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Safe Administration of Medicines – Intervention

(SAM-I)

A study aiming to assess the feasibility, acceptability and readiness of transitioning towards safe-single checking of medicines.

You have been invited to take part in a research study

Before you decide whether or not to participate it is important for you to understand why the research is being carried out and what it will involve.

Please take time to read the information, discuss it with others and ask questions you may have.

Summary of this study

- Evidence shows that double checking medication may not work as planned
- We are running this study to assess under what conditions services can reduce routine double-checking and transition towards safer single-checking
- Anyone involved in medicines preparation and/or administration can take part
- Option to take part in observations, study questionnaires and/or an interview

This study is being run by Bradford Teaching Hospitals NHS Foundation Trust.

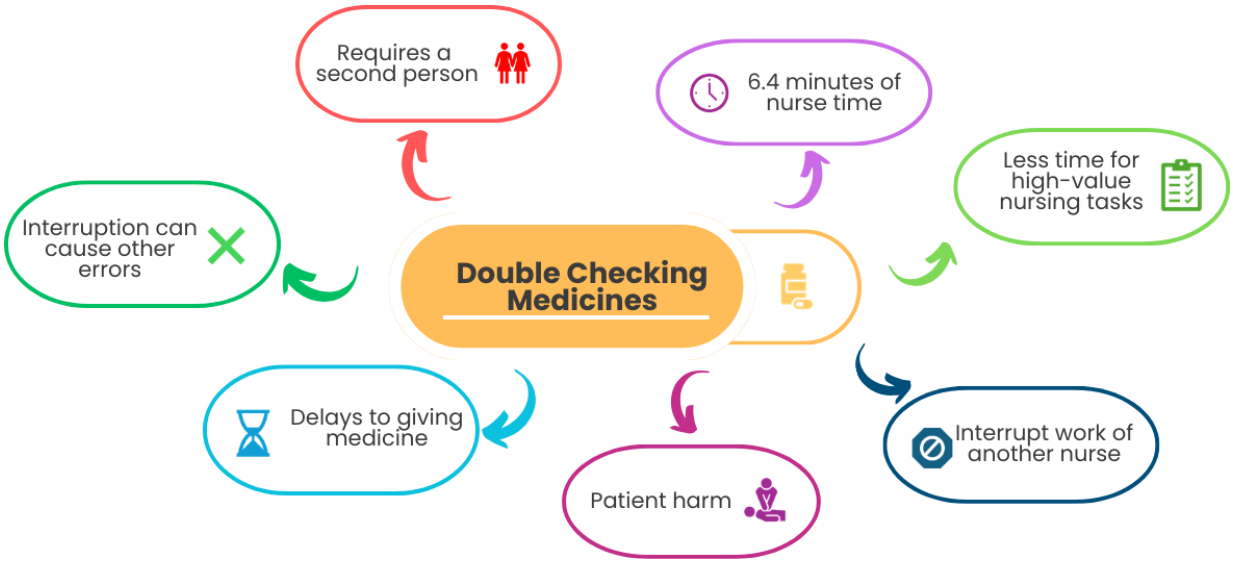
Funded by NIHR | National Institute for Health and Care Research

This study is funded by the National Institute for Health and Care Research (NIHR) PGfAR NIHR206796. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Contents

1. What is the purpose of this study?

'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.



Why have I been asked to take part?

Your ward is participating in this research project; you specifically have been asked to take part because you are directly involved in medicines preparation and/or administration.

Do I have to take part?

Participation is completely voluntary. If you decide to take part, consent will be obtained. You may stop or withdraw from this research without giving a reason and there will be no negative consequences if you decline to take part.

2. What would taking part involve?

To assess what is feasible and acceptable to change for safer medication administration we will undertake:

A. *Observations*

Our research nurses will visit the ward you are working on to observe you preparing and administering medications to patients. To protect your anonymity, you will be given a sticker containing your participant number, this is to be attached on the inside of your staff ID badge. Information such as how much time it takes, double-checking and any errors identified will be recorded. You won't be observed every time our nurses visit your ward, this will depend on how many medicines you are administering during the time of each research visit. If you agree to take part, you will be asked by the research team to provide verbal consent due to the nature in which data is being collected. A copy of the consent form will be provided to you to keep.

B. *Study Questionnaires*

You will be invited by email to complete an online questionnaire at the start of the study and again 3-4 months later. This link will contain a questionnaire asking you questions around administering medicines and care tasks and should take no longer than 5-10 minutes to complete. The questionnaire link can also be found on a trial poster, via QR code, on your ward. If you agree to take part, you will be asked to provide electronic consent. A copy of the questionnaire can also be completed via paper and consent provided on paper.

C. *Implementation*

Following collecting observational and questionnaire data, we will implement an approach to reduce double-checking and support safe, single checking for medication administration.

D. *Interviews*

Following the intervention, we would also like to explore your experience of the SAM-I approach and understand how it operates in practice. To ensure that we get views across wards, roles, experience and shifts the SAM-I team will liaise with ward managers to support in identifying potentially eligible participants. If you agree to take part in an interview your consent form and contact details will be sent to the University of Manchester. If you agree to take part, you will be asked to provide consent and given the option for the interview to be recorded. If you prefer not to be recorded you can still take part in an interview, and the researcher will take notes instead. Please confirm your preference with the study team. You will be given a copy of this consent form, and a copy will also be stored at the University of Manchester.

Do I have to take part in all elements?

As the implementation approach (**C**) is delivered at ward level, staff cannot opt out of exposure. However, participation in the observations (**A**), study questionnaires (**B**) and/or interviews (**D**) is completely voluntary. You also do not have to participate in all of these elements, you decide if you wish to take part and what elements you take part in.

How long do I need to be involved for?

The research project will take place over the course of 12 months.

What happens if I no longer wish to take part?

If you agree to take part, but later change your mind, you can withdraw at anytime without giving reason. Should you wish to withdraw your consent, please contact the principal investigator or research nurse on the contact details found at the end of this information sheet (Section 7). If you leave the study, we would like to use the data we have already collected, as this is important to the study. However, to safeguard your rights, we will use the minimum personally identifiable information possible. If you do not want this to happen, please let us know by getting in touch with the principal investigator or research nurse, contact details for whom can be found below.

3. What happens if I make an error while being observed?

If you notice and fix a medication error during the double check, no further action is needed. If the research nurse spots a possible error, they will discreetly inform you and step back to let you respond. Errors may also be found later when reviewing patient records; if they could cause harm, they will be reported and followed up. Any serious safety concerns, whether related to medication or not, must be shared with the ward nurse in charge.

4. What are the possible benefits of taking part?

Although there are no immediate benefits for nurses participating in the project, 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 which 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.

5. What are the possible disadvantages and risks of taking part?

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.

6. More information about taking part

Will I receive payment for my time?

There are no payments involved for taking part in this study and participation in this study should not cost you anything. On completion of the observation(s) you will be sent a certificate of participation / CPD evidence.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name, email address, gender, ethnicity and job information. People will use this information to do the research or to check your records to make sure that research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. Bradford Teaching Hospitals NHS Foundation Trust is the sponsor of this research.

Bradford Teaching Hospitals NHS Foundation Trust is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Bradford Teaching Hospitals NHS Foundation Trust
- York Trials Unit
- (Optional) If you agree to take part in an interview these details will also be held by the University of Manchester.

We will keep all information about you safe and secure by:

- Keeping it in a safe and secure location (e.g. locked or password protected), accessed by authorised personnel and processed in compliance with applicable data protection legislation and organisational security procedures

Your data will not be shared outside the UK

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for a maximum of **5** years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- our leaflet http://www.hra.nhs.uk/patientdataandresearch and https://www.bradfordhospitals.nhs.uk/our-trust/our-policies-and-procedures/
- by asking one of the research team, contact details below
- by sending an email to dataprotectionofficer@bthft.nhs.uk
- by ringing us on 01274 542200

What will happen with the results of the study?

At the end of the study, we will publish findings in peer-reviewed scientific journals and conferences. You will not be identified in any reports or publications. The data collected in this study may be used in additional or subsequent research.

Who is organising and funding the research?

This study is funded by the National Institute for Health Research Programme Grants for Applied Research (Project Number: NIHR206796) and sponsored by Bradford Teaching Hospital Foundation Trust (BTHFT) who is responsible for the conduct of this study. York Trials Unit at the University of York are supporting the delivery of this research project.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. The aim of a Research Ethics Committee is to protect your interests. XXXX (Reference: XXX) and the Confidentiality Advisory Group (Reference: XXX) have reviewed and approved this study.

What if something goes wrong?

If you have any concerns about any aspect of this trial, you should ask to speak to one of the researchers or research nurse, contact details for whom can be found at the end of this information sheet. The team will do their best to answer your questions, however if you remain unhappy, please speak to your line manager/supervisor. A range of free support is available for NHS staff, access of which can be found at: https://www.england.nhs.uk/supporting-our-nhs-people/support-now/

If you wish to make a complaint you can contact the advice and complaints service on the following:

Phone: [INSERT TRUST COMPLAINTS DETAILS].

Email: [INSERT TRUST COMPLAINTS DETAILS].

In person/post: [INSERT TRUST COMPLAINTS DETAILS].

What do I do now?

If you wish to take part in an ***observation***, contact the research team, details of which can be found below. Alternatively, speak to our dedicated research nurses who you may see on your ward during handovers/information sessions.

If you wish to take part in a ***study questionnaire***. A questionnaire link will be circulated to you via email at two different time points in the research study, we would appreciate if you could complete this both times. If you have not received this link, please speak to your ward manager. Alternatively, scan the QR code on our posters around your ward. You can

also complete a paper questionnaire, simply speak to our research team on site or your local principal investigator, details below.

Our ***interviews*** will be completed following the implementation of the intervention, if you are interested, please contact the PI, details for whom can be found below. Please note we will not be able to include everyone who agrees to take part in the interview, so you may not hear anything regarding this participation.

7. How to contact us

If you have any questions, please contact us:

Principal Investigator: [INSERT SITE PI CONTACT DETAILS- EMAIL AND PHONE]

Research Nurse(s): [INSERT RESEARCH NURSE CONTACT DETAILS- EMAIL AND PHONE]

Researchers:

If you would like specific information about this study, you may contact Katherine Jones (Senior Research Fellow) at Katherine.Jones@bthft.nhs.uk. Alternatively, you can contact Lynn McVey (Programme Manager) at Lynn.McVey@bthft.nhs.uk. The chief investigators and overall leads for this study are Professor Rebecca Lawton (R.J.Lawton@leeds.ac.uk) and Professor Beth Fylan (B.Fylan@bradford.ac.uk).

Thank you for reading this information sheet and for considering taking part in this study