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Safe administration of medicines intervention: a feasibility study

Submission date
15/07/2026

Recruitment status
Not yet recruiting

Registration date
07/08/2026

Overall study status
Ongoing

Last Edited
07/08/2026

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Double-checking a medicine before giving it to the patient is often used to reduce medication errors. However, there is no convincing evidence that it works. Nurses spend a lot of time double-checking (6.4 minutes per check), which is estimated to cost the NHS between £412 million and £1.28 billion per year. If double-checking reduces error and patient harm, then this might be time well spent. But evidence shows that double-checking can harm patients by causing delays to them getting critical medicines.
This study aims to assess 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.

Who can participate?
Staff members over the age of 18 years employed within a participating ward/service during the study period (e.g., permanent, bank or agency workers) and directly involved in preparing and/or administering medications

What does the study involve?
The study involves assessing the feasibility and acceptability of implementing a ward-level de-implementation intervention (the SaSI-MEDs Observation Tool) to reduce routine double-checking of medicines and support safe single-checking and to test the study procedures and outcome measures required for a future definitive randomised controlled trial.
We will undertake 5-7 observation sessions (lasting about 4-6 hours each) shadowing 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. Observations will take place before and after implementation. All staff involved in medication preparations and/or administrations will also be invited to complete a questionnaire to explore views on single checking and nursing care activities.

What are the possible benefits and risks of participating?
Although there are no immediate benefits for the nurses participating in the study, it is hoped

that the findings of this work will lead to improvements in safely administering medicines in hospitals. If we find that double-checking is no safer than single-checking, it could lead to changes in policy that could reduce double-checking in certain circumstances. This could reduce nursing workload and free up time for staff to carry out more patient-centred tasks and potentially improve the quality of care.
We do not expect any disadvantages or risks to being involved. It is important that you understand that we are interested in assessing what is feasible and acceptable to change for safer medication administration. We are not examining your individual knowledge or skills. There is a possibility that you will experience discomfort when being observed. To minimise this, we will try to ensure you are familiar with the research nurse and have had the opportunity to ask questions.

Where is the study run from?
The study is run from Bradford Teaching Hospitals NHS Foundation Trust and York Trials Unit (University of York) (UK)

When is the study starting and how long is it expected to run for?
September 2026 to April 2028

Who is funding the study?
The National Institute for Health Research (NIHR) Programme Grants for Applied Research (UK)

Who is the main contact?
1. Chief Investigator: Professor Beth Fylan, b.fylan@bradford.ac.uk
2. Programme Manager: Dr Lynn McVey, lynn.mcvey@bthft.nhs.uk
3. Senior Research Fellow: Dr Katherine Jones, katherine.jones@bthft.nhs.uk

Contact information

Type(s)
Principal investigator, Scientific

Contact name
Prof Beth Fylan

ORCID ID
https://orcid.org/0000-0003-0599-4537

Contact details
University of Bradford, Richmond Building, Richmond Road
Bradford
United Kingdom
BD7 1DP
+44 (0)1274236952
B.Fylan@bradford.ac.uk

Type(s)
Public

Contact name
Dr Lynn McVey

ORCID ID
https://orcid.org/0000-0003-2009-7682

Contact details
Bradford Teaching Hospitals NHS Foundation Trust, Bradford Royal Infirmary, Duckworth Lane
Bradford
United Kingdom
BD9 6RJ
-
lynn.mcvey@bthft.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
367872

Central Portfolio Management System (CPMS)
74129

National Institute for Health and Care Research (NIHR)
206796

Study information

Scientific Title
Safe Administration of Medicines Intervention (SAM-I): a feasibility study of an intervention to de-implement unnecessary double-checking of medicines in hospital

Acronym
SAM-I

Study objectives
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)?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/06/2026, London - Queen Square Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; queensquare.rec@hra.nhs.uk), ref: 26/LO/0402

Primary study design
Interventional

Study design
Non-randomized study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Public health

Interventions
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.

Intervention Type
Behavioural

Primary outcome(s)
1. Observed medication administration errors measured using the SAM-I Case Note Review Form at pre- (month [M] 0) and post-implementation (M8-10), recording observed errors where a double-check would previously have been mandated by policy. This will be recorded as 'yes' or 'no' per observed medication administration.

Key secondary outcome(s)
1. Nurse attitudes to single-checking measured using the validated Single Checking and Administration of Medications Scale (SCAMS-II) at pre- (M0) and post-implementation (M8-10)
2. Omission of care measured using the care left undone scale at pre- (M0) and post-implementation (M8-10)
3. Double-checking practices measured using the SAM-I Observational Tool at pre- (M0) and post-implementation (M8-10)
4. Service readiness for single checking measured using a checklist and single binary measure at pre-implementation (M0)
5. Length of patient stays measured using routine data collection from electronic Prescribing and Medication Administration systems (ePMA) at post-implementation (M8-10)
6. Reported patient safety incidents (medication-related) measured using routine data collection from Local Risk Management Systems (LRMS) at post-implementation (M8-10)
7. Time spent implementing checks measured using the SAM-I Observational Tool at pre- (M0) and post-implementation (M8-10)
8. Delays in time-critical administrations measured using routine data collection from electronic Prescribing and Medication Administration systems (ePMA) at post-implementation

Completion date
01/04/2028

Eligibility

Key inclusion criteria

Ward inclusion criteria:
1. NHS-funded inpatient wards within a participating NHS Trust
2. Wards where medicines administration is frequent and routinely undertaken by nursing staff
3. Wards where double-checking of medicines is embedded within local policy and/or established practice
4. Wards able to support implementation of the intervention, including staff training, policy updates and ward-level engagement activities
5. Wards able to support feasibility data collection, including structured observation of medication administration and access to relevant routine data sources (e.g., ePMA and incident reporting systems)

Staff participant inclusion criteria:
Staff will be eligible to participate in observation and qualitative evaluation components if they meet the following criteria:
1. Employed (permanent, bank or agency) within a participating ward/service during the study period
2. Directly involved in medicines preparation, administration or supporting the double-checking process (e.g., registered nurses, nurse associates)
3. Aged 18 years or over, consistent with their professional role
4. Willing and able to provide informed consent to participate in observations and other evaluation activities (e.g., questionnaires or interviews where applicable)

We will aim to recruit staff representing a range of professional seniority and experience (from newly qualified to senior nurses), diverse ethnic backgrounds, and both substantive ward staff and those working bank or agency shifts to reflect the typical ward workforce.

Patients:
With CAG approval in place, case note review will be conducted for patients whose medication administration episodes are observed. This will allow comparison between observed practice and prescribed medicines without requiring individual patient consent in order to calculate primary and secondary outcomes.

Where paediatric or neonatal wards are included, this may involve review of records for patients under the age of 18 years. Only the minimum necessary patient-identifiable information will be temporarily accessed for linkage purposes, in accordance with CAG approval and data governance procedures.

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

0

Key exclusion criteria

Patients:
Patients will not be directly recruited; however, case note review will not be undertaken where:
1. The medication administration episode was not observed as part of the study
2. The patient (or parent/guardian, where applicable) has exercised their right to opt out of the use of their data for research purposes

Only the minimum necessary information will be accessed under CAG approval, in line with approved governance procedures.

Date of first enrolment
01/09/2026

Date of final enrolment
01/04/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
RRDN Yorkshire and Humber
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	25/06/2026	06/08/2026	No	Yes
Protocol file	version 1.2	01/06/2026	06/08/2026	No	No