Participant Information Sheet - Healthcare professionals

Finding measures of insulin safety within digitally integrated care systems

We invite you to take part in a research study.

- Joining the study is entirely up to you.
- Before you decide, you need to understand why the research is being done and what taking part would involve.
- One of our team will go through this information sheet with you and answer any questions you may have.
- Ask questions if anything you read is not clear or you would like more information.
- Please feel free to talk to others about the study if you wish.
- Take time to decide whether or not to take part.

What is the purpose of the study?

Keeping patients safe from harm is a central goal of health services. Harm can often happen when mistakes are made with medicines, for example if the wrong doses are given, or doses missed out unintentionally. This happens more when patient care is shared between more than one service, for example a GP and hospital specialists, when there can be problems with communication. We need to find ways of monitoring people's safety as they move between services and can do this by monitoring information gathered by the electronic record. Insulin is a medicine that is especially important to get right when people are admitted and discharged from hospital.

Upcoming changes in health and care aim to make sure services are working more closely together in what are called Integrated Care Systems (ICSs). ICSs will aim to bring GP practices, hospital services, community pharmacies and social care among others, together into one co-ordinated system. ICSs will be supported by the introduction of shared electronic records, and wider availability of real-time information for patients and those health and care professionals who need access to it. These changes will provide opportunities to reduce the risks of mistakes.

The London School of Hygiene and Tropical Medicine (LSHTM) is conducting research to explore how the development of ICSs and improvements in shared electronic records can be used to indicate how safe the use of insulin is. This will allow future projects to improve the safety of insulin use to be directed to the areas that will make the most difference, and then the impact measured.

We want to understand how insulin is being used and managed when people move between hospital and go home. We would like to find out what works, where problems can occur, and where improvements can be made. To do this we want to interview people who use insulin and the health and care professionals that support them to understand their experiences. We would also like to spend time in healthcare settings watching how insulin is used in everyday situations, with all the interruptions, challenges and issues that can occur. This information will be used to make a map of all the activities that need to be done to make sure insulin is used safely when people go into hospital and when they return home.

Using this map, we will test how feasible it is to create measures that can be used to monitor key activities with staff currently responsible for creating electronic integrated care records and gather the opinions of patients, carers, and health professionals on how useful they would find these measures for improving the safety of care. Possible measures that can provide an indication of safety for insulin use will be considered and recommended.

Why have I been asked to take part?

You have been invited to take part in this study because you provide healthcare for someone who uses insulin and who has recently been admitted and discharged from hospital.

Do I have to take part?

No. It is up to you to decide to take part or not. If you don't want to take part, that's fine.

A researcher will discuss the study together with you and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form.

What would taking part involve?

If you take part, there are several ways you can be involved. You will be asked whether a researcher could spend time watching you work. The researcher will aim to be as unobtrusive as possible but may ask questions, at an appropriate time, to make sure they understand what you are doing. The aim of the research is to find out how insulin is managed in a real-life setting, where this can be impacted by other activities that need to be prioritised, interruptions and the many issues that arise. The researcher will not be looking at whether policies are followed.

You would be asked to check with patients whether they are happy for the researcher to observe relevant activities that involve insulin and invite the researcher to observe these if they consent. You would also be asked to invite the researcher to observe any other activities you do to manage insulin when patients are admitted and/or discharged from hospital.

If you take part, you will be invited by the researcher to participate in an interview. If you choose to be interviewed, a researcher will contact you to arrange an online interview. During the interview, the researcher will talk to you about your experiences with managing insulin when people who use insulin are admitted and discharged from hospital. We would like to hear about what you think goes well and whether there were any problems or things that could be done better.

The interviews are expected to last between 60 to 90 minutes, depending on how much you would like to share. They will take place over Microsoft Teams. With your permission, the interview will be recorded so that the researcher can make sure the conversation is copied down accurately, and then the recording will be deleted.

The interviews will be a safe space and anything you share with us will be kept strictly confidential and will not be shared.

Later in the research project, there will be a focus group with up to 8 people who are involved with insulin across the different healthcare settings, and with people who use insulin. You may be invited to participate in this focus group. The aim of the focus group will be to make a map of all the activities that need to be done to make sure insulin is used safely across the whole journey when people are admitted and discharged from hospital. The focus group would be expected to last between one to two hours and will take place either in person or on Microsoft Teams. If you are interested in being part of this group, or contributing to this map, let the researcher know.

Once the research has been completed, there will be seminar to share the findings. You may be invited to participate in this event. This would involve a half day online event held on Zoom, where the researcher will share the findings of the study. You will be invited to share your opinions and feedback on whether you agree with the findings. If you are interested in being part of this seminar, let the researcher know.

What are the possible benefits of taking part?

We cannot promise the study will help you, but the information we get from the study will build our knowledge and understanding of how to use insulin safely when people are admitted and discharged from hospital.

What if something goes wrong?

There is unlikely to be any harm to you from participating in this study, however if you have a concern about any aspect of it, you should ask to speak to the researchers who will do their best to answer your questions.

The best way to contact the researcher is by emailing Catherine.Leon@lshtm.ac.uk. If you remain unhappy and wish to complain formally, you can do this by contacting Patricia Henley at rgio@lshtm.ac.uk or +44 (0) 20 7927 2626.

You can also contact the UCLH Patient Advice and Liaison Service on 02034473042 or email Uclh.pals@nhs.net.

Can I change my mind about taking part?

Yes. You can withdraw from the study at any time.

If you withdraw from the study, we will destroy all your recorded interviews. The anonymous interview transcripts will still be used. You will not be contacted again to participate in the focus groups or seminar.

What will happen to information collected about me?

All information collected about you will be kept private. Direct quotes taken from interviews, focus groups and seminar participants will be used in publications as part of the research. Quotations will be anonymised, and you will not be able to be identified from these. Only the study staff and authorities who check that the study is being carried out properly will be allowed to look at information about you. Information will include your name, contact details and a code used to make sure your response remains anonymous for the research project. We will keep all information about you safe and secure. Details of relevant healthcare professionals you share with us will be kept separately.

Data may be sent to other study staff in London, but this will be anonymised. This means that any information about you which leaves the university, will have your name and address removed so that you cannot be recognised, and your data will have a code number instead.

Your personal details, meaning your name and other identifiable information will be kept in a different safe place to the other study information and will be destroyed within 3 – 6 months of the end of the study. Your electronic signed consent form will be stored on the secure network at the London School of Hygiene and Tropical Medicine for 10 years and will not be shared with anyone other than authorities who check the study has been carried out properly.

At the end of the project, the study data will be archived at the London School of Hygiene and Tropical Medicine. The data will be made available to other researchers worldwide for research and to improve medical knowledge and patient care. Your personal information will not be included and there is no way that you can be identified.

What are my choices about how my 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.

We need to manage your records in specific ways for the research to be reliable. This means we won't be able to let you see or change the data we hold about you.

Where can I find out more about how my information is used?

You can find out more about how we use your information

- At https://www.lshtm.ac.uk/files/research-participant-privacy-notice.pdf
- By asking one of the research team
- By sending an email to DPO@lshtm.ac.uk
- At https://www.hra.nhs.uk/information-about-patients/

What will happen to the results of this study?

The study results will be published in a medical journal so that other doctors can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it.

Who is organising and funding this study?

The London School of Hygiene & Tropical Medicine is the sponsor for the research, and they have full responsibility for the project including the collection, storage and analysis of your data, and will act as the Data Controller for the study. This means that we are responsible for looking after your information and using it properly.

The study is funded by the National Institute of Health Research (NIHR) Applied Research Collaboration, North Thames.

Who has reviewed this study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The London School of Hygiene and Tropical Medicine Research Ethics Committee (Ref: 28148). The NHS Research Ethics Committee has also reviewed the study and have agreed that it is okay for us to ask people to take part.

Further information and contact details?

Thank you for taking time to read this information sheet. If you think you will take part in the study, please read and sign the consent form. The consent form can be found by scanning the QR code over the page or by clicking this link:

If you would like any further information, please contact Catherine Leon (Catherine.Leon@lshtm.ac.uk) who can answer any questions you may have about the study.

A copy of this informed consent document to be offered to the participant

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Principal Investigator: Catherine Leon
Participant Information Sheet

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