Appendix 1: Key intervention components and anticipated outcomes

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<th>Cyclical Activities</th>
<th>Facilitative Processes</th>
<th>Anticipated outcomes</th>
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<td>- 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]</td>
<td>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)</td>
<td>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]</td>
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### Appendix 2: Trial design and results

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<th><strong>Trial design</strong></th>
<th><strong>Trial results</strong></th>
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<td>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.</td>
<td>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%.</td>
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Appendix 3 - Holly ward pen portrait

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.

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.

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.

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.

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.
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).

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.

**Engagement 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

Engagement typologies

Consistently engaged throughout

Upward engagement as trial progressed

Partially engaged throughout

Disengaged throughout

Downward engagement as trial progressed

Elm (Trust A)

Maple (Trust A)

Birch (Trust C)

Beech (Trust A)

Holly (Trust B)

Willow (Trust B)

Poplar (Trust C)

Linden (Trust C)

Sycamore (Trust C)

Oak (Trust A)

Rowan (Trust C)

Cherry (Trust B)

Juniper (Trust C)

Chestnut (Trust C)

Beech (Trust A)

Holly (Trust B)

Willow (Trust B)

Poplar (Trust C)

Linden (Trust C)

Sycamore (Trust C)

Oak (Trust A)

Rowan (Trust C)

Cherry (Trust B)