such uniformity.

Dixon-Woods et al (2011) [22] developed a post theorisation of why impressive results were seen in the original Michigan intervention - to decrease central line infections - in the U.S. Six reasons are proposed as to why the program worked. Of particular applicability is the 'creation of a networked community' where ward teams came together to build rapport and support for each other whilst identifying and resolving common barriers. Although part of the facilitative processes within the PRASE intervention aimed to attend to this need, it is likely that the community of wards involved in the study never reached a critical threshold in becoming an organic community who regularly reached out to each other. Further, specific leaders were targeted in the Michigan programme including hospital executives and clinical team leaders. This involvement of leaders at differing levels of the organisation is theorised as being integral to the success of the programme. Conversely, we found that involving senior management and matrons prior to the start of the study and then throughout its entirety had minimal effect on strengthening engagement with the intervention on the ground by frontline ward staff. Questions regarding the ability of senior management to support consistency of intervention adoption throughout an organisation, and the processes required to enable this further, were raised by our study and certainly warrant further exploration.

In this study, the relationships between different parts and levels of the organisation from senior management to ward teams to individuals were vital in achieving success. When these levels align well, as they appeared to do in one Trust - with respect to a culture shift around introducing and communicating to patients via an external patient experience campaign - it appears that much can be achieved. When they do not – e.g. Apple ward who did not get buy in from the pharmacy department - staff at the ward level can become

frustrated and demotivated. We therefore question the capacity of an externally designed intervention, even one with significant resources and facilitative processes, to provide the mechanisms to be continually adaptive to the organisational alignment between the sharp and blunt end at differing institutions. The challenges revealed here are about deeper organisational culture, systems and processes that need longer-term development.

Our findings support the growing understanding that emphasis in patient safety research must continue to shift from the measure and manage orthodoxy of data collection to interpretation and process [10]. In this research, the collection of patient feedback was the least problematic element. The complexity of what staff are being asked to do in interventions like PRASE (navigating multi-layered organisational systems to implement improvements) requires much more consideration. In the broader but related policy area of patient experience, the overt emphasis and huge resource allocated to collecting patient experience data has not been matched by efforts to utilise and evaluate the impact of feedback on service improvement [23]. There is increasing recognition that using data sources to change practice demands creativity and skills from staff; hence the tendency to present staff with data and expect change to happen as a result [24]. Our intervention considered these issues a priori and hence facilitative processes were built into the trial yet they were not sufficiently robust enough to ensure a standardised implementation across intervention wards.

One interpretation of PRASE could be that it 'failed' due to showing no effect between the intervention and control wards. We believe this a simplistic view which does not take into account the wealth of positive benefits which patients and staff gained. Firstly, it showed that patients are able to give feedback about the safety and quality of care and that they want to do this en masse (our consent rate was 85% of those patients approached by researchers and the number of patients recruited to the study was 2400 across five different hospital sites). Secondly, the process evaluation showed that most staff *do* believe the patient voice is important and there is an imperative to listen to, and act on, this voice. Thirdly, despite local struggles, most staff do want to action plan to improve their patients' care. The majority of the wards were receptive to receiving patient feedback – it is when they tried to move improvement work forward that problems arose [25]. An additional gain which some staff identified was the ability of the patient feedback to allow staff to understand not only the patient perspective but also their priorities and to visualise the ward environment and systems 'through the eyes of the patient'.

Limitations

We cannot know whether positive attitudes towards patient involvement in patient safety have continued on the intervention wards after the trial was completed. Improvements that staff were working towards may have gained impetus since the research team left. Equally, involvement in the trial may have kick-started ideas which, although did not come to fruition within its life span, may now be fuelling ward level action. Conversely, staff may have felt disempowered to enact improvement to the ward environment if their PRASE action plans had floundered. We have no format for measuring this 'after effect' – either positive or negative – and little scope for knowing at what time point the evidence of a more long lasting effect may be captured.

Our pen portrait methodology is a culmination of all sources of qualitative data collected and has its inherent weaknesses. This methodology is still in its relative infancy in relation to the way in which we have utilised it here. We were careful to draw equally on all sources of data in order to build a comprehensive narrative of the engagement trajectory of each ward. However, a differing analysis paying attention to fewer sources or an unequal weighing of sources may have pulled the narrative account in a slightly different direction. Further, it was difficult to categorise some wards firmly into their allocated engagement typology and

arguably some could fit into several. Finally, process evaluation methods were developed a priori to the start of the trial so the design was very open. We devised a loose structure to capture qualitative intelligence on key trial processes. If prior knowledge existed that diversity of engagement within the intervention wards was to be so significant, it may have been possible to target a particular process evaluation framework for analysing outcomes in relation to this diversity, such as the 'diffusion of innovation model' [26]. It is a possibility that utilisation of differing methods may have provided other answers as to where different elements of the intervention worked, for whom and why.

CONCLUSION

Whereas previous process evaluations point towards specific pinch points or broader cultural issues to understand why an intervention showed no effect, this study points to an overall 'dilution effect' of the intervention. This was largely due to wards engaging with the intervention in highly divergent manners despite the standardisation of key components by the research team. The facilitative processes were inadequate to ensure full engagement across all wards in the study. A disconnect existed between senior management support for the study and how ward staff on the ground engaged with it more locally. The above findings assist in explaining why the trial saw no effect between intervention and control wards.

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Competing interests

The authors declare they have no competing interests

Authors' contributions

RL, GA and JW are grant holders of the programme grant. LS devised the methodology of the process evaluation and wrote the qualitative protocol, with assistance from CM. LS, CM and JOH all collected data. LS and CM analysed and interpreted all data, with intellectual input from GA. LS and CM co-wrote the first draft of the paper. All authors edited the first draft of the paper. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by South Yorkshire NHS Research Ethics Committee on 15th March 2013 (Ref: 13/YH/0077). All participants gave informed consent to take part in this study.

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Data sharing statement

Unpublished data is not available

FIGURE HEADINGS

Appendix 1 – Key intervention components and anticipated outcomes
Appendix 2 – Trial design and results
Appendix 3 – Holly ward pen portrait
Appendix 4 – diagram of engagement typologies

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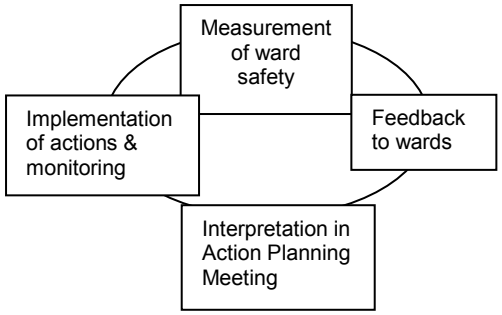
Appendix 1: Key intervention components and anticipated outcomes

Cyclical Activities	***Facilitative Processes***	***Anticipated outcomes***
-Patient Measure of Organisational Safety (PMOS) - a 44 item questionnaire which asks patients at the hospital bedside about safety concerns and issues [5, 6]. -The second is a reporting proforma for patients to provide detailed safety incidents or positive experiences [7]. -The questionnaire items are theoretically-informed from a systems understanding of patient safety whereby experience of care is understood to arise from a complex interaction of factors that include staff team-working and access to resources as well as more traditionally-considered factors such as the physical environment - After patient feedback has been collected it is collated and presented in a feedback report to each ward. Ward staff are then asked to interpret this feedback to identify and target areas for improvement. Finally they are asked to implement agreed action plans and monitor progress in a cyclical manner. - Significant further detail about the cyclical activities is contained in the published protocol of the study [8] and the PRASE RCT results paper [9]  	The design of PRASE recognises that ward staff need support to implement the intervention. An understanding of some of the facilitative processes required was derived from a feasibility study, prior to finalising its design [7]. Specific facilitative processes involved are: - *Independent collection of patient feedback by the research team* to enable not only objectivity but from a resource and logistics viewpoint as ward staff do not have the capacity to collect this data themselves - *Independent production of feedback reports by research team* - *Negotiation with senior management* by the research team to embed the intervention into usual practice - *Ward staff training* in interpretation of data and role playing of optimum action planning to enable them to tackle systemic issues effectively - *Facilitation of the action planning meetings by a senior researcher* to i) convene the meeting ii) encourage ward staff to devise action plans which tackle systemic issues - *Motivation of staff and cross team learning and support* via the format of three pan Trust meeting involving representatives from the hospital senior management (Start Up meeting pre-trial, Mid-Point meeting half way through trial, Closing meeting after trial had concluded)	It was hypothesized that the intervention would lead to safety improvements in terms of both ward culture and ward performance (distal outcomes) alongside a development of a shared, collaborative understanding of the patient's perspective of safety (proximal outcomes). For more detail on this, consult the logic model developed from the feasibility work [7]

Appendix 2: Trial design and results

Trial design	***Trial results***
PRASE was trialled within a multi-centre, cluster, randomised controlled trial. The study was undertaken across 33 hospital wards in three NHS Trusts (five hospital sites). Seventeen wards were randomly assigned to an intervention group and 16 wards to a control group. Feedback was collected from approximately 25 patients per ward, collated and fed back to staff for interpretation and action planning. This whole process was then repeated in a second cycle so staff were able to see changes to feedback over time. The study was powered to detect a small to medium difference (0.3) between the intervention and control groups with respect to a Primary Outcome which was the Patient Safety Thermometer (PST). PST data is routinely collected from every ward in England on a monthly basis and reports on harm free care associated with: i) pressure ulcers, ii) venous thromboembolisms, iii) catheter associated urinary tract infections and iv) falls. PMOS was chosen as a secondary outcome. This was obtained twice from the intervention wards within their intervention cycles. It was also taken at the same three time points in the control wards. For further detail, consult Sheard et al (2014) [8].	No significant effect of the intervention between the allocation groups was found for either of the primary outcomes PST (p=0.98) or PMOS (p=0.09) at 6 or 12 months, nor other secondary outcomes. However, a post hoc analysis on new harms (contained in the PST) found a non-significant increase in harm free care of 1.60 for intervention wards over control wards. All wards were retained throughout the trial. Patient response rate for completing the PMOS tool was 86%. For further detail, consult Lawton et al (2017) [9]

Appendix 3 - Holly ward pen portrait

Facilitator's field notes

Phase one – The action planning meeting (APM) consisted of five staff who had all read the report before the meeting. These were: a sister, a staff nurse, a ward clerk and two HCAs. The ward manager had attended the Trust wide PRASE start-up session but was not able to come to the APM so the facilitator had to give an extensive introduction about the study to the group. The ward clerk did not understand what the term 'patient safety' meant so the facilitator had to go back to basics to make sure that everyone in the room knew what PRASE was about.

Taped APM discussion

Facilitator's field notes

The APM was difficult to convene as discussion tended to jump around. The ward clerk was very vocal and the rest of the group seemed to defer to her opinion. Overall, this was a positive meeting and the group seemed engaged with the study by the end of it. The main action plan was to explore whether better systems/communication could be put in place between theatre and the ward to try to reduce the amount of patients who are starved all day only to have their operation cancelled at the last moment. This action plan was challenging in its approach as it sought to redesign well established systems.

Follow up phone interviews

The phone interview found that the action plan about changing the system of communication between theatre and ward was not realised at all because the theatre matron had not responded to the sister about this despite the sister requesting to meet about the issue several times.

Follow up phone interviews

Phase two – The sister attended the Trust wide PRASE midpoint meeting and reported that she found it useful especially to see that many of the problems which patients were reporting on her ward were the same across other wards in the Trust.

Taped APM discussion

Facilitator's field notes

The sister convened another APM although this was smaller in size than the APM in phase one. The failed action plan from phase one about improving communication between theatre and the ward was discussed again. There is acknowledgement that there are not enough qualified staff at night who are able to put a central line in and this is having a knock on effect on the ward. An action plan was developed to talk to the central line team about this problem of lack of qualified staff.

Follow up phone interviews

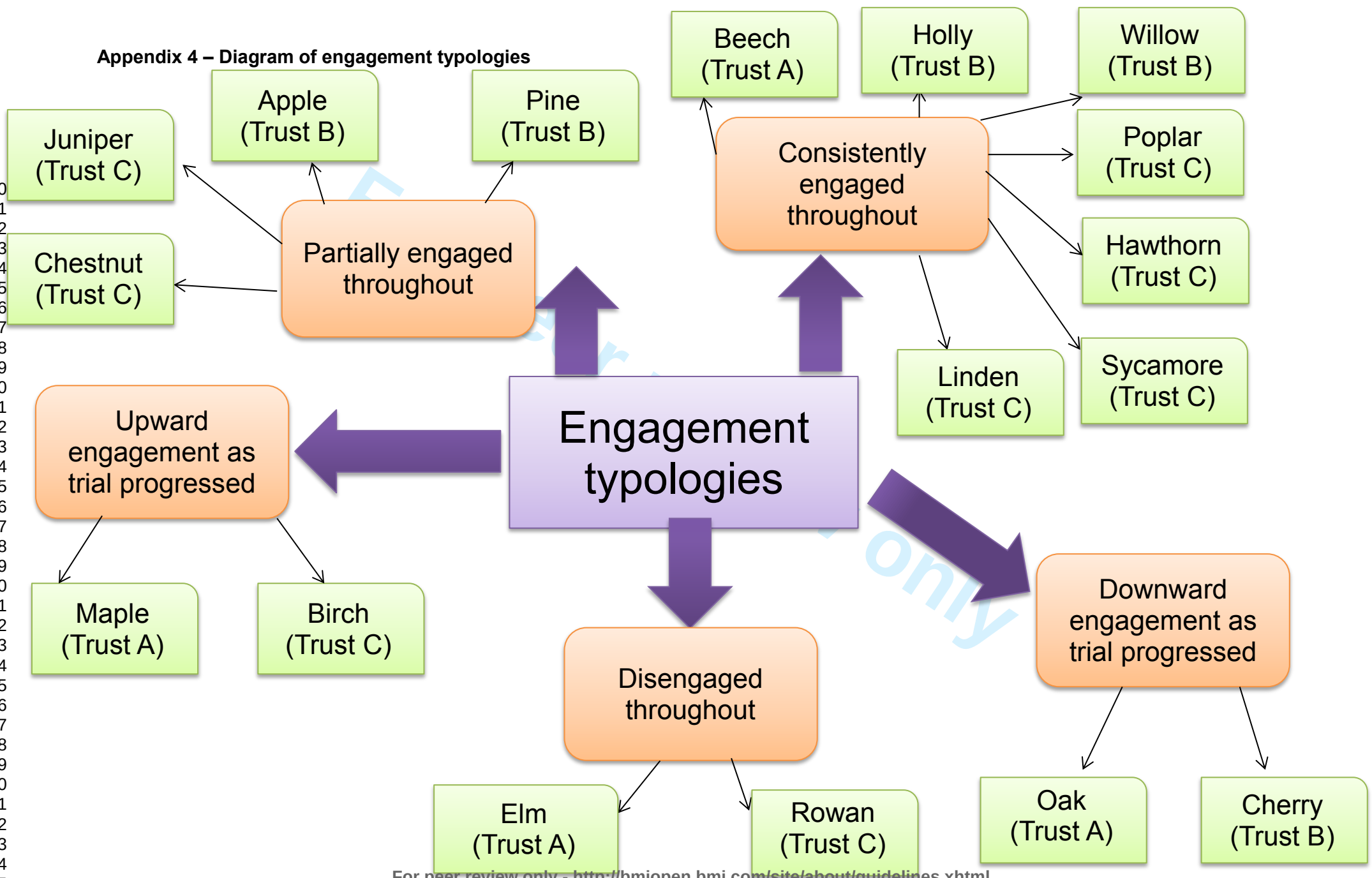
The follow up phone interview for this phase found that implementation had floundered. The APG were far reaching in what they want to happen but were dependent on other departments for buy in and the interest from personnel in other departments was just not there. The sister reported via the phone interview that the Trust are not interested in training more people to be qualified in putting central lines in and the theatre matron is still not interested in rectifying the issue of patients being starved on the ward for days at a time. This ward seemed to be less involved in other safety, quality and experience initiatives than other wards were (even at the same Trust).

Facilitator's field notes

The sister came in on her day off to attend the Trust wide Closing meeting. She was firmly committed to the study throughout and indeed to improving patient safety.

Engagment profile: This ward team did everything that was asked of them and they were highly engaged as a group with the purpose of PRASE. They made some far reaching action plans which sought to challenge underlying structural barriers but made little progress with these when they tried to implement them as other departments on which they depended for buy in were not interested. **Engaged throughout despite organisational setbacks.**

Appendix 4 – Diagram of engagement typologies



Manuscript: Exploring how ward staff engage with the implementation of a patient safety intervention: A qualitative process evaluation

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the inter view or focus group?	Top of page 5
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Top of page 5
3. Occupation	What was their occupation at the time of the study?	Top of page 5
4. Gender	Was the researcher male or female?	Irrelevant
5. Experience and training	What experience or training did the researcher have?	Top of page 5
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	5
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	5
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	5

Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	6
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Universal sample of all intervention wards in study (page 5)
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	5
12. Sample size	How many participants were in the study?	5
13. Non-participation	How many people refused to participate or dropped out? Reasons?	None (page 5)
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	5
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	5
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	5
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	Two phases of study so all described methods were conducted twice (page 5)
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	5
20. Field notes	Were field notes made during and/or after the inter view or focus group?	5
21. Duration	What was the duration of the inter views or focus group?	5
22. Data saturation	Was data saturation discussed?	Saturation not relevant to this process evaluation

23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	6
25. Description of the coding tree	Did authors provide a description of the coding tree?	No
26. Derivation of themes	Were themes identified in advance or derived from the data?	Inductive (page 6)
27. Software	What software, if applicable, was used to manage the data?	No
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	8-10
30. Data and findings consistent	Was there consistency between the data presented and the findings?	7-10
31. Clarity of major themes	Were major themes clearly presented in the findings?	7-10
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	7-10