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SAM-I Safe Administration of Medicines - Intervention

YQSR Yorkshire Quality and Safety Research Group

SAM-I Work Package 3 Research Protocol

WP3 FULL STUDY TITLE: Safe Administration of Medicines Intervention (SAM-I): feasibility study of an intervention to de-implement unnecessary double checking of medicines in hospital

WP3 SHORT STUDY TITLE: Safe Administration of Medicines Intervention (SAM-I): feasibility study

RESEARCH REFERENCE NUMBERS

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STUDY SUMMARY

Medication administration errors are a major source of avoidable harm in healthcare. Independent double-checking of medicines is widely used in NHS hospitals to reduce such errors; however, evidence shows limited effectiveness and highlights unintended consequences, including delays to time-critical medicines and substantial demands on

nursing time. Despite this uncertainty, double-checking remains embedded in medicines policies and routine practice, making any move towards reduced double-checking a complex organisational change.

This study is a non-randomised representative feasibility study assessing the feasibility, acceptability and readiness for implementing a co-designed de-implementation intervention that aims to reduce routine double-checking and support safe single-checking of medicines. The study will run over 12 months across three NHS hospital Trusts and include six clinical services.

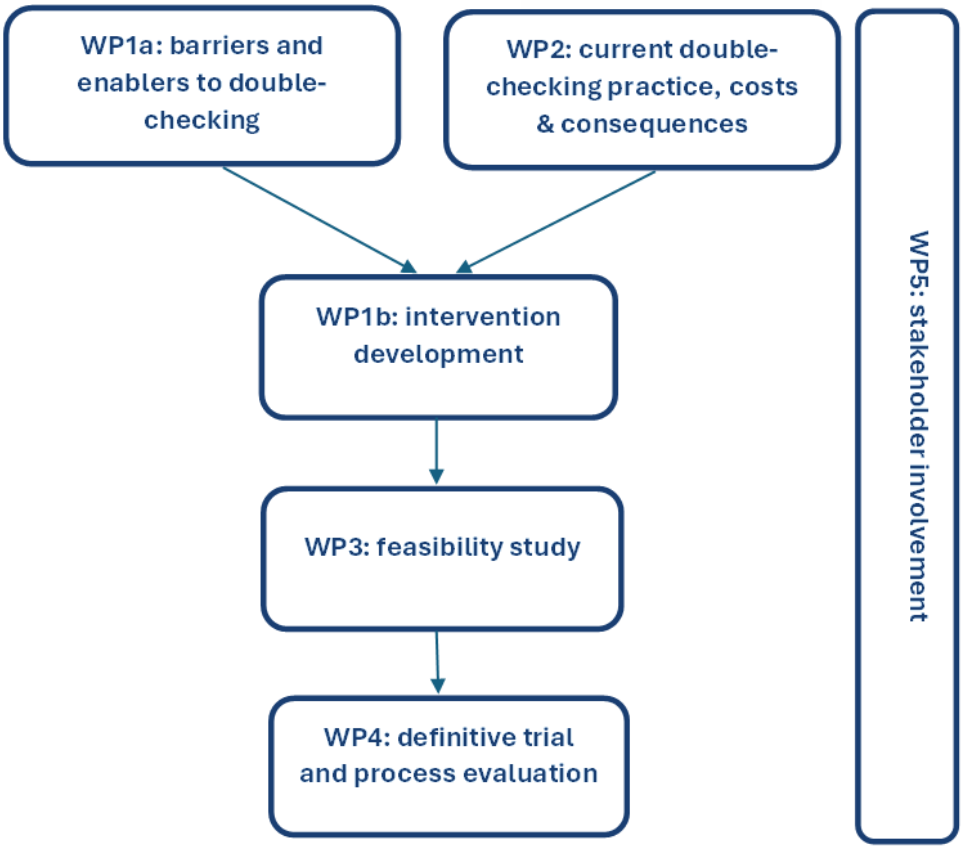
The intervention will be implemented at service level and includes updated local medicines policies, and changes to electronic systems requiring double checks, staff training, local instructions on a safe single check, endorsement by senior leaders and support from local managers. Implementation of the intervention will be staggered across services over three months to allow refinement and accommodate variation in staffing and workflows.

Quantitative data will include direct observations of medication administration at baseline and post-implementation, nurse questionnaires assessing attitudes to single-checking and care left undone and routinely collected data from electronic prescribing and medication administration systems and local risk management systems. Data will be analysed descriptively to assess the feasibility, completeness and consistency of outcome measures required for a future definitive trial.

Findings will inform refinement of the intervention, confirm outcome measurement methods, support development of the health economic model, and guide governance decisions for a future randomised controlled trial.

PROGRAMME FLOW CHART

Figure 1. A flow diagram of the Research Programme. This protocol will focus on WP3 only.



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KEY WORDS

Medication Administration Errors

Medication Errors

Double-checking

De-implementation of low value care

Observation

1. BACKGROUND AND RATIONALE

Medication errors are a leading cause of avoidable harm in healthcare systems globally (World Health Organisation, 2021). In England, medication errors are estimated to contribute to or cause approximately 12,000 deaths per year in the National Health Service (NHS) and add upto £1.5 billion to annual healthcare expenditure (Sutherland et al, 2020). Of the estimated 237 million medication errors that occur each year in England, over half arise during the administration of medicines (Elliott, 2021). Although most medication errors (72%) result in no harm, around 66 million are potentially clinically significant. A medication administration error (MAE) is defined as a deviation from the prescriber's medication order as written on the patient's charts or relevant administration instructions (Keers et al, 2013). MAE rates vary by route, with approximately 5.6% of oral and 35% of intravenous administrations found to be erroneous (McLeod et al, 2013). Medication administration is a complex, multi-step process involving counting, calculating, measuring, mixing, and ensuring that the right patient receives the right medicine, dose, route and timing for the right reason (Manias, 2014).

To reduce MAEs, a range of strategies have been implemented in secondary care, including technological support systems, training, distraction reduction techniques, checklists and interruption management approaches such as 'quiet zones' and 'do not disturb' tabards (Keers et al, 2014; Ruano et al, 2016). Independent double-checking of medicines is one of the most commonly used strategies (Lapkin et al, 2016; Keers et al, 2014) and is widely embedded in medicines policies across the NHS. Double-checking is also used to prevent diversion of controlled drugs, including opioids and benzodiazepines, which are subject to legal regulation due to their potential for misuse. The practice involves two healthcare professionals, usually nurses, checking a medicine before administration (O'Connell et al, 2013). Double-checking introduces redundancy into the medication administration process and is based on the premise that one individual's error can be detected and corrected by another (Schobel & Manzey, 2011; Schwappach et al, 2016).

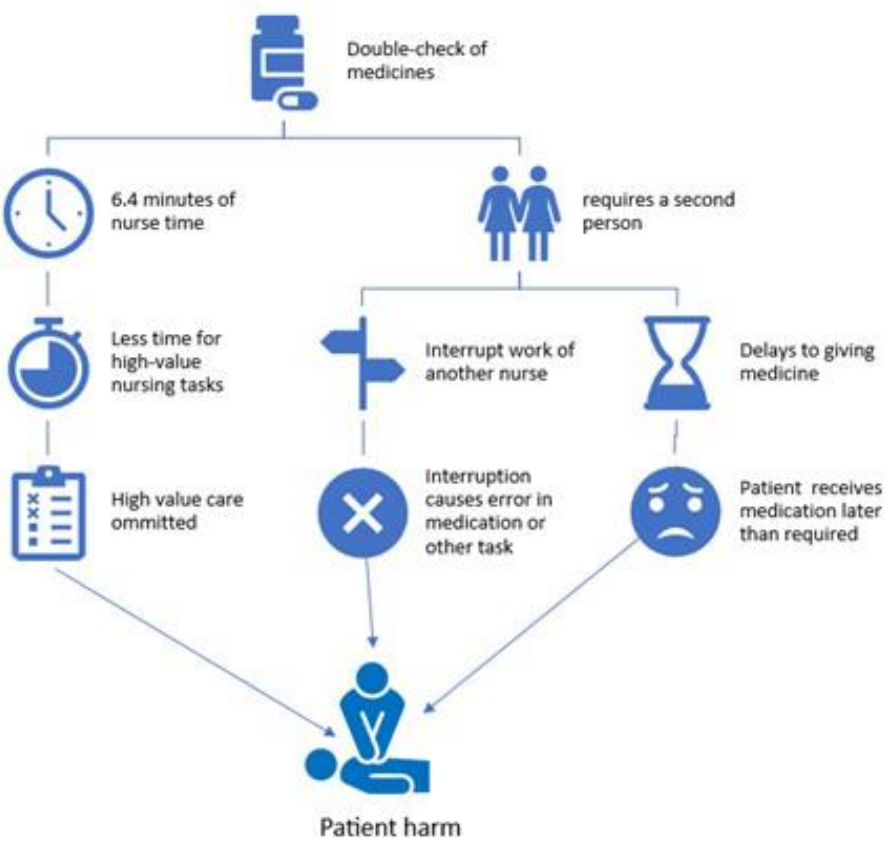
Despite its intuitive appeal and widespread use, evidence supporting the effectiveness of routine double-checking remains limited. A systematic review published in 2020 found insufficient evidence that double-checking reduces MAE rates (Koyama et al, 2020). Of the 13 included studies, most were of poor methodological quality; among the three higher-quality studies, findings were inconsistent. These conclusions are consistent with a more recent systematic review of high-risk industries, such as aviation and chemical processing, which found no improvement in error detection when tasks were checked by two people rather than one (McMullen et al, 2023).

Previous research suggests several reasons why double-checking may fail to prevent errors. The task is cognitively demanding but highly repetitive, meaning it may become habitual and automatic over time, reducing the attentional resources applied to it (Toft & Mascie-Taylor, 2005). Double-checking may also be undermined by social and organisational factors such as

deference to authority, diffusion of responsibility, social loafing, and frequent interruptions and distractions (Armitage, 2008; Cymek, 2018; Hayes et al, 2015; Latane et al, 1979). These issues are exacerbated when checks are primed rather than independent, with previous studies demonstrating that truly independent double-checking is uncommon in practice (Westbrook et al, 2021).

In addition to uncertain effectiveness, double-checking is time-consuming and resource intensive. An Australian study of 5,000 paediatric medication administrations found that 69% required a double-check, with each double-check taking an average of 6.4 minutes, equating to approximately 133 nursing hours per day and an estimated annual cost of £1.3 million for a single 340-bed hospital. Similarly, Pronovost et al. (2014) reported that time spent double-checking medicines in one US intensive care unit was equivalent to one full-time nurse. Importantly, double-checking may also have unintended negative consequences, including delays to the administration of time-critical medicines and reduced time available for other high-value nursing activities, potentially increasing patient risk (Schutijser et al, 2019; Turecek, 2018). Figure 2 illustrates how double-checking may contribute to patient harm through interruptions, delays and reduced care capacity.

Figure 2. Impact of double-checking medicines on patients and service



In summary, nurses across the NHS spend substantial amounts of time double-checking medicines based on an assumption of safety benefit, despite limited evidence of effectiveness and increasing concern about unintended harms. While WP2 of this programme (IRAS ID 356129) addressed this evidence gap by describing double-checking practices, processes and outcomes in detail, uncertainty remains about how services can safely move away from routine double-checking in practice. This study therefore focuses on the feasibility and acceptability of implementing a structured de-implementation intervention, assessing whether and under what conditions services can reduce routine double-checking and transition towards enhanced single-checking in preparation for a definitive trial.

2. RESEARCH AIMS & OBJECTIVES

2.1 Aim

This non-randomised feasibility study aims to assess the feasibility of implementing a co-designed intervention, determining procedures for a future definitive RCT.

2.2 Research questions

1. Are the systems for collecting our primary and secondary outcome measures compatible for use in WP4?
2. Can we improve the efficiency of observational tools for WP4?
3. Is the de-implementation intervention feasible and acceptable to frontline ward staff and how long does it take? Why/ why not?
4. Does the intervention require modifications prior to the main trial to ensure success? If so, what are they and how can they be integrated?
5. Under what conditions does a service become ready to de-implement double checking (time span, appropriate personnel, infrastructure or policy changes, etc.)?

3. STUDY DESIGN

This study is a non-randomised, representative feasibility study conducted over a 12-month period. Reporting will follow the principles of the Consolidated Standards of Reporting Trials (CONSORT) extension for non-randomised pilot and feasibility studies (Lancaster et al., 2019). The primary intervention deployment period will last 3-4 months, embedded within the overall study timeline.

The Feasibility study uses a service-level before-and-after design comprising:

- Baseline period, during which existing medication administration processes and double-checking practices are measured (1-3 months)
- Implementation and embedding of the intervention (3-4 months)

- Post-implementation assessment (1-3 months).

Figure 3. Feasibility study timeline

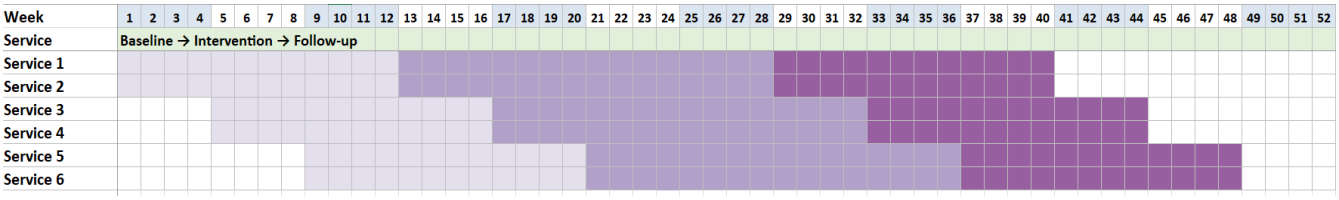
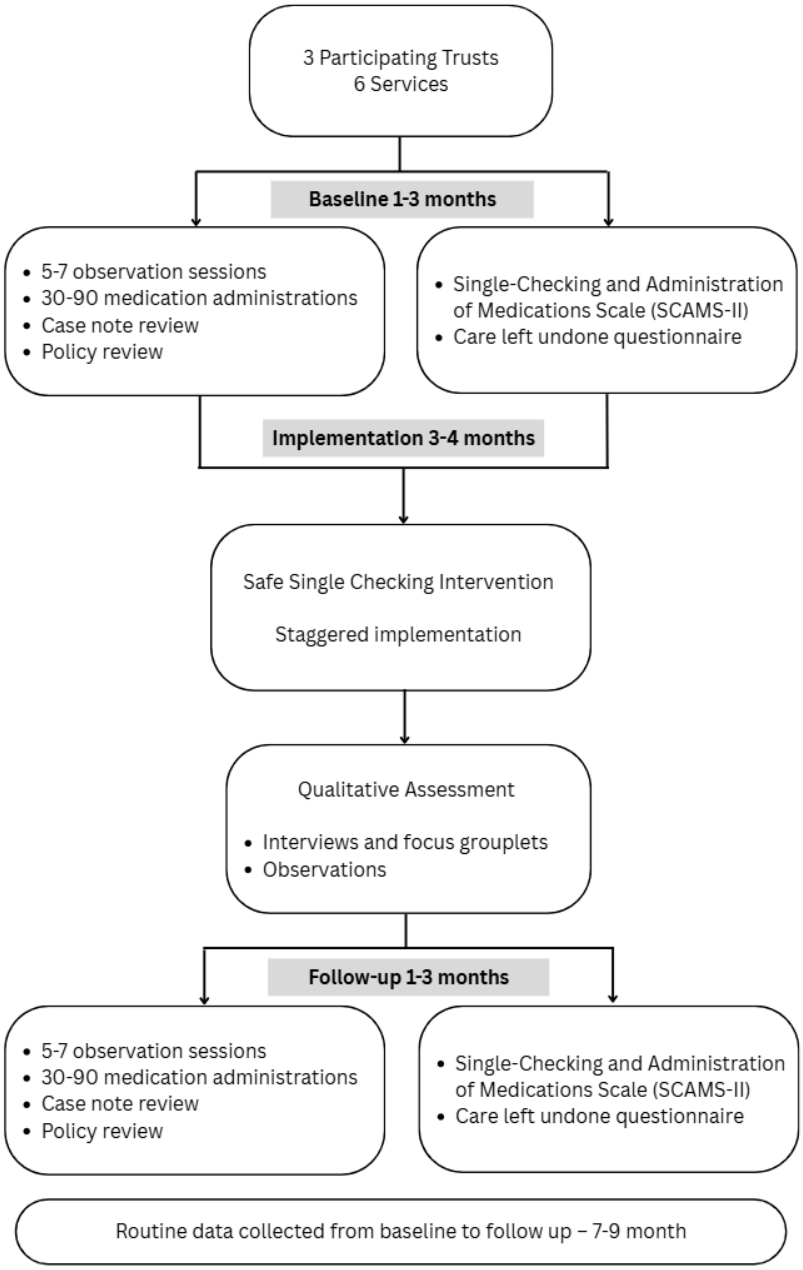


Figure 4. Feasibility study flow chart



All participating services will contribute data at both baseline and follow-up. The design will enable estimation of key feasibility parameters (e.g., recruitment, data completeness and intervention uptake) and exploration of changes in medication checking behaviours and safety outcomes.

4. WARD ELIGIBILITY

The study will take place in inpatient areas where medicines are routinely prepared and administered by nursing staff and where double-checking is embedded in local policy and everyday practice. We will include a diverse range of ward types/specialities where medication administration is frequent and operationally complex (e.g. general medicine, elderly care, orthopaedics, respiratory, surgical wards, cardiology, ICU, paediatrics), in order to test feasibility across varied contexts.

4.1 Inclusion Criteria

Six hospital wards/ clinical services across 3 Trusts that meet the following eligibility criteria will participate in the feasibility study:

- NHS-funded inpatient wards/services within a participating NHS Trust
- Wards/services where medicines administration is frequent and routine
- Wards/services where double-checking is routinely undertaken as part of local policy and/or established practice
- Wards/services able to support implementation activities, including staff training, and ward-level engagement activities
- Wards/services able to support feasibility data collection, including observation periods and access to relevant routine data sources (e.g., ePMA systems, incident data).
- At least one Trust will not have taken part in this programmes previous work packages.

4.2 Exclusion Criteria

The following wards/services will be excluded from the study:

- Oncology and haematology/oncology settings due to distinct medicines governance and existing checking procedures
- Wards/services currently participating in another intervention study likely to influence medication administration processes or checking behaviour

4.3 Ward Identification

Senior leaders in the Trusts will be approached to invite their Trust to take part in the feasibility study. Once organisational agreement is in place, the research team will work with Trust stakeholders (e.g. nursing leads, pharmacy leads, patient safety leads) to identify services meeting the eligibility criteria. Researchers will then approach the relevant clinical leaders (e.g. matrons and ward managers) to confirm interest and assess local readiness to participate. Reasons for wards/ services declining participation will be fully documented.

5. PARTICIPANT ELIGIBILITY

5.1 Staff inclusion criteria

Staff will be eligible to take part in the feasibility study if they meet all of the following criteria:

- Employed (permanent, bank or agency) within a participating ward/service during the study period
- Directly involved in medicines preparation and/or administration (e.g., registered nurses, nurse associates, student nurses)
- Aged ≥18 years
- Willing and able to provide informed consent to take part in the study (e.g., complete questionnaires and/or interviews), where required.

5.2 Patient participation

Patients are not directly recruited into the study, as the intervention is implemented at ward level and patients will not be able to opt out of the change in practice. Individual patient consent will therefore not be sought.

Patients will be informed of the study via ward posters and will be able to opt out of the use their data for research purposes. While patients will not be recruited to the study (our patient advisory group did not believe it was in their best interest to be made aware of the switch from double-checking to single checking as patients rarely know about checking practices), the primary outcome for this study relies on accessing data about medicine prescription and administration (so as to calculate errors) and the collection of routinely available patient data is also required for secondary outcomes of reported medication errors and other patient safety incidents. This routinely collected patient data will be used under approval from the Confidentiality Advisory Group.

6. RECRUITMENT PROCESS

6.1 Identification and approach

Eligible wards/services will identify staff groups involved in medicines administration. Researchers will liaise with ward managers/local implementation leads to agree the most appropriate timings for staff information sessions, with minimal disruption to clinical care (e.g., handover periods, safety huddles, staff briefings and ward meetings).
Information about the study will be provided by researchers and research nurses during information sessions. They will explain the purpose of the study, what participation involves, and the service-level nature of the intervention.

Staff may be approached directly by a member of the research team or introduced via the ward manager/local lead. All staff will be provided with a Participant Information Sheet and given opportunities to ask questions before deciding whether to participate in the evaluation components of the study (e.g. observations, questionnaires, interviews).

6.2 Consent

As the intervention is implemented at ward/service level, staff cannot opt out of exposure to the intervention (i.e., the change in medicines administration checking processes). However, participation in observation, questionnaires and interviews is voluntary.

Consent to participate in an observation
Consent will primarily be obtained during ward information sessions (which may take place during handover or huddles). Staff who are not present at these sessions (for example, agency staff) will be approached at the earliest opportunity and asked to provide consent before they are observed or invited to complete questionnaires.

For observations, nurses will provide verbal consent, which will be recorded on REDCap (Research Electronic Data Capture), a secure online system hosted by York Trials Unit. A paper enrolment log will be kept securely at each participating trust in the investigator site file. Nurses who consent to participate will be assigned a unique participant ID and provided with a small sticker for the inside of their Trust ID badge to enable identification during observation sessions. Bank and agency nurses, nurse associates and student nurses will also be eligible to participate; student participation will be noted due to their trainee status.

Consent to participate in a questionnaire

Written informed consent or electronic informed consent will be obtained from staff for study questionnaires, depending on whether the questionnaire is completed online or on paper. Participants who take part in an observation will be encouraged to use the same ID number provided on their ID badge. All participants will be asked to create their own unique ID (e.g. first two letters of your first name and surname, followed by the day you were born JOSM13) to allow for data to be linked at different timepoints. Demographic information (e.g., role, years of experience, employment status, country of training, and ethnicity) will be collected as will views on single checking. Where paper forms are used data will be subsequently entered into an electronic database by the research team and destroyed on completion. Written informed consent will be stored in the site's investigator site file.

Consent to participate in an interview

Written or verbal informed consent will be obtained from staff for interviews and focus grouplets and stored at the University of Manchester.

We will compare the demographic profile of consented participants with anonymised ward-level demographic data (where available) to assess whether the sample of participating nurses is broadly representative of the ward workforce.

6.3 Withdrawal

Staff may decline to take part in observations, questionnaires and interviews without giving a reason. Where reasons are offered, these will be recorded to inform feasibility assessment. Staff may withdraw from observation and/or questionnaires at any time without penalty.

7. INTERVENTION:

The intervention is a structured, ward-level approach to reducing routine double-checking and support safe, single-checking for medication administration. It targets ward-level policies, and systems, staff motivation, capability and opportunity, norms and practical workflow processes checking behaviours.

7.1 Intervention Rationale

The intervention is co-designed with healthcare professionals, based on principles from behavioural science and human factors, and aims to implement consistent and reliable single-checking behaviours. While independent double-checking - where two nurses independently verify that they have the right medicine, at the right dose, for the right patient, and the correct route of administration - is a safety strategy used in medication administration to avoid errors in the administration process, this practice is rare. Busy nurses generally check medicines quickly with a colleague; therefore, the checking is not independent but rather primed checking. Primed double-checking can introduce confirmation bias and diffusion of responsibility.

7.2 Intervention Components

The intervention comprises the following core components:

1. **Electronic system change**
   A system change that means a second signature is no longer required in ePMA to administer medicines that were previously required to be double-checked by policy.
2. **Ward/ service policy change**
   A local medication administration policy stating that safe-single checking is the default, with supported single-checks encouraged for newly qualified nurses, bank and agency staff.

A supported single check involves independently preparing and checking the medication, while seeking support or guidance from a colleague through a brief discussion about a specific element (e.g., a complex calculation), rather than completing a full double check together.

3. **Visible leadership and safety culture support**
   Clear organisational support from Trust leadership and ward managers and an explicit commitment to a no-blame culture will be required should an incident occur during single checking.
   Persuasive communication will be provided as well as a problem-solving meetings/discussion.
4. **Educational materials**
   Convincing, evidence-based messaging emphasising the disadvantages of double-checking and benefits of single checking and alignment with existing nursing education (e.g. Five Rights).
5. **Instructions on how to perform safe single-checking**
   Training on how to conduct a safe single-check may be delivered virtually or face-to-face by nurse educators. Environmental prompts such as a poster outlining the steps to perform a safe-single check will be displayed in medication rooms. Posters will emphasise that asking for advice remains expected and fully appropriate.
6. **Access to decision support tools and workflow support**
   Ensuring staff have access at all times to tools that support medication administration (e.g. Medusa [NHS Injectable Medicines Guide] and British National Formulary [BNF] app). Where feasible, wards will also implement actions to reduce workflow interruptions (e.g. do not disturb signs on medication room doors).
7. **Ward champion**
   A nominated ward champion to promote engagement, support local problem solving and reinforce practice change.
8. **Endorsement video**
   A short video from a senior national figure that aligns with evidence and endorses the change from double checking to safe single checking.
9. **Feedback**
   Regular feedback on the impact of single-checking on medication errors, delays to administration of time-critical medicines and efficiency or time-saved.

7.3 Implementation

Each participating service will identify a ward champion, who will work with the research team to introduce the intervention to staff, organise training sessions, and support implementation fidelity. Implementation will be staggered, allowing iterative refinement of

the implementation process. This staged approach is intended to optimise feasibility in settings with high staff turnover and shift work.

The research team will maintain regular contact with the implementation lead to identify challenges, provide clarification and monitor adherence.

8. NURSE QUESTIONNAIRE

All consented nurses involved in medication preparation and administration on participating wards will be invited to complete two questionnaires. The first is the Single Checking and Administration of Medications Scale (SCAMS-II) (Cross et al., 2015), a validated 12-item measure assessing nurses' attitudes towards single-checking. Items are rated on a five-point Likert scale ranging from "completely disagree" to "completely agree" and generate scores across three domains: confidence in knowledge, perceptions of efficiency, and professional accountability associated with single-checking. The second measure is a validated care left undone questionnaire (Ball et al., 2014). This instrument asks nurses to indicate whether specific nursing care activities were necessary but left undone during their most recent shift due to lack of time. The measure captures missed or incomplete care across 13 common nursing tasks.

Participants will provide a unique nurse study ID at the point of consent, which will enable questionnaire responses to be linked with pre-post implementation questionnaires and/or observations, while maintaining anonymity in the analysis dataset.

Questionnaires will be administered at baseline, prior to the start of observational data collection, and again during the follow-up period after implementation of the intervention. Questionnaires will primarily be completed electronically, accessed via a secure study iPad or through a link distributed to staff email addresses. Ward managers will support distribution of the questionnaire link to facilitate staff participation. A poster with information on how to complete both the questionnaire via paper or online will be placed in ward staff rooms. At baseline, the research team will aim to recruit as many nurses as possible to complete the questionnaire during staff information sessions held on the ward. Staff who are unable to attend these sessions will be able to complete the questionnaire later using a link sent via email.

Where electronic completion is not possible, paper questionnaires may be used, and responses will subsequently be entered into an electronic database by a member of the research team.

9. OBSERVATION

Trained research nurses will conduct 5-7 observation sessions at baseline and 5-7 observation sessions post-implementation of the intervention at each ward. Each observation session will last approximately 4–6 hours and will be purposively scheduled across different times of day, days of the week (including weekends where feasible), and shift types (e.g. early, late, and night shifts where appropriate). This approach is intended to

capture variation in staffing levels, skill mix, and patterns of medication administration across the ward.

During each observation session, the research nurse will undertake non-participant observation of routine clinical practice. They will primarily shadow one or more consenting nurses involved in medication administration, positioning themselves so they can observe practice without obstructing care delivery. The focus of the observation will be on medication administration processes rather than individual staff performance. The research nurse will observe all medication-related activity occurring within the observation period. This includes scheduled medication rounds as well as unscheduled or PRN (as required) medication preparation, administration, checking practices, and relevant communication between staff relating to medicines. This will provide a comprehensive picture of medication administration practice at baseline and follow-up including data on approximately 30-90 medicines per ward. At baseline, this will include approximately of 30 medicines mandated for double-checking. A follow-up this will include approximately 30 medicines for which double-checking requirement has been removed.

Research nurses will undertake a familiarisation period before observation data collection, spending time on the ward to understand local routines, medication workflows, and staffing patterns. They will consent as many nurses as possible during this period. In an earlier work package this process was useful in minimising disruption when observations began and promoted trust between ward staff and researcher nurses.

Observers will use an electronic or paper version of a structured data collection tool called the 'SAM-I Observation Tool' (SOT). This tool was developed to capture key information of medicines being administered in practice. The electronic version of the tool will be hosted on a secure data collection platform such as Research Electronic Data Capture (REDCap) hosted by York Trials Unit or Work Observation Method by Activity Timing (WOMBAT). Research nurses will receive training in the form of classroom-based scenarios as well as several pilot practice sessions in the field. Interrater reliability of observations will be assessed prior to data collection.

Observers will record in real time:

1. Information about the medicine/s being administered e.g. name of medicine, route, dose.

2. Information about the administration process e.g. whether a double-check or single check was carried out and if a medication error was detected during the checking process.

3. Time taken to conduct the double-check or single check. Time stamps (a digital record of the time of occurrence of a particular event) will also be recorded as a separate function within the SOT.

4. If an error is detected by either nurse during the medication administration process, the observer will input information into SOT about what the nature of the error is using the categories outlined in the SAM-I Error Taxonomy.

10. CASE NOTE REVIEW

Following each observation session, the research nurse will access patient health records and extract information from the patient's medication chart in relation to the medicines they observed being administered into a case note review form. CAG approval is being sought to enable this data collection. This information will be used to retrospectively identify discrepancies between the observation data and the patient's prescription. This will provide the primary outcome data for WP4– medication error – YES or NO.

Case note reviews may be conducted on the ward at the end of an observation session or at a later date with support from the Principal Investigator (PI) or research team. All researchers will have the appropriate authorisations and training to access Electronic Health Record (EHR) systems at each participating Trust. Researchers will use the Medication ID Log to identify the relevant patient records corresponding to medicines observed during the observation session. The Medication ID Log will be maintained as a paper document and stored securely at each site in a locked location with restricted access.

Once the correct EHR has been identified, key information (e.g. prescribed medicine, dose, duration, route, administration time) will be extracted and recorded on a case note review form. Data will be entered directly into an electronic data capture platform, or if initially collected on paper forms, entered into an electronic data base by a member of the research team. Data will be pseudonymised using a unique Medication ID number, allowing linkage with observation data without including patient identifiers. The Medication ID Log, which contains identifiable information, will be retained securely at the site. Once case note review data collection and verification are complete, and all required data have been entered into an electronic database, the Medication ID Log will be destroyed using local confidential waste procedures to protect patient anonymity.

11. POLICY REVIEW

Principal investigators at each site will obtain the necessary Trust permissions to share local policies governing the administration of medicines. Observational data from medication administration episodes collected pre- and post-intervention will be analysed against the relevant local medicines administration and double-checking policies in place at each time point.

Prior to implementation, analysis will identify double-checking practices that were required by policy, as well as any additional voluntary double-checking undertaken by nurses. Following implementation of the intervention to transition from double-checking to single checking of medicines, analysis will determine the extent to which double-checking persists

in practice. This will include identifying instances where nurses continue to double-check voluntarily, despite this no longer being required by policy.

This approach will allow calculation of the proportion of medication administrations where practice aligns with current hospital policy at each time point, and the proportion where double-checking occurs beyond policy requirements.

12. ROUTINE DATA COLLECTION

Using the electronic Prescribing and Medication Administration (ePMA) systems in participating Trusts, we will obtain routinely collected data on scheduled and recorded medication administration times and length of stay data (e.g. admission/discharge dates and times) across baseline, implementation, and post-implementation periods. This component will evaluate whether routine ePMA systems perform consistently and reliably in supporting the collection of primary and secondary outcome measures required for the definitive trial.

Data will be anonymised and extracted by Trust ePMA teams and descriptively analysed using a pre-established definition of a critical delay (as defined in WP2). This will enable identification of overall medication delays and delays to time-critical medicines.

Where feasible, observational data will be used to aid interpretation of routine records, including linking observed checking process times with recorded administration times for a subset of medication administrations. This will support analyses of the relationship between checking practices and delays in the definitive trial.

Where patient characteristics (e.g. age, sex, ethnicity, deprivation) are routinely recorded and extractable, these data will be included in analyses of medication delays and medication-related incidents in accordance with the approaches established in WP2.

In parallel, routinely collected data on medication administration errors, all medication errors and broader patient safety incidents will be obtained from Local Risk Management Systems (LRMS) across the study periods. These data will be categorised where possible and used as secondary outcome measures in the definitive trial, consistent with the hypothesis that reducing time spent on routine double-checking may increase nursing capacity for other care activities, reduce care left undone and hence lead to fewer patient safety incidents.

13. READINESS ASSESSMENT

A core aim of the study is to determine when and under what conditions services become ready to safely discontinue double-checking. Readiness will be determined using predefined criteria to ensure that key requirements have been met before the transition.

Ward managers will be asked to complete a structured implementation checklist confirming that essential conditions are met. This will include confirmation that the Safe Single Check guide is displayed in medication rooms; relevant medicines information resources (e.g.

Medusa and BNF apps) are accessible; any required ePMA system changes have been completed; staff are aware of and prepared for the change (informed by data on the number of ward-based nursing staff who have completed the safe single-check training, provided by the research team); and a confirmed date for transition has been set.

Readiness will additionally be assessed using a single-item binary measure completed by the ward manager:

"Is your ward ready to stop routine double-checking of (agreed list) medicines and implement safe single-checking?" (Yes/No)

14. OUTCOMES

- **Nurse attitudes to single-checking:** Measured using the validated *Single Checking and Administration of Medications Scale (SCAMS-II)*, a 12-item, 5-point Likert scale (Completely disagree to Completely agree), generating total and subscale scores (accountability, efficiency, knowledge) (Cross et al., 2015).
- **Care left undone:** Self-reported omission of care using a 13-item checklist; nurses indicate which care tasks were left undone on their last shift (Ball et al., 2014).
- **Reported patient safety incidents (medication-related):** All reported patient safety incidents, medication errors, medication administration errors, and associated level of harm.
- **Double-checking practices:** Frequency and type of double-checking during medication administration, including policy-required double-checking (primed and independent) and voluntary double-checking initiated by nurses.
- **Observed medication administration errors:** Rate of medication administration errors identified through direct observation.
- **Delays in time-critical administrations:** Proportion of time-critical medications not administered within the predefined time window.
- **Time spent implementing checks:** Mean time spent per medication administration undertaking checking procedures.
- **Service readiness for single-checking:** A set of indicators for readiness including a structured implementation checklist and single-item binary measure completed by the ward manager.
- **Length of patient stays:** Average length of patient stays on the ward for the baseline and follow-up.

15. PROGRESS CRITERIA

The following criteria will be used to guide progression to WP4:

1. We have a refined intervention that is feasible and acceptable to services and Trusts.

2. The time needed for the intervention to transition to implementation within and across services and Trusts is established and is practical and achievable to implement.

3. The systems for collecting medication administration errors and time spent implementing checks has been established, is practical and achievable.

4. The length of follow up required has been established, is practical and achievable.

5. A non-inferiority margin for medication administration errors is established and the subsequent sample size is practical and achievable.

16. ADVERSE EVENTS

The study intervention could impact on patient safety so it will be necessary to monitor this during the recording of observations collected at baseline and post-intervention implementation. Adverse events (AE) will be defined as any untoward medical occurrence to a patient. A medical occurrence will be defined as when there has been an error in the administration of a medication specifically for those that are to be second checked as per local policy. Only medical occurrences that are categorised as a serious adverse event (SAE) will be reported as defined as follows:

- Results in death.
- Is life threatening (that is it places the patient, in the view of the Investigator, at immediate risk of death).
- Requires hospitalisation
- Requires prolongation of existing inpatients' hospitalisation (that is hospitalisation is longer than was expected).
- Results in persistent or significant disability or incapacity.
- Consists of a congenital abnormality of birth defect.
- Is otherwise considered medically significant by the site investigator.

All SAEs that are expected or not and meet the definition of medical occurrences will be reported within 24 hours of the site investigator becoming aware of them. An appropriate member of the research team at the site will record SAEs on the appropriate CRF on paper/electronically. In addition, wards should follow their own local procedures for the reporting of any adverse events linked to clinical care.

Minor medication errors that do not result in significant patient harm are expected and will not be subjected to expedited reporting to the main Research Ethics Committee (REC). All 'unexpected' SAEs and those considered 'related' to the study intervention by the site investigator will be reviewed by the Chief Investigator and subject to expedited reporting to

the main REC within 15 days of the Chief Investigator becoming aware of them. All SAEs will be reported to the independent oversight committees when they meet.

Finally, the sponsor or site investigator may take appropriate urgent safety measures in order to ensure patient safety without prior authorisation from a regulatory body. REC must be notified by email about urgent safety measures within three days.

17. ANALYSIS

Full details of analyses will be provided in the Statistical and Health Economic Analysis Plan (SHEAP), which will be written before the follow-up period concludes. Wherever possible the trial will be reported in accordance with the recommendations of the CONSORT extension for non-randomised pilot and feasibility studies.

17.1 Statistical Analysis

We will consent as many nurses as possible that work on participating wards. We are recruiting from six hospital wards/clinical services across three trusts; however the anticipated number of research participants will vary on the size of the ward/services. On the basis that we want to recruit all nurses employed by the ward/service at the time observation sessions (5-7 sessions at baseline and follow-up; lasting approx. 4-6 hours per session). We anticipate observing approximately 30–90 medicines per ward at baseline and 30–90 medicines per ward at follow up:

Baseline: 180–540 observed medication administrations

Follow-up: 180–540 observed medication administrations

Total: 360–1,080 observed medication administrations

Based on data collected from work package 2, we estimate that approximately 6–35 nurses (average 20) per ward will participate in observations, giving an anticipated total of approximately 36–210 nurse participants. Because medication administration is delivered by shift-based teams, the exact number of individual nurse participants cannot be predetermined. Quantitative data reported using appropriate summary statistics. Continuous variables will be summarised using means and standard deviations or medians and interquartile ranges where appropriate. Categorical variables will be summarised using frequencies and percentages. No inferential analysis is planned.

Analyses will focus on describing:

- The proportion of medication administrations performed using single-checking, voluntary double checking and policy required double checking.
- The duration of checking.
- Medication errors and their types (based on the SAM-I error taxonomy).

- Length of patient stays.
- Time-critical medication delays.
- Questionnaire responses and changes between baseline and follow-up.
- Patient safety incidents and adverse events.

Medication errors will be reported descriptively at baseline and post-intervention for:

- Medications requiring double-checking by policy
- Medications requiring single checking
- All medications

17.2 Medication Error Judgement

Research nurses will assess observed medication administrations using a predefined medication error taxonomy. Any suspected error will be recorded in detail, and if an imminent risk to a patient is identified, the researcher will follow a standard operating procedure to notify the nurse in charge immediately. If an error is identified retrospectively during case note review or data checking, the same escalation procedure will be applied.

17.3 Health Economics Assessment

A health economic feasibility assessment will be conducted to inform the design of a full economic evaluation alongside a future definitive trial of the intervention. This will explore the feasibility of identifying, measuring, and valuing the key costs and outcomes required for a subsequent cost-effective analysis.

Methods for estimating the costs of implementing the intervention will be developed. Key resources required to deliver the intervention will be identified and measured, including staff time required to attend or deliver training, time spent supporting implementation activities, and any materials or consumables used to support the intervention (e.g. educational or environmental prompts). A micro-costing approach will be used to estimate implementation costing framework for the economic evaluation in the definitive trial.

Methods for measuring resource utilisation associated with the medication administration process will also be assessed. Structured observations using the SAM-I Observation Tool (SOT) will be capture the time taken to undertake medication checks under safe-single checking practices, with time stamps used to estimate the time spent on medication checking activities. Similar observation methods were used in WP2 to estimate the time spent on medication administration during double-checking. This will allow assessment of whether a consistent observation tool and data collection approach can be used to measure staff time associated with both single and double-checking practices in the definitive trial.

The study will also examine the availability and sustainability of out come data required to inform an economic model. The feasibility of extracting relevant outcomes from routine data

sources will be assessed, including medication administration errors, errors detected during the checking process, and delays in the administration of time-critical medicines. The completeness, accessibility and reliability of these data will be evaluated to determine whether they can be used to parameterised an economic model and estimate the downstream consequences of different medication checking practices, and where other approached, such as expert clinical opinion may be required to address evidence gaps.

17.4 Non-Inferiority Margin

A key objective of this feasibility study is to refine the non-inferiority margin for MAEs based on earlier work, to be used in the future definitive trial. The margin represents the maximum acceptable increase in MAEs that could occur following the movement from double checking to single checking while still being considered acceptable given the potential benefits of single checking, such as reduced delays to time-critical medicines and increased nursing time available for patient care.

The margin will be informed through structured stakeholder engagement to capture both clinical and patient perspectives.

The first workshop will include approximately 5–6 healthcare professionals with experience of medication administration, including nurses (newly qualified nurses), pharmacists, and doctors. Participants will be presented with evidence on double-checking practices, including potential benefits, limitations, and resource implications. Facilitated discussion will explore what level of potential increase in medication administration errors would be considered acceptable when weighed against the potential benefits of reducing routine double-checking. A second workshop will be conducted with a patient and public group (approximately 5–6 members). This will explore patient and public views on acceptable trade-offs between medication safety and potential improvements in timeliness of care and staff availability.

Findings from these workshops will be synthesised by the research team and reviewed by the study governance and data monitoring committee, which includes site principal investigators, research investigators, and patient representatives. The final non-inferiority margin will be guided by stakeholder perspectives, empirical estimates of MAE rates from observational data, and consideration of the practical implications for a future trial.

18. QUALITATIVE ASSESSMENT OF FEASIBILITY

A qualitative evaluation will be undertaken to explore the feasibility and acceptability of the intervention during the intervention deployment period. The qualitative work will focus on understanding how the intervention is experienced by ward staff, how intervention components operate in practice, and what contextual factors support or constrain implementation. The readiness conditions required for successful adoption of enhanced single-checking will also be identified.

18.1 Setting

All participating wards/services will be included in the qualitative evaluation (between three and five services). The research team will engage with relevant clinical teams on each ward, in particular ward managers, to support recruitment and ensure appropriate representation across roles and shifts. Sampling will be purposive to capture variation in staff experiences and perspectives. We will include nurses working across different shifts (day and night) and aim to recruit a mixture of senior and junior staff with different levels of experience. This will support a rounded understanding of the practical realities of delivering the intervention and how acceptability and feasibility may vary according to role, workload, and seniority.

18.2 Participants and Recruitment

We will invite approximately five frontline nurses per service to participate in the qualitative research. This will include the ward manager and the lead nurse responsible for implementing the move to single-checking on each ward (these roles may be held by the same individual). This approach will generate a total sample of approximately 15–25 participants across the pilot wards/services. Ward managers and local intervention leads will support identification and approach of eligible participants. Participation will be voluntary, and all participants will receive an information sheet and provide informed consent prior to taking part.

The intervention deployment period will be approximately four months. Qualitative fieldwork will be concentrated towards the end of this period to enable participants to draw on experiences from the full pilot implementation, including initial introduction, early adoption, and later routine use. This timing will support reflection on how the intervention performs under different ward conditions over time and allow the research team to capture any longer-term adaptations or sustainability concerns emerging.

18.3 Data collection

18.3.1 Interviews and focus grouplets

Participants will be invited to take part in either individual semi-structured interviews or focus grouplets, depending on participant preference and time constraints. Focus grouplets are a pragmatic adaptation of traditional focus groups that have been developed to answer specific applied health research questions within constrained settings such as busy hospital wards with time-pressured staff. Interviews and focus grouplets will explore participants' perceptions of the intervention and its individual components, focusing on feasibility in routine medication administration and acceptability for frontline staff.

During interviews or focus grouplets, participants will be asked to talk through each stage of the intervention, including circumstances in which it works well and circumstances in which it works less well. Participants may refer to non-identifiable patient examples to illuminate their responses. The researcher will probe for practical details of use, including the extent to

which intervention procedures align with day-to-day ward pressures, interruptions, staffing levels and competing demands.

A specific focus will be the identification of adaptations, informal workarounds and deviations from intended intervention delivery. This will include voluntary double-checking where nurses choose to double-check because they feel they lack the skills, competence, or confidence to administer safely under a single-checking process. The researcher will explore the circumstances in which this occurs, why it occurs, and how staff navigate risk perception and accountability. Where feasible and appropriate, the stepwise walkthrough approach may involve a nurse demonstrating how the intervention is enacted in practice or physically showing the researcher issues with IT systems, documentation, processes, equipment, or logistics that affect feasibility.

In addition to frontline nurse data collection, we will undertake an individual interview with the ward manager and/or the lead nurse responsible for intervention deployment on each ward. These nurse leader interviews will be central to answering the research question related to readiness conditions, as these participants are likely to have a “bird’s eye view” of how implementation varies across teams and shifts. The interviews will explore ward-level implementation planning, communication and staff engagement strategies, the nature of problems encountered during deployment, solutions developed locally, and perceived requirements for sustained adoption.

With participant consent, interviews and focus grouplets will be audio recorded using an encrypted digital audio recording device. Audio files will be transferred as soon as possible after the interview to secure University of Manchester storage and deleted from the recording device. Audio recordings will be transcribed verbatim, and transcripts will be anonymised to remove any identifying information relating to participants, staff or patients. Audio files and anonymised transcripts will be stored securely on University of Manchester secure servers, accessible only to authorised members of the research team. Audio recordings will be deleted once transcription and verification are complete.

18.3.2 Observations

During site visits, focused observations will be conducted to understand checking of medicines in practice. This will involve an experienced researcher shadowing front line staff as they undertake medicines rounds and medicine administration duties. We anticipate this may take up to 3 hours.

The researcher will observe naturally occurring behaviour in the clinical setting and may ask follow-up questions to gain a deeper understanding of actions or decision-making. Follow-up questioning will be carefully timed so as not to interrupt critical moments during medicines administration and will never compromise patient safety.

In addition to medication rounds, observations may also take place during other routine ward activities where checking practices and safety processes are discussed or enacted. These may include:

- **Handover periods**, to understand whether single- or double-checking is discussed, including any risks, concerns, or escalations
- **Safety huddles**, where staff may raise uncertainties, share concerns, or reflect on checking practices with colleagues and senior staff
- **Informal interactions between staff**, such as conversations during breaks, to understand experiences and perceptions of checking practices in everyday working environments
- **Relevant team meetings**, where changes to checking practices may be formally discussed by senior staff

These observations are intended to capture both formal and informal aspects of practice to better understand how checking processes are implemented, discussed, and sustained in real-world settings.

We anticipate conducting approximately 3-5 observation sessions per ward, depending on local activity and feasibility. Consent to take part in the research will be an ongoing process, with researchers checking and discussing with participants and reaffirmed as the study progresses.

Research nurses will undertake structured observations of medicines administration processes (detailed in Section 10). The qualitative researcher will hold several analytic meetings with research nurses to learn from their 'on the ground' perspectives in relation to medicines practices pre and post.

Observational data will be captured through researcher field notes taken during and immediately after observation sessions. Field notes will be typed up as soon as possible after the observation session and stored electronically on secure University of Manchester servers. Field notes will not include identifiable patient information and any staff references will be anonymised. Access to these data will be restricted to authorised members of the research team.

18.4 Outcomes

- **Feasibility of delivering the intervention:** Assessed through qualitative evaluation of implementation processes, barriers, and facilitators.
- **Acceptability of delivering the intervention:** Assessed through qualitative evaluation of staff perceptions and experiences of the intervention.

18.5 Qualitative Analysis

The analysis will mainly focus on four deductive constructs aligned with the feasibility evaluation aims: feasibility, acceptability, modification, and optimisation. Feasibility will capture practical issues affecting intervention delivery and day-to-day use, such as time pressure, staffing, workload, and fit with existing medication administration routines. Acceptability will capture the extent to which nurses judge the intervention to be satisfactory, appropriate, and workable in practice, including perceived impacts on medication safety, confidence, and accountability. Modification will capture the extent and nature of adaptations made during delivery, including informal workarounds and instances of continued voluntary double-checking. Optimisation will focus on identifying actionable refinements to intervention components, implementation supports, and ward-level processes to improve future implementation and sustainability.

Alongside this deductive framework, analysis will be informed conceptually by the theory of organisational readiness. This lens will support interpretation of the conditions linked to intervention uptake and implementation success at the service/ward level. Organisational readiness will be used to explore how readiness is shaped by infrastructure, processes, staffing configuration, leadership, local culture, and competing demands. In particular, this approach will guide examination of how ward teams come to collectively share (or fail to share) beliefs about the change being implemented, including the perceived value, appropriateness, and feasibility of enhanced single-checking. Understanding why readiness may not develop, and which contextual factors are most influential, will provide a practical basis for specifying readiness conditions and implementation requirements for a future evaluation.

19. ETHICAL AND REGULATORY CONSIDERATIONS

19.1 Ethical Approval

The study will require NHS Research Ethics Committee approval, HRA approval, and approval from the Confidentiality Advisory Group. Each participating Trust will provide local capability and capacity approval. Any amendments to the protocol or supporting documents will be submitted for review.

19.2 Confidentiality

All participating staff and services will be anonymised in study outputs. Data will be pseudonymised before analysis. Identifiable information will not be stored with research data and will be destroyed when no longer required.

19.3 Right to Withdraw

Participation is voluntary. Nurses may withdraw from the study at any time without consequence. Patients may opt out of having their data used. Services may also discontinue participation subject to local agreement.

19.4 Observer Conduct

Research nurses will be trained to minimise disruption during medication rounds. If the presence of an observer appears to interfere with clinical duties or create stress for staff, the observer will withdraw from the situation immediately.

19.5 Identification of Harm

During the course of the project, if the researcher sees or hears something which reveals that people are at risk of harm they will be required to act on the information and make a disclosure to the nurse in charge on the relevant ward. WHO guidance defines such a disclosure as information about an imminent error or action that could result in severe and irreversible harm and where intervention from the researcher may prevent or limit this harm. If such a disclosure were made, the researcher would work with ward staff to involve the person(s) at risk of harm as appropriate. Advice would also be sought from the wider project team.

In the unlikely event that a research nurse identifies a medication administration error that is not picked up by either ward nurse during the double-checking process, the research nurse should refer to the Standard Operating Procedure (SOP) which provides guidance for how the research nurse should deal with this issue. This SOP will also provide guidance on what the research nurse should do if a medication administration error is identified when extracting information from the patients records during the case note review or when conducting the error judgement process.

In the event that malpractice is suspected, it will be reported immediately to the Ward Manager and Principal Investigator. This will be escalated in line with the Trust's incident reporting and misconduct policies. This may include notification to the Trust's Research & Development department and involvement of clinical leads.

19.6 Data Management

All study data will be handled in accordance with the UK General Data Protection Regulation (GDPR), the Data Protection Act 2018, and sponsor information governance policies. Data will be processed in line with Research Ethics Committee, HRA, and Confidentiality Advisory Group (CAG) approvals.

19.6.1 Observational data capture

Observational data will be recorded by trained research staff using the SAM-I Observation Tool (SOT). The SOT will be completed either on paper forms or on a password-protected iPad using an approved electronic data capture platform (e.g. REDCap or WOMBAT). Only authorised members of the research team will have access to study iPads.

Where paper SOT forms are used, these will be securely transported and entered into the electronic database by authorised research staff. Data entry accuracy will be checked using routine verification procedures.

19.6.2 Questionnaire data capture

Questionnaire data (including SCAMS-II and care left undone measures) will be collected either using paper questionnaires or electronically using an approved secure online data capture platform system hosted by Qualtrics. Only authorised members of the research team will have access to study devices.

Paper questionnaires will be securely transported to the research office and entered into an electronic study database by authorised research staff. Data entry accuracy will be checked using routine verification procedures.

19.6.3 Qualitative interview and focus group data capture

Qualitative interviews and focus groups will be audio recorded using encrypted digital recorders. Audio files will be transferred securely to an encrypted storage location accessible only to the research team. Recordings will be professionally transcribed under a confidentiality agreement or transcribed by members of the research team.

Transcripts will be anonymised, with names and other identifying details removed or replaced with study IDs prior to analysis. Audio recordings will be deleted once transcription accuracy has been checked.

19.6.4 Storage of devices and paper records

When not in use, study iPads will be stored in a locked cabinet at the Bradford Institute for Health Research (BIHR) on the Bradford Royal Infirmary campus. Any paper data capture and consent forms will initially be stored in a locked cabinet at the participating NHS Trust site and later transferred to a locked cabinet at BIHR for secure archiving. Access to both paper and electronic data will be restricted to members of the research team.

19.6.5 Patient-identifiable information and linkage

Limited patient-identifiable information will be recorded temporarily within a secure Medication ID Log at Trust sites to enable linkage between observed medication administrations and electronic health records for case note review. This log will not be removed from Trust premises. Once case note review and error verification are complete, all identifiable information within the Medication ID Log will be permanently destroyed at the Trust site.

Case note review data will be pseudonymised using a unique study medicine ID. Linkage between observation records and patient medication charts will be performed by authorised research nurses at the participating NHS Trust site. No directly identifiable patient data will be included in research datasets used for analysis.

19.6.6 Electronic data storage

Electronic study data captured will be stored on secure servers managed by the University of Manchester, University of Leeds, BTHFT and York Trials Unit as appropriate for analysis activities.

19.6.7 Data transfer

Pseudonymised study data will be shared between participating NHS Trusts, BTHFT, University of Leeds, University of Manchester and York Trials Unit for the purposes of data management, statistical analysis, and health economic analysis. Each organisation will process data in accordance with agreed Data Sharing Agreements and sponsor-approved data management procedures.

Only the minimum necessary pseudonymised data required for analysis will be transferred between organisations. No directly identifiable patient information will leave NHS Trust premises, except where explicitly permitted under CAG approval for on-site linkage activities.

All data transfers will be conducted using secure, encrypted methods approved by the relevant organisations. Access to shared datasets will be restricted to members of the research team.

Anonymised research data will be retained for 5 years after study completion in accordance with sponsor and university research data management policies.

20. PATIENT & PUBLIC INVOLVEMENT

The SAM-I programme is hosted within the NIHR Yorkshire and Humber Patient Safety Research Collaboration, which has a strong culture of patient and public involvement. Two lay leaders are applicants on the Programme Grant and contributed to the planning and development of this WP3 feasibility study and protocol. Additional members of the public were also consulted during development of the funding application and individual work packages.

For this study, six members of the public provided feedback to inform the application for Confidentiality Advisory Group (CAG) approval. Contributors represented a range of ages and ethnic backgrounds and links to diverse community groups. They were provided with written and verbal explanations of the study aims, use of confidential patient information without consent, opt-out mechanisms and data safeguards. They also reviewed draft CAG posters and leaflets and provided structured feedback, which informed the final study procedures.

21. INDEMNITY

This study is sponsored by Bradford Teaching Hospitals NHS Trust (BTHFT). BTHFT indemnity will cover liabilities arising from the management and design of the study, and NHS indemnity will cover liabilities arising from harm to participants during the conduct of the research.

22. END OF STUDY

The feasibility study will last approximately 10–12 months, including familiarisation, data collection and extraction of routine data. The end of the study will be defined as completion of the final study activity, anticipated to be receipt of the final routine data extract. Access to confidential patient information under CAG approval will cease at the end of the study.

23. DISSEMINATION

Findings will be disseminated in collaboration with the Programme Management Group, with input from the Independent Steering Committee and patient and staff advisory groups, and shared with participating Trusts. Dissemination will be tailored to academic, improvement and policy audiences and is expected to include presentations at professional forums, stakeholder workshops, peer-reviewed publications and presentations at relevant conferences.

As part of the wider NIHR Programme Grant for Applied Health Research – findings from this study will inform refinement of the intervention and the design of subsequent work packages, including the definitive trial.

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