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Developing a service user centred co-designed patient safety intervention for acute mental health wards: A mixed methods process evaluation

Research Protocol

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Version Control Table

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Version	Date Implemented	Details of key changes made to document
1.0	23.07.2019	Not applicable.
1.1	17.11.2021	This document has been modified to reflect necessary adaptations in response to COVID-19. 1. The project GANTT chart (p. 18) has been updated to reflect adjusted timescales. 2. Co-design activities were amended from multiple face to face workshops via networks, to a mixture of face to face and ad hoc contributions at one trust. 3. Phase 2 small-scale testing (p. 13) – following agreement from funders this phase was removed, and modification to main study. 4. Amendments to our patient and public involvement and engagement approach. Instead of setting up a project specific Lived Experience Advisory Group (LEAG), due to pragmatics around COVID, we linked to existing stakeholder groups hosted by Leeds and York Partnership NHS Foundation Trust. 5. Due to delays in progress and priorities in response to COVID-19, we did not set up a Project Reference Group, and instead sought advice from the wider Project Management Group.

1. **Title:** Developing a service user centred co-designed patient safety intervention for acute mental health wards: A mixed methods process evaluation

2. Summary of research

Evidence shows there are large numbers of safety issues on acute mental health wards, frequently involving violence and self-harm, associated with increased costs, physical and psychological harm. Safety data is currently only collected retrospectively and very little is collected from the service user perspective. This study aims to co-design with service users and staff a technological intervention that collects data about the perception of safety from service users, in order to support staff to anticipate and avoid developing incidents.

The project has two phases and uses different methods during each phase. Phase 1 uses a co-design approach to developing the intervention, supported by an 'environmental scan' consisting of a scoping review and the collection and qualitative analysis of interview data. Phase 2 will be a mixed-methods process evaluation. A focused ethnography will explore how staff communicate and use safety data supported by interviews with service users and staff to further understand feasibility and acceptability. We will simultaneously collect routine data including incidents, NHS mental health safety thermometer (if available), workforce and ward occupancy. Measures relating to safety culture and ward atmosphere will be completed pre and post intervention, as well as real-time measures of these concepts on three occasions. The synthesis of these data will assess the impact of the intervention on outcome measures; enhanced understanding of feasibility and acceptability.

Stakeholder and lay input has informed the development of this project, specifically through discussions with service users and co-applicant representation. We will link to existing stakeholder groups hosted by Leeds and York Partnership NHS Foundation Trust to support the project via co-app WALKER. The key outputs of the research will be a new intervention in the form of a licenced product to enable the collection of and response to real-time service user generated safety data. The research will produce traditional and non-traditional publications in a variety of media. Dissemination will target key stakeholders: mental health service providers, commissioners, regulators, practitioners, policy makers, and academic researchers and make effective use of social media. We will publish in high-impact open access academic journals and present and discuss our findings at conferences to a wide range of practitioners, academics, and service users. We will also devise and host a digitally supported dissemination event and invite representation from all stakeholders. The resulting product has the potential to improve safety and well-being for service users and staff on acute mental health wards, a key concern of the CQC and an NHS priority.

3. Background and rationale

Patient safety within mental health services

Mental health services report high levels of safety incidents that involve both patients and staff, with 243,974 incidents reported in 2016-17(1). More detailed data from acute mental health wards show that the most frequently occurring incidents in this setting involve violence and self-harm(2). On acute mental health wards safety incidents are often associated with increased costs including the costs of restraint, seclusion and rapid tranquilisation, increased one-to-one nursing, as well as physical and psychological harm to the patient, which may increase length of stay as well as having a negative impact on the patient's health related quality of life(3). In some cases injuries to staff may occur, leading to costs of replacement staff. A further characteristic of safety on acute mental health wards is the issue that one incident may influence the probability of further incidents occurring via a disturbed ward milieu and social contagion(4), thus successfully avoiding one incident may

have additional positive externalities in that it reduces the probability of future incidents. Previous work examining contributory factors to safety incidents in secondary care hospital settings produced the Yorkshire Contributory Factors Framework (YCFF)(5), describing 20 separate domains (e.g., team factors, supervision, leadership). After recognition of patient safety as an important, albeit under researched, aspect of mental healthcare, the YCFF was adapted by researchers within the co-applicant team to focus on contributory factors within a mental health setting(6) co-apps BERZINS, BAKER & BROWN. This involved exploring sevice user' persepectives of safety, highlighting wider issues than those currently captured on incident reporting systems, for example, factors such as 'not being listened to', or not feeling psychologically safe(7) co-apps BERZINS, BAKER, LOUCH, O'HARA & BROWN.

The need for service user feedback in mental health services

The Berwick Report into care failures at Mid Staffordshire concluded that *'the patient voice should be heard and heeded at all times'(8)* and one of the principles of NHS England's Sign up to Safety initiative is to *'Continually learn….Listen, learn and act on the feedback from patients and staff and by constantly measuring and monitoring how safe your services are.'*(9). However, across the majority of NHS services, current safety data collected by staff is unlikely to be accurate in terms of number of incidents(10, 11). Further, despite the policy focus, very little patient reported safety data is collected in health services although patients have been shown to have different perspectives on safety than staff(12). Our previous research demonstrates how patient safety is conceived by mental health service users, as qualitatively different from the commonly accepted definition of *'the prevention of errors and adverse effects to patients associated with health care'*(13). In recognition of this, a recent international Delphi study which aimed to identify research priorities for safety in the mental health field emphasised the patient perspective as a key priority(14). Further research by co-applicants has showed that patients believe physical safety to be prioritised by healthcare staff, often at the cost of psychological safety, e.g., a person might experience restraint or forced medication in order to prevent them from self harming. The intervention might then cause psychological (and also physical) harm, although they might have been initally prevented from causing physical harm to themselves(15) co-apps BERZINS, LOUCH, BROWN & BAKER. Indeed, staff might not be aware of the psychological harms evident on wards, whether caused by staff behaviour, treatment, or other patients, as service users and carers struggle to raise safety concerns. This is due to fear of repercussions of raising concerns, the onerous process, particularly while experiencing poor mental health(7) co-apps BERZINS, BAKER, LOUCH, O'HARA & BROWN. This evidence shows that service users are likely to be experiencing harm while resident on acute mental health wards and may experience raising concerns with staff. If service users were given the opportunity to report safety issues in real-time staff may be able to respond and potentially intervene before situations escalate.

How might patient feedback support the safety of mental health services?

Studies in secondary care hospital settings have found that patients can be a valuable source of safety data and that participating in such activities is both acceptable and feasible for patients(16-18) co-app O'HARA. However, less empirical work has sought to develop interventions to allow staff to use patient feedback about safety to improve service-level safety performance. To address this need, a group of UK researchers (represented in the co-applicant team) developed and tested the Patient Reporting and Action for a Safe Environment (PRASE) intervention[1]. The intervention serves as a theory and evidence-based approach to systematically collect hospital inpatient feedback about safety, together with a framework for staff to interpret and act on that feedback. Research on the potential for ward staff to respond to patient generated feedback is limited and restricted to secondary

[1] https://www.improvementacademy.org/tools-and-resources/patient-reporting-and-action-for-a-safe-environment.html

care hospital settings: two studies have found that ward staff required additional support to respond to patient feedback((19, 20) co-apps O'HARA & LOUCH) and real-time data has been found to support staff in proactively responding to safety issues(21). It is entirely unknown how these practices might translate across to an acute mental health wards.

Some data relating to the safety of mental health wards is collected from patients by staff using the monthly Mental Health Safety Thermometer, however a recognised limitation of this measure is its 'snapshot' nature (opportunity sample of patients on one predetermined day per month). Incident data that is recorded through NHS systems is also collected and reviewed retrospectively and as such the opportunity to anticipate and prevent incidents is absent, data is described as lagging rather than leading, i.e., although harms that have already occurred are measured, there is no way in which to measure how safe care is today(22). At present, there is no means of capturing leading safety data from service users on acute mental health wards which is subsequently made available to staff in real-time. Managers in acute mental health care have been found to be more positive about change than ward staff(23) and recent research looking at barriers to change on acute mental health wards found that burnout is likely to contribute to this resistance, although changes that staff are involved in the development of (and therefore perceive as feasible) may moderate these effects(24).

There are different potential mechanisms for safety feedback to be received and discussed by ward staff in an acute mental health ward. For instance, in our previous research relating to the PRASE intervention ((16-18)co-app O'HARA) feedback was collected over a 3-4 week period, with staff coming together in a facilitated Action Planning Meeting (APM) to consider the feedback report, and produce action plans to facilitate service improvements. However, shift handovers occur routinely on wards as a way of passing on information to incoming staff and can be successfully modified to incorporate standard items such as evidence(23). Safety huddles originated in secondary care as daily focused brief meetings and have been found to facilitate real-time identification of and response to safety concerns(24), and have previosuly been successfully implemented in a mental health setting(25).

In 2014 VINCENT (co-app) and colleagues(22) proposed a theoretical framework for the measurement and monitoring of safety, with a focus on moving from the measurement of past harm to the prevention of future harm by the assessment of current safety. The Measurment and Monitoring of Safety Framework (MMSF) informed the NHS Sign up to Safety initiative(26), and has been applied to a range of health care services as case studies, including mental health services, to test its utility. It was found to broaden participants thinking on the concept of safety. Patient involvement in safety measurement and monitoring was part of the evaluation and staff in all test sites reported greater recognition of the value of patient experience as a 'barometer' of safety(21). Thus, this framework provides an innovative organising theory within which we can explore how patient feedback might improve the safety of inpatient acute mental health settings.

The need for real-time patient feedback to improve the safety of inpatient acute mental health services

Evidence suggests that there are large numbers of reported and unreported safety issues on acute mental health wards, with data collected retrospectively, and almost none relating to the service user perspective. Through co-design with service users and ward staff there is the potential to develop a monitoring system that allows the collection of safety data directly from service users that can be fed back to staff on a daily or real-time basis. Using the MMSF as our theoretical foundation, this project seeks to develop a mechanism for collecting data directly from service users on acute mental health wards in 'real-time', and explore whether this information can be used by staff on a daily basis to anticipate and avoid developing incidents, and thereby proactively manage safety of acute mental health settings.

See Figure 1 below for a diagrammatic overview of how we hypothesise capturing real-time feedback around safety from service users could prevent incidents and subsequent contagion.

Figure 1. Diagrammatic overview of how a real-time intervention could prevent incidents and subsequent contagion.

We would seek to incorporate the patient safety data generated by our system into an existing mechanism, for example, shift handovers or existing safety huddles. Therefore, the project has the potential to improve safety on wards for both service users and staff. As the definition and measurements of safety used will be that derived from service users, this will be a broader definition than is currently used in incident reporting, ultimately this is expected to improve the safety and quality of care on acute mental health wards from the service user perspective.

4. Aims and objectives

This project aims to co-design an intervention that improves patient safety on acute mental health wards through the collection of daily data about the perception of safety from service users to support staff in monitoring and improving the safety of the clinical environment. The intervention will be tested, and its' feasibility and acceptability explored.

To achieve these aims, we have the following objectives:

1) to co-design with service users and staff an intervention that will allow real-time monitoring of safety on acute mental healthwards;
2) to explore the feasibility and acceptability of capturing real-time feedback from service users about safety;
3) to explore how staff use this information when reported during daily handovers (or other mechanism);
4) to explore how the resulting data is related to quality and safety metrics;
5) to explore how these data can be used longitudinally to promote safety.

5. Research Plan / methods

5.1 Design and theoretical framework:

Co-designed technical development, mixed methods process evaluation.

This implementation and evaluation literature posits a number of key principles around generating a programme theory/theory of change to underpin an intervention(27, 28). Based on our work to date and drawing upon the wider literature and the MMSF(22), we have produced a logic model to describe the programme theory/theory of change for our proposed intervention (Figure 2). The programme theory delineates the hypothesised processes through which we expect the intervention activities to result in both proximal and distal outcomes, with explicit reference to moderating factors which may affect these processes. We will continually revise the programme theory as the project progresses.

In this project, informed by the theoretical principles of the MMSF(22) (See Table 1), our approach would be to produce an intervention to capture 'real-time' data regarding the extent to which service users feel safe on acute mental health wards. The MMSF has been well received by academics and the international healthcare community alike, with the original paper being highly cited and adoption of the framework evident at an international level, for example the Canadian Patient Safety Institute[2]. We propose to focus our research in one domain - 'sensitivity to operations' - which describes the need for a collective awareness by staff of the workings of the service, and their ability to be sensitive and responsive to subtle changes and disturbances(22). Put simply, this domain describes the critical, but often overlooked, activity of 'monitoring' safety as care is delivered in 'real-time'. We are choosing to base our programme theory upon this domain for a number of key reasons. First, as demonstrated within Table 1, it is the domain for which patients and families can provide a key contribution, as highlighted by co-app VINCENT and colleagues, who suggested that *"Patient interviews and conversations are a particularly vital form of safety monitoring and have been the most potent warning of recent tragedies… When patients ask 'Am I safe?' they draw to some extent on their knowledge of the organisation and available public information. The experience of safety probably depends very much on their moment-to-moment experience of care*."((22) p673). Despite this, the role of patient feedback in activity that may fall within this domain – for example, in 'safety huddles' or daily safety briefings – is largely absent(22, 29). Furthermore, whilst patients and families can provide data that supports assessment of safety within the other domains, this is arguably more routine within health services, via established patient feedback services such as the inpatient survey, the 'friends and family test', and existing mandated complaints and incident investigation processes. Second, it is recognised within the initial framework that this is the domain that often neglected, and has hitherto failed to receive significant recognition(22), perhaps due to the focus in patient safety management upon the use of metrics to observe safety 'performance'(30). Despite this apparent lack of credence within governance structures, in a recent funded implementation programme exploring the MMSF with healthcare organisations and frontline teams, this was the domain that was most understood and implicitly 'useful' for staff, resulting in participating teams successfully implementing safety huddles(21, 31). Elsewhere, the power of measurement 'close to the frontline' has been seen as a key success factor in the scale of safety huddles across the Yorkshire and Humber region(29).

Finally, the legitimacy of safety 'monitoring' as opposed to measurement is gaining traction within the patient safety literature, with a number of authors demonstrating the need for, and the potential of, 'prospective clinical surveillance' as a means of promoting safety within organisations(32, 33).

[2] (https://www.patientsafetyinstitute.ca/en/toolsResources/Measure-Patient-Safety/Pages/default.aspx)

We believe that focusing on supporting critical safety monitoring, is particularly important within acute mental health wards, which can be volatile, safety critical spaces. Changes in the dynamic of the inpatient group can occur rapidly, with individual service user need creating immediate knock-on effects for other service users, their quality of care and their safety. Thus, supporting staff to be able to better anticipate and respond to shifts in the 'safety dynamic' on acute mental health wards as close to 'real-time' as possible, may allow more effective management of the safety and quality of care. The MMSF has recently been explored as a basis for improving the safety of mental health services by a further co-app (O'HARA), with staff in these services shown to successfully implement safety huddles to support safety monitoring, alongside an appetite to engage with service users to understand safety from their perspective(31).

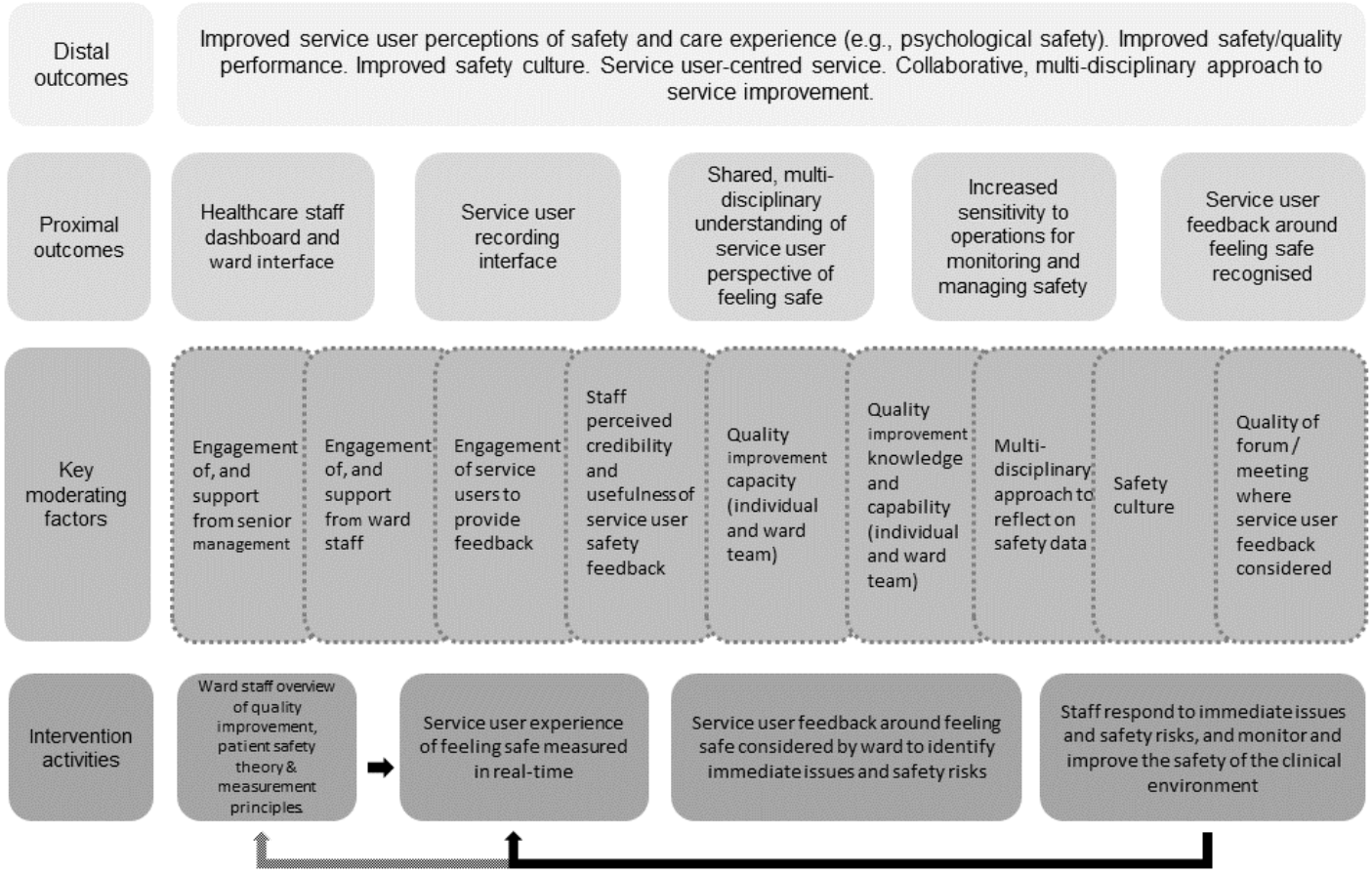
Table 1. Five dimensions of the Measurement and Monitoring of Safety Framework (taken from co-applicant Vincent et al., 2014(22))

MMSF 'Domains'	**Illustrative information that staff provide within this domain?**	**Illustrative information that patients/families provide within this domain?**
Past harm: this encompasses both psychological and physical measures.	Case record review. National audits. Patient safety indicators. Incidence of falls. Mortality and morbidity.	Patient-reported safety events, concerns and complaints.
Reliability: this encompasses measures of behaviour and systems.	Observation of safety critical behaviour. Monitoring of stroke care bundles. Venous thromboembolism risk assessment. Assessment of suicide risk.	
Sensitivity to operations: the information and capacity to monitor safety on an hourly or daily basis.	Safety walk-rounds and conversations. Ward rounds and routine reviews of patients and working conditions. Briefings and debriefings. Observation and conversations with clinical teams.	Talking to patients and families about concerns.
Anticipation and preparedness: the ability to anticipate, and be prepared for, problems.	Structured reflection. Risk registers/safety cases Human reliability analysis. Safety culture assessment. Anticipated staffing levels and skill mix.	Patient reported safety concerns.
Integration and learning: the ability to respond to, and improve from, safety information.	Aggregate analysis of incidents, claims and complaints. Feedback and implementation of safety lessons by clinical teams. Regular integration and review by clinical teams and general practice.	

5.2 ***Phase 1: Intervention development (12 months)*** **Objective 1**

This research will take place across two Mental Health trusts: Leeds and York Partnership NHS Foundation Trust and Bradford District Care NHS Foundation Trust.

Figure 2. Capturing real-time data about safety from service users on acute mental health inpatient wards to support staff in monitoring and improving the safety of the clinical environment: A logic model to demonstrate programme theory**.**



5.2.1. Phase 1a: Environmental scan

Phase 1 will commence with a synthesis of the previous work in this area via environmental scan(34). We are aware that much of the information in this area is contained in the grey literature and environmental scanning methods were developed to identify broader information than that retrievable solely from published literature. In healthcare settings this has been used to inform future planning and provide evidence of current practice(35). Environmental scans can take a *'passive'* approach where existing data, both published and unpublished are collected and analysed, or an *'active'* approach where additional knowledge is generated through primary data collection. We will take an active approach incorporating a scoping review(36) with primary data collected through interviews.

5.2.1.1: Scoping review

Search and review strategy:

Aims: 1) To understand service user involvement in patient safety research within mental healthcare; and 2) To identify interventions aimed at improving the quality and safety of care by involving patients and service users.

Method: We will use a recognised scoping review methodological framework(37), and the scoping review protocol will be drafted in line with the PRISMA Extension for Scoping Reviews (PRISMA-ScR)(38). Research, policy and grey literature will be searched using comprehensive search strategies framed around the review aims. We have already piloted and refined the search. The first aim will identify evidence around patient (service user) involvement within mental healthcare. The second aim focuses on identifying evaluative and descriptive studies of documented interventions to improve quality and safety by involving patients within mental healthcare. Search terms will be identified in collaboration with the project team, consulting the known literature and database thesauri (e.g., Medline, Cinahl Plus, Psyc INFO, Web of Science, Scopus), and be limited to publications since 2000 (publication of 'To Err is Human: Building a Safer Health System'(39). The search strategy will be reviewed by academic researchers (patient safety and mental healthcare), healthcare staff and lay representatives. Additional studies will be identified via bibliographies of reviews and retrieved articles, targeted author searches and forward citation searching. Other grey literature will be sought from internet searching of key health organisations, training manuals, policies and guidance. Authors of current and recently completed research projects will be contacted directly. Documents will be collected using Endnote and screened for inclusion. The full texts of retained studies will have data relating to the review aims.

Data analysis: Extracted data will be organised into a framework to facilitate the generation of a narrative synthesis identifying gaps in the research and other evidence. Findings will be taken back to the Project Management Group to check validity(40, 41).

Output: Scoping review identifying current knowledge and gaps.

5.2.1.2: Semi-structured qualitative interviews

Sample and setting: Interviews with service users (n=15) and staff of all types (n=15) recruited from the two trusts involved in the project and via Social Media. Our lay co-apps (BROWN, WALKER) will assist in the preparation of recruitment materials to ensure they are accessible. The sample size of 15 has been selected as a minimum appropriate for qualitative interviews when the participants are homogeneous(42). The interviewer(s) will have regular discussions to debrief about the interviews, and to reach a consensus on whether new content is arising in order to identify redundancy in the data.

Data collection: Informed by the scoping review, and Project Management Group opinion, service user interviews will explore participant's perspectives of the digital collection of safety data from service users on acute mental health wards, and the staff interviews will also focus on the concepts contagion and milieu.

Data analysis*:* Interviews will be digitally recorded, transcribed and uploaded to NVivo(43) for coding using a priori categories from the scoping review with scope for further themes to be identified. The data will be analysed via a framework approach(41).

Output: A narrative account of detailed stakeholder perspectives.

5.2.1.3 Synthesis and integration of data from Phase 1a

At this stage we will integrate the findings from the environmental scan (scoping review and qualitative interviews). Summary documents will be produced for the scoping review and interview findings. In a series of meetings, using these documents as a basis, the core researchers working on the project and key qualitative co-apps (JB, KB, GL) will come together. These meetings aim to identify key findings that span across the two methods, in order to frame the key findings in the context of the programme theory, and produce a revised programme theory. Subsequently, in advance of the first co-design workshop, the core research staff will meet with the co-design team to discuss the integrated findings and implications for the co-design phase. These data will also be discussed with the Project Management Group and lay stakeholder groups.

Environmental scan output: Narrative synthesis of scoping review and interview data; programme theory refined.

5.2.2 Phase 1b: Co-designed technological development

Informed by the environmental scan, the intervention technical development of this study will be co-produced by mHabitat (latterly renamed 'Thrive by design') and Ayup Digital in consultation with our service user networks, healthcare staff and wider stakeholders using a collaborative, human-centered and sprint-based/agile approach(44, 45).

Sample and setting: Cycles of co-design activities such as workshops, attendance at service user forums, in addition to more opportunistic in-person feedback and feedback via email (with health professionals) at one trust. Participants will be facilitated via our links with the Patient and Public Involvement and Engagement networks at Bradford Institute for Health Research (Yorkshire Quality and Safety Research Group Patient Panel; NIHR Yorkshire and Humber Patient Safety Translational Research Centre (YH PSTRC) Lay Leaders and Citizen Participation Group) and Leeds University, participating NHS Trusts, and from (ex)service users and staff contacts. Typically, each workshop will run for two hours. Ground rules will promote safety, confidentiality and reduce distress. We will have a quiet room available for anyone who becomes distressed during the workshop and a protocol in place for supporting them. Supporting people to ensure full participation is vital, co-apps BROWN and WALKER via Thrive by design/Ayup Digital have considerable skills and experience in enabling this.

Data collection: The purpose of the co-design activities is to establish user requirements for the patient safety data recording interface. We will undertake design activities: Personas (typical users with specific characteristics which will include experience of disability and low digital skills); storyboards (to elicit user goals); customer journey mapping (the path of an individual service user and healthcare staff member on an ward); user stories (to elicit specific user requirements); prototyping (rapid creation of paper prototypes of a digital tool); prioritisation (exercise to create constraints so top features are prioritised). Throughout the co-design activities, the goals, requirements, barriers and design preferences will be identified.

Analysis: The content of each activity will be synthesised to prioritise outputs which are acceptable to end users; technically feasible and efficacious. These priorities will then be used to move towards the technical prototype development. Where there are divergent requirements (for example, a specific feature important to service users but disliked by healthcare staff) these will be noted and recommendations made to the project team or expert advisors if required. Once requirements have been generated from the first cycle of co-design activities we will then use subsequent activities to test and refine the digital tool as it is developed and to consider its use within the clinical workflow of the ward environment.

Technical considerations*:* Our approach is informed by the Human Centred Design ISO(46); NHS Digital, Data and Technology Standards Framework(47). We will ensure the digital tool developed complies with the Digital Assessment Questionnaire (DAQ) that is required for inclusion in the NHS Apps Library(48). The DAQ has stringent criteria for meeting the standards required for digital products and services being deployed in the NHS including clinical safety and the potential for evaluation. Thrive by design has a Clinical Safety Officer, accredited via NHS Digital, who will undertake an outline clinical safety assessment of the alpha version in terms of compliance with clinical risk management standard SCC10129. This will involve identification of potential hazards along with suggestions for mitigations that will be used to inform further development. Thrive by design has developed a framework for the effectiveness evaluation of mobile (mental) health tools(49) in partnership with NIHR and MindTech. We will embed the principles of this framework into our co-design process so that the alpha is developed in such a way that it can be evaluated and appropriate evidence generated. The digital products/tools developed will be built using open web standard technologies (e.g., HTML5, CSS3, PHP) in a componentized and scalable way, to allow modifications and future developments to easily happen. Considerations will need to be given to potential issues such as WiFi dead-spots and technology constraints within clinical settings. Collaborative work (with Information Governance leaders and Caldicott Guardians) will be undertaken to conform to information governance and data protection standards prior to any technical development happening.

Output: We envisage that the digital intervention ***might*** consist of up to four discrete 'products': a service user recording interface to collect data; healthcare staff dashboard for data analysis; a ward interface for public consumption; and an Application Program Interface (API). Each product is described in more detail below.

Service user recording interface: The primary tool to be developed will facilitate the collection of patient safety data and measures within acute mental health wards. Data reporting from service users will be anonymous and they will be asked to answer a series of questions about how safe they feel. Data will be recorded in real-time and sent to an API *(see below)* for data processing. The measures to be asked will largely be determined from the environmental scan findings and co-design activities. Particular attention will be paid to the user experience (UX) of the interface, especially in understanding contextual constraints and pressures that service users may be experiencing (e.g., location when entering data, what device they will be using, what might their mental state be at the time of data entry). Similar attention to detail with respect to accessibility is also important to ensure the interface can be used by a wide range of users with varying abilities. As a minimum, the interface will be built to WCAG 2.1 AA(50) standard and be device agnostic (that is, usable across all devices, platforms, operating systems and internet browsers). Service users might be prompted at set times throughout the day to help ensure consistent reporting and uptake of the intervention. Service users may also be able to respond via their own device (mobile, tablet, laptop) or a device supplied at the ward level. All these requirements will be explored during the co-design process throughout the development of the project.

Healthcare staff dashboard: The dashboard will be the main interface used by staff to view data submitted by service users. It will primarily be accessed in specific, authorised locations, such as the ward office and provide real-time snapshot data and greater informational insights through the use of interactive data visualisations (e.g., thermometer/smiley faces). Co-design work with healthcare staff, statisticians and researchers will determine the exact requirements of how data should be represented. It's anticipated at a minimum that yearly/quarterly/monthly/weekly/daily/shift aggregate data would be available and comparable to historic time periods (once enough data has been collected). The dashboard (and indeed, all of the digital tools) will comply with NHS approved security standards and only allow authorised and authenticated users to view data.

Ward interface: A simple ward interface may be created (subject to co-design) to communicate a subset of outcome measures for public consumption. Through co-design work, the specific outcome measures (or indeed, abstract pictorial representations) will be determined. The ward interface might be displayed on a TV, desktop computer monitor or tablet devices. Central to all of the above digital products an API would be created that conforms to best practice government and health standards(51) and used to link them all together with the underlying data storage engine. The API would facilitate data recording, processing, representation and exporting. Where possible, we would use an open data format standard so that the data can be interoperable with other systems/products. A subsequent part of this project will explore how this patient safety data is incorporated into existing shift handovers or safety huddles, transferable data would facilitate this process (Objective 3).

5.4 Phase 2: Testing of the developed patient-centred real-time monitoring intervention, through a mixed-methods evaluation using ethnographic methods, routine data and standard measures (9 months) Objectives 2, 3, 4, & 5

The specific research questions for this phase are as follows:

1. Does data collected from service users accurately reflect the safety of the ward?
2. Does collecting data from service users and feeding it back to staff in real time improve the safety of the ward?
3. Is it feasible and acceptable to collect safety data from service users on mental health wards?
4. How do staff use the data collected from service users?

To test the developed intervention, we will carry out a nine-month mixed-methods evaluation, using ethnographic methods and analysis of routine data plus additional standard measures. This study will begin w/c 10th January 2022. In order to address the research questions, we consulted MRC guidance(52) on the development and evaluation of complex interventions and a recently proposed conceptual framework for feasibility studies(53). The quantitative and qualitative components of this study will be underpinned by the refined programme theory and the theoretical principles of the MMSF(22).

For the quantitative evaluation, we are proposing to gather continuous routine safety data plus standard measures of safety culture and ward atmosphere (from staff) pre and post intervention, and in real-time on three occasions, for each participating ward, to explore the 'effect' of the intervention on patient safety(54) and to utilise as contextual information. For the qualitative component of the evaluation, we propose to undertake a focused ethnography to explore the use of the intervention across a variety of wards and organisational settings. This combination of data will support an exploration of the intervention in terms of its' use within each context, the challenges of engaging with the intervention, unintended consequences (positive and negative, and how these are mitigated). This will be presented as a case study for each ward.

Sample and setting: We propose to recruit from the Mental Health Collaborative in Integrated Care System of West Yorkshire. This includes the two mental health trusts of Leeds and York Partnership NHS Foundation Trust (LYPFT) and Bradford District Care NHS Foundation Trust. Within these trusts there is sufficient diversity of wards (acute mental health and psychiatric intensive care), serving people from diverse socio-economic and ethnic backgrounds, and IT systems to be able to test digital interfaces and the adoption of the developed technological intervention. The two trusts are experienced at collaborating on large-scale projects. LYPFT has agreed to be the lead trust for this project. BAKER PI is a non-executive director of LYPFT with a portfolio for patient safety and quality and has gained assurance of access across the Integrated Care System. Additionally the close geographical

proximity of these services will facilitate primary data collection. Six wards will be recruited at this stage.

Procedure
Once wards have agreed to participate, we will work with them in a staggered way across the nine-month study period. For each ward, we will include one week of baseline ethnographic observation to understand what 'normal operations' are within each context. Following this, for each ward we will have a four-week implementation phase (the intervention will be implemented on week 5), during which time research staff will offer support. We envisage staff attending 'start up' sessions comprising brief information about patient safety theory, measurement, the intervention and what ward level involvement means. Following the four-week implementation phase, we will move into a 10 week follow up phase. The ethnographic observations will be specific to the intervention being used. We will carry out a minimum of three observation periods (visits of six hours each) in each ward over the 14 weeks, one before implementation (at approx. week 2, to understand what 'normal operations' are within each context) and two after the intervention has been introduced (at approx. weeks 8 and 13). These will be at different times of day / night. This will include observing staff handovers/other relevant meetings and interaction on the ward but the focus will mainly be on staff rather than service users. We envisage that the ethnography would proceed sequentially across the wards in each trust concurrently.

We will collect routine data for 14 weeks. This will include incidents, NHS mental health safety thermometer (monthly), workforce data, admissions/discharges and ward occupancy and acuity (drawn from Mental Health Act and clustering information). To ensure these data can be gathered efficiently and accurately, we will work up protocols for drawing down data with information services from participating trusts, in advance of Phase 2.

Additional quantitative measures
In addition to capture of ward-level routine data, and to supplement the case-study approach for each ward in this mixed-methods evaluation, we will collect a number of other key safety measures - safety culture, the ability of staff to practice safely, and the ward atmosphere. These measures will be collected during the pre-observation period prior to implementation on each ward, and then again at the end of the implementation period. We will recruit a minimum of 50% of staff on each ward (approx. 15 staff per ward, 90 staff in total).
Furthermore, to understand how data collected from service users reflects the safety of the ward in real-time, we will administer brief real time measures of safety culture, the ability of staff to practice safely, and ward atmosphere. These measures will be framed to capture perceptions 'right now' and will be administered at three occasions (once at baseline, twice during implementation).
Ward Safety Culture: Staff will be asked to complete measures from the Agency for Healthcare Research and Quality (AHRQ), Hospital Survey on Patient Safety Culture (HSOPC)(55). We will also assesses the extent to which an individual member of staff feels they are able to act as a *safe practitioner on their ward* (amended from co-apps LOUCH and O'HARA; and Johnson et al, 2017(56). Additionally, we will measure staff perceptions of 'ward atmosphere' using the EssenCES scale(57). Additional data will be collected from the refined intervention prototype (i.e., service user perceptions of feeling safe, number of times service user recording interface, number of times staff facing dashboard used. The accessibility of timely retrieval of such data will be assessed in terms of potential impact on analysis.

Ethnography

We will undertake a focused ethnography(58) on participating wards, using a staged approach to implementation and observation. This focused ethnography study will assess the feasibility and acceptability of the monitoring tool and the accompanying intervention, as a mechanism for managing safety within acute inpatient wards. The ethnography will seek to explore the experiences of stakeholders – service users and staff – and how the data is used in practice. Ethnographic research is most often concerned with developing a rich descriptive account of social activities, including the meanings, beliefs, and customs of social groups, and explaining these in the context of broader social, cultural and political institutions(59). Whilst there is recognised variation in the exact nature of ethnographic research, within this project we will adopt a focused, pragmatic ethnographic approach(59), where we will explore how the developed monitoring intervention might promote patient feedback, and support staff to manage safety day-to-day. As we are conducting this phase of research across three organisations, we will explicitly seek to explore how the tool and associated intervention is enacted and experienced in different socio-cultural and organisational contexts.

We will observe the potential forums where the safety feedback is considered, and how staff use the feedback to manage safety. We will observe handovers, patient safety huddles, relevant meetings, staff-patient interactions and have opportune conversations with key people. We will be particularly concerned with understanding competing 'threats' – for example, competing interventions, random fluctuations associated with acuity, changes in patient demographics, staffing levels or skill mix, which might influence our findings or adoption of our intervention. Based on our programme theory, we will also be interested in exploring how the data generated by patients might influence the ways in which staff manage patient safety incidents on the ward, both in proactive and reactive terms. In addition to using observational techniques, the focused ethnography will involve 'in situ' ethnographic interviews with participating professionals and service users.

The ethnographic data will take the form of field notes, electronic summary records, interview transcripts and documents relating use of the safety data. These will be collated and managed in specialist computer software (NVivo, v12)(43) for the purpose of interpretive data analysis. We will carry out week long observations in each ward at three time points, once prior to implementation and twice during implementation.

Finally, we will undertake short interviews with service users (n=20) and in-depth interviews with staff (n=20) to further understand feasibility and acceptability.

Data analysis

Quantitative: Descriptive analysis will provide initial summary statistics and plots; an overview of adoption of the intervention; variation in service user measure responses, staff response rates (e.g., survey). We plan to analyse the routine safety and organisational data in the form of run charts/scatter plots(60, 61) to plot key data over time to examine the impact of the intervention. To aid the interpretation of any changes in the outcomes we will produce charts for balancing measures, to provide more contextual information over the same time period. These charts will be produced at an individual ward level and for the six wards combined. For the additional non-routine quantitative data - safety culture, the ability of staff to practice safely, and the ward atmosphere – we will undertake repeated measures t-tests to maximise available power in the analysis. We will also examine how the real-time assessments of safety culture, the ability of staff to practice safely, and ward atmosphere are associated with intervention data over a similar time period. These data will feed into the six ward-level 'case studies' across our evaluation if appropriate.

Qualitative: Interview data will be analysed thematically (62). We will use pen-portraits to synthesise the qualitative data to produce case studies (generated from focused ethnography (e.g., observations, interview, fieldnotes, data from opportune conversations) to answer the objectives (co-apps LOUCH & O'HARA(20)). At this stage, we aim to bring findings from all phases together to inform outputs. We will integrate our developing findings from the varied data sources using mixed methods research principles(63) to inform the development of our programme theory.

Outputs: Impact of the intervention on routine data, and other measures of ward-level safety; a detailed description of how the intervention is used across different organisational settings; enhanced understanding of feasibility and acceptability; revised programme theory.

6. Outputs, dissemination and anticipated impact

6.1 Outputs

The project will produce a range of outputs throughout its duration. The key outputs of the research will be a new intervention in the form of a licenced product, free for NHS use, to enable the collection of and response to real-time service user generated safety data on acute mental health wards. The research will produce traditional and non-traditional publications. The research will generate an extensive final report for HS&DR and a number of peer-reviewed academic journal articles:

Phase 1 – One paper presenting the environmental scan data (scoping review and interview data), and one paper reporting the co-design process. One paper reporting qualitative exploration of the experience of patients, and healthcare professionals;

Phase 2 – Two papers presenting the feasibility and acceptability of the intervention, ethnography and quantitative data.

Other outputs - We will produce a report suitable for a lay audience, a series of lay summaries and a report aimed at healthcare staff suitable for publication in trade sector press. The findings of the research will also be presented in a variety of other media, for example, blogs, conference presentations, powerpoint slides, infographics, press release, audio / video summary using animation, or video interviews with service users or healthcare staff. The project, if funded, will sit in the NIHR Yorkshire and Humber Patient Safety Translational Research Centre (YH PSTRC) – involving patients and families in patient safety theme (led by co-app O'HARA, BAKER deputy lead). As such, the research outputs and findings will achieve an enhanced national and international profile as part of the wider YH PSTRC dissemination and engagement strategy.

6.2 Dissemination

The research will have a clear dissemination strategy, based on proven effective mechanisms(64, 65) and co-designed with our Project Management Group at the start of the project. Our team has considerable skills in dissemination with all members having active local, national and international networks via which they will publicise and distribute our outputs. Dissemination will target key stakeholders: mental health service providers, commissioners, regulators, practitioners, policy makers, and academic researchers. Our membership of both the NIHR Patient Safety Translational Research Centre network, Yorkshire & Humber Academic Health Science Network and the newly funded NIHR Applied Research Collaborations, will enable us to spread our findings across the region, and if demonstrated as feasible - support wider adoption of the intervention.

We will disseminate our written reports through via the NIHR. We will publish in high impact open access academic journals e.g., BMJ Quality and Safety, Journal of Patient Safety, British Journal of Psychiatry and trade sectors press such as Mental Health Today. To make these accessible to as wide an audience as possible, we have included costs for open access publication. We will present and discuss our findings at conferences and meetings with a professional, technical and/or patient safety focus (e.g., New Minds Network,

Mindtech Annual Symposium), aiming to present to a wide range of practitioners, academics, service users. We will also devise and host a digitally supported dissemination event and invite representation from all stakeholders.

Outputs (blogs, podcasts, and webinars) will be disseminated using social media (Twitter), which has been used successfully in the past for this purpose by the co-applicants. We will provide web links to our institutional websites, published reports and other outputs. Our use of social media provides extensive international reach. Our Twitter followers include the general population, practitioners (of all types, including trainees), as well as diverse service users with extensive networks that could otherwise be hard to reach. We will use our research group webpages to host a project summary and regular updates and publicise these via Twitter. We will retain legacy webpages after completion. All participants and stakeholders involved in the study will be kept informed throughout and receive output materials that they can disseminate through their own networks.

6.3 Impact

The product developed within this proposal has the potential to improve safety and well-being for service users and staff on acute mental health wards, which represents a key concern for the CQC and an NHS priority. It will inform mental health service managers' decision making about implementing initiatives to improve patient safety, which in turn could impact on everyday practice of professionals and promote therapeutic relationships. It has the potential to substantially reduce NHS costs particularly if there are fewer incidents and complaints. It has the potential to be translated and tested across the NHS and as such benefit many thousands of patients, service users and staff within a few years. The new information generated by this study will add to the research evidence base in the form of a comprehensive description of the intervention development, and testing in a very challenging clinical environment. This information will inform future research priorities for interventions to involve service users in promoting safety in mental health services, enabling NIHR and other funders to commission targeted research in this area.

Our IP strategy and licensing arrangements will allow us to track impact by monitoring use of the intervention. The digital products use of open technology will allow modifications and future developments. With a view to increasing impact, encouraging collaborative working and in line (where appropriate) with Government Digital Service Standard/NHS Open Source Programme, we propose to release the digital tools and technical infrastructure under an open source license to allow others to benefit from the work and learnings from this study. Our use of open source software allows our product to be refined in response to technological changes. This project will strengthen our collaboration and develop our research group's skills in this area and lead to future collaborations and applications for funding as well as informing our teaching.

Our strategy for impact will be designed with advice from the University of Leeds Faculty of Medicine and Health Research and Innovation service, our Project Management Group in line with ESRC Pathways to Impact toolkit(66). We will ensure this strategy is founded on the active engagement of stakeholders, particularly mental health service managers, regulators and commissioners. By disseminating our findings through written and oral presentation we will promote knowledge transfer across mental health services including the NHS, private providers and interest groups, e.g., Royal College of Psychiatry.

In international terms, our project will be of interest to both academics and clinicians. Indeed, we believe that through engaging with service users and healthcare staff throughout this study, we will minimise barriers to future implementation. The immediate potential barrier will be lack of engagement from service users and healthcare staff. This is addressed by our previously tested co-design process that will ensure our intervention is developed according

to the needs of users. The external policy context remains a potential barrier, as well as health service restructuring. We will seek to mitigate these through linking into NHS stakeholders through our Project Management Group and via additional connections and collaborations.

7. Project / research timetable

Phase	Month	Tasks
1 Intervention development **1a Environmental scan** **1b Co-designed technological development**	**1**	Project Management Group & monthly project meeting. Protocol finalisation & ethics applications for 1b.
	2	Monthly project meeting. 1a. Environmental scan: Synthesis of previous work & literature searches.
	3	Monthly project meeting. Environmental scan: Full text extraction and synthesis, co-design workshops recruitment.
	4-10	PPIE activities & monthly project meetings. Environmental scan: service user and staff interviews.
	10-14	Project Management Group & monthly project meeting. Co-design workshops: service user & staff: interface and dashboard.
	15-18	PPIE activities & monthly project meeting. Intervention technical development.
	18-22	Monthly project meeting. Intervention technical development, ethics applications for phase 2.
	22-24	Monthly project meeting. Testable intervention completed, programme theory revisited.
2 Mixed methods process evaluation	**24**	PPIE activities & monthly project meeting. Data collection baselines: routine data, safety culture staff measure, staff ward atmosphere measure, focused ethnography.
	25	Monthly project meeting. Intervention implemented over a 10 week period.
	26	Monthly project meeting. Post data collection. This includes baseline, routine data, safety culture staff measure, staff ward atmosphere measure, and focused ethnography.
	27	Monthly project meeting. Ongoing data collection until 14 week end date.
	28	Monthly project meeting. Analysis.
	29	Monthly project meeting. Analysis.
	30	Monthly project meeting. Analysis.
	31*	Monthly project meeting. Analysis.
	32-33	Project Management Group & monthly project meeting. Data analysis continues.
	34	Monthly project meeting. Data synthesis.
Dissemination	**35-36**	Monthly project meeting. Programme theory refined. Finalise report.

***Accounting for 6 months costed extension agreed in principle.**

8. Project management

The project will be managed by a Project Management Group consisting of all co-applicants, research staff, and representatives from trust sites that will meet every six months. It will monitor the progression of the project against milestones and provide overall study management. An Advisory Group will be set up to provide independent oversight of the project, this group will meet annually. Monthly project meetings will be held which focused on the day-to-day study management, chaired by PI BAKER, attended by research staff and co-applicants involved in the study at that point, video/teleconferencing will facilitate participation. Line management of researchers will be provided by PI BAKER. The co-design process will be managed by Thrive by design/Ayup Digital. We will link to existing stakeholder groups hosted by Leeds and York Partnership NHS Foundation Trust. Communication between co-applicants will be ad hoc depending on expertise required and all co-applicants will be kept updated by a monthly update. Communication between the different management groups will be facilitated by the project manager (co-app BERZINS) attending all meetings. A Mental Health Patient Safety Reference Group consisting of

clinician independent of this study will be arranged should advice be required regarding duty to report disclosures made during fieldwork.

9. Ethics / Regulatory Approvals

NHS Research Ethics Committee (REC) approval and NHS permissions will be sought via the Health Research Authority (HRA). To mitigate any potential delay, initial applications will commence immediately following notification of funding. The key ethical issues are anticipated to be unintentional harm, confidentiality and the duty to report, potential participant distress, capacity and informed consent. The team have extensive experience of researching sensitive subject including those relating to safety in mental health services, and consenting within inpatient mental health services.

9.1 Unintentional harm: All interventions carry the risk of unintentional harm and as such we will develop appropriate safety-netting procedures with participating trusts, Project Management Group, our lay co-apps, and with lay stakeholder groups. At the point we apply for ethical review we will know the basic form of the intervention and be clear about clinical escalation in terms of responsible person and timescale.

9.2 Confidentiality and the duty to report: Participants may be concerned about the confidentiality of information they provide in the interviews or co-design workshops which may impact on the data collected. Detailed co-produced participant information sheets will be provided to participants with full details relating to confidentiality and anonymity which should allay fears and enhance the data collected. With any research around healthcare there may be disclosures made that the research team have a duty to report. This is defined by the World Health Organisation(67) as information about an imminent error or action that could result in severe and irreversible harm and that intervention from the research team may prevent or limit this harm. Or that if an incident has already occurred, intervention may reverse the effects. This is a risk in this study and will be covered in both the Participant Information Sheet, Consent Form and further mitigated by the establishment of a virtual Mental Health Patient Safety Reference Group to ensure the team can access independent advice in such an event**.**

9.3 Distress: Many people enjoy being interviewed although there is always a risk that people may become distressed when describing difficult personal experiences. As a result the research will have a participant distress policy to ensure that participants are supported both during and after participation, if this should become necessary. All researchers will be sensitive to these issues and experienced at supporting people experiencing distress and signposting further support. Researchers will, in turn, be supported through team debriefing processes and supervisory structures.

9.4 Capacity and consent: There will be a minimum time delay between the potential interviewee receiving the information about the interview and the interview taking place. Ward staff will be asked to assess the capacity of service users to take part in the study. Participants may change their mind and withdraw from the interview at any point. The team have considerable experience in undertaking research in mental health services.

10. PPI

Please see PPI sections in the application for further detail. Lay input has informed this proposal (discussions with service user consultants, co-apps BROWN and WALKER). We will link to existing stakeholder groups hosted by Leeds and York Partnership NHS Foundation Trust via co-app WALKER. In addition, as this research will sit in the Patient Involvement in Patient Safety theme within the NIHR YH PSTRC (led by co-app O'HARA, BAKER deputy lead), we will draw upon the significant PPIE infrastructure this affords us,

specifically four Lay Leaders with diverse expertise, and a wider Safety in Numbers Group. We will also be supported by the Yorkshire Quality and Safety Research Group patient panel.

Engagement activity will be undertaken with the two mental health trusts where the project will run with representatives from each trust invited into the wider Project Management Group. Throughout Phase 1 we will involve key stakeholders to undertake real time synthesis of the emerging evidence, synthesising the knowledge from multiple perspectives, and exploring ways to make the evidence accessible to incrementally feed into the co-design stage.

11. Project / research expertise

Professor John **BAKER** (0.20WTE) will provide leadership for all stages. He will provide mental health subject expertise. John is an experienced mental health nurse researcher particularly in acute mental health wards and patient safety. John is also a non-executive director at LYPFT with responsibility for patient safety and quality.

Dr Kathryn **BERZINS** is a mixed methods researchers with expertise in mental healthcare, specifically the safety of both service users and staff. She has previous experience of NIHR programme grant management.

Mark **BROWN** has lived experience of mental health difficulty. He has worked on a number of co-designed digital mental health projects including Doc Ready with Future Gov and Neon Tribe and The Leeds Young People's Digital Innovation Lab with Thrive by design. Mark is currently writer in residence with Centre for Mental Health. He has also provided strategic support to the National Survivor User Network since 2016.

Lauren **WALKER** has lived experience of acute mental health wards. She has previously worked as a service user researcher.

Professor Jane **O'HARA** (0.10WTE) has extensive expertise in the involvement of patients in patient safety, and co-designing interventions to support patient involvement and engagement. Jane has also undertaken a number of feasibility trials, and has experience of process evaluations within controlled trials, and mixed-method evaluations of implementation. Jane has a particular research interest in the measurement of safety, and patient safety theory.

Professor Chris **BOJKE** (0.05WTE) is an empirical health economist and statistician specialising in the analysis of observational datasets.

Dr Gemma **LOUCH** (0.2WTE) will provide input at all stages and provide a substantive link into the NIHR YH PSTRC, Patient Involvement in Patient Safety theme. Gemma is a mixed methods researcher, with expertise in the area of patient engagement and involvement in safety, most recently within a mental healthcare setting.

Professor Charles **VINCENT** (0.05WTE) is an internationally renowned expert in patient safety, with extensive expertise in leading and supporting studies seeking to measure patient safety across secondary care and mental health settings. Charles will support study design, analysis and interpretation

Ayup Digital is a Leeds based Tech for Good digital product studio. They co-design, engineer and deliver people-centred digital products that help improve people's health and wellbeing. Ayup's have a wealth of experience including developing and delivering on NIHR and NHS funded.

Thrive by design is NHS hosted (hosted by LYPFT) team specialising in co-design, digital skills & inclusion, policy & strategy, evaluation. Thrive by design supports people-centred co-designed digital innovation in health and social care. They have extensive experience of co-designing with the NHS and service users and carers. They are currently working with NHS England and NICE to support IAPT digital tools and services to get through the DAQ process. Thrive by design are one of only a handful of organisations formally working with NHS England to assist digital products and services in meeting the standards of the DAQ.
Ayup Digital and Thrive by design have a strong working relationship, forged over the past three years through joint work on various digital projects. We have substantial experience of delivering mental health digital products and services.

12. Success criteria and barriers to proposed work

Our flowchart and corresponding timetable set out key targets to be achieved throughout the duration of the study. Our success criteria include: Recruitment of research staff; and successful linking to existing lay stakeholder groups; research governance permissions secured; completed environmental scan; development of testable intervention; intervention tested, data collected and analysed, research questions answered; reports completed and published; peer-review publication strategy achieved. Identified barriers include difficulties recruiting research staff although we have potential applicants in mind and will ensure realistic time scales are in place for any external recruitment. The loss of staff through changing jobs / long term sickness remains a barrier although this can be mitigated by awareness of notice periods; task sharing between staff; clear record keeping; succession planning if necessary; clear line management; open communication; regular supervision and the potential for contract extensions. Difficulties linking to existing lay stakeholder groups will be mitigated through commencing engagement when funding is confirmed, using technology to facilitate participation, flexibility with times, dates and locations. Study timescales will be managed by the clear identification and communication of external deadlines with internal deadlines set accordingly; monitoring by PI through meeting minutes and communication with researchers; ad hoc meetings called to anticipate any slippage. Any under recruitment to study will be managed by liaison with and research team presence in study sites; monitoring of recruitment rates and potential addition of additional sites.