IMAB-Qi study - Participant Information Sheet

[content will remain but format will be updated for readability]

Invitation to take part in a research study

We are inviting you to take part in a study at our practice. A team of researchers at the University of East Anglia want to find a better way to help people take the medicines that are prescribed for them. This leaflet explains what they, and we, are doing. Please take time to read it thoroughly. You can talk to us about the study here:

- **Contact Name:** <insert name of PI/researcher at site>
- **Address:** <GP practice address>
- **Phone/Email:** <Tel: XXXXX XXXXXX> / <Email: XXXXX>

If you require any adjustments to take part in this study, please contact the University of East Anglia research team on 01603 59 1120 or email imabqi.study@uea.ac.uk. We will accommodate where possible.

What is the study about?

The study looks at a new type of medication review. A medication review is a meeting with a health professional to check your medicines are doing what they are supposed to do, not causing you problems and to answer any questions that you have about your medicines. Researchers have designed a new way for these meetings called IMAB-Qi. This new way is supposed to help our staff find out why patients might not be taking their medicines and work with them to find ways to provide support.

How does the study work?

To see if the IMAB-Qi review works well, it needs to be compared to the medication review that is usually given. Some GP practices in this study will use the new IMAB-Qi review and other GP practices will continue giving their usual medication review. The University of East Anglia is in charge of the study, and they will decide which group our practice is in.

Why am I invited?

We have invited you because our records show your blood pressure may be above the recommended range. You are also due for your regular medication review soon.

Do I have to take part?

No, it is your choice. If you choose not to take part, it will not affect your care in any way. You can use the information in this leaflet to make your decision. If you have any

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IRAS ID: 355538 REC Reference 25/SC/0404

questions, please contact us using the details on the front page of this information leaflet.

What happens if I take part?

1. **Before your medication review:** You will be asked to sign a consent form and then you will be asked to fill out a questionnaire about you, your health and wellbeing and your use of healthcare services (this takes about 20 minutes). These can be completed online via an email link, at the practice or we can send you a paper copy., You will have the opportunity to ask questions by contacting us. You will also provide a blood pressure reading at home or at the practice.

   It is possible that after completing the initial blood pressure reading you may not be eligible to continue in the study. However, this will not impact the care you receive nor affect the medication review you receive.

2. **During your review:** You will have your appointment at the practice, by phone, or by video. We might record this meeting so the research team can see how the new approach works, but only if you agree.

3. **After your review:** You will be asked to fill in a 5-minute survey (online via a link or on paper) about the medication review process and your medication review experience. You may be invited by your healthcare professional to attend a follow-up to your medication review. After 4 weeks you will complete a blood pressure reading and after 12 weeks, you will complete another blood pressure reading and a final survey (this takes about 20 minutes).

Your part in the study finishes 12 weeks after you have your medication review

Information from your medical records

If you agree, the research team will look at your GP medical record from 12 weeks before your review until the study ends. This helps them see whether the review helped your health and what healthcare services you have used.

Optional – conversation with a researcher

If you agree, a researcher may contact you after your medication review— by email with a link to complete the questions online, by phone, or by post. They'll arrange a time to talk to you about your experiences of taking your medicines, the medication review and what it was like taking part in the study.

This will usually happen two to four weeks after your review by video call or phone, at a time that suits you. The conversation will take about 30 minutes and will be audio or video recorded, then typed up with any identifying details removed. After that, the recording will be deleted. With your permission, the research team may include quotes

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from your conversation when they share the study results, but your name will never be used.

Blood pressure readings

If you haven't had a blood pressure reading recorded in your GP records in the past 4 weeks, you will be asked to provide one in one of two ways: either by visiting the practice to have it taken, or by using a home blood pressure monitor they will send to you (like the one shown on the right).[alt-text is in place]

Whether you visit the practice or take readings at home, you'll share your result by calling us or the research team or using a link the research team send by text or email to enter it online. You will be given clear instructions on how to use the monitor, report your readings, and return the monitor—at no cost to you—once your participation in the study ends.

What are the possible benefits and risks of taking part?

There may not be any direct benefits to you. However, you will be helping the research team learn if they can run a bigger study in the future to improve care for people with high blood pressure. They do not think there are any risks or disadvantages to taking part.

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 the research team will keep the information about you that they already have. If you are happy to tell them why, they would like to know. To stop taking part contact them on [01603 59 1120] or email imabqi.study@uea.ac.uk.

If you choose to stop taking part, the research team would like to continue collecting information about your health and healthcare from your GP medical records as planned. If you do not want this to happen, tell them and we will stop.

You have the right to ask the research team to access, remove, change or delete data they hold about you for the purposes of the study. You can also object to them processing your data. They might not always be able to do this if it means they cannot use your data to do the research. If so, they will tell you why they 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.

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How will we use information about you?

We will need to use information from you, from your medical records and your GP for this research project.

This information will include your:

- name, Date of Birth and contact details,
- information about you (demographics) your health, well-being and care services you receive (e.g., prescriptions, GP appointments and any visits to A&E)

People will use this information to do the research or to check your records to make sure that the 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.

The University of East Anglia is the Sponsor of this research. The University of East Anglia is responsible for looking after your information. They will share your information related to this research project with the following types of organisations:

- authorised study collaborators
- regulatory authorities, i.e. Health Research Authority (HRA)

The researchers will keep all information about you safe and secure by:

- Secure storage: Your study data will be entered into a secure database at the University of East Anglia.
- Limited access: Only specific members of the research team can view your data.
- Separate details: Your name and contact details will be stored separately from your study data.
- Unique code: Your study data will be identified by a unique code, not your name. This will allow us to link information held in your GP medical records, date of birth and postcode, for the duration of the study
- The research team at the University of East Anglia will keep your study data for a maximum of ten years. The study data will then be fully anonymised and securely archived or destroyed. Consent forms: A digital copy of your consent form will be stored securely at UEA, and a paper copy will be kept securely at your GP practice.
- Your data will not be shared outside the UK.

If you agree to have your medication review recorded, it will be kept strictly confidential. Recordings will be securely transferred to UEA, stored in a restricted-access SharePoint folder, and accessed only by researchers who collect and analyse data. They will be typed up by authorised team members and then securely destroyed when no longer needed.

Quotes from your review may be used in reports or publications, but no one will be able to identify you.

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

Once we have finished the study, we will keep some of your information so we can check the results and for future research. 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 ten years. The study data will then be fully anonymised and securely archived or destroyed. After the study we will deposit anonymised data in a public repository so other researchers can use it for research and learning purposes.

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

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

- At www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team.
- by sending an email to the Sponsor's Data Protection Officer at the University of East Anglia: dataprotection@uea.ac.uk.

Who is running the study?

The University of East Anglia is the Sponsor of the study and has overall responsibility. It is funded by the National Institute for Health and Care Research [NIHR206808]. Independent experts (a Research Ethics Committee) have checked the study to make sure it is safe and ethical [ref 25/SC/0404].

What will happen to the results of this study?

The research team will share the results of this study in scientific journals, online, and at academic conferences, as well as with relevant public and professional groups. Updates will also be posted on the study website and social media (: IMABQI.org : IMAB-Qi Study : IMAB-Qi Study : IMAB-Qi Study)]. If you'd like, the research team can send you a link to a summary of the results or post a paper copy to you by selecting this option in the consent form.

Your personal information will never be identifiable. We may include quotes from your conversation in reports or publications, but these will be written so no one can tell you took part in the study.

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What if there is a problem?

If you have any worries about your health, please speak to us at the practice. If you have a concern or complaint about the study, please contact:

Dean of Health Sciences at the University of East Anglia:

Professor Christopher Burton, School of Health Science

University of East Anglia, Norwich

NR4 7TJ, Christopher.R.Burton@uea.ac.uk

This will not affect your care or treatment in any way

You can also talk to the team running the study: IMAB-Qi study team (University of East Anglia, Norwich, UK, by telephone or text at [01603 59 1120] or email imabqi.study@uea.ac.uk.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against either the University of East Anglia (who designs and manages the research) or the GP practice (who conducts the research), but you may have to pay your legal costs. The University of East Anglia holds liability insurance at the employee, public and clinical trials level.

Thank you for considering taking part in this study.

If you would like to take part please complete the attached consent form <or link to QR code if available>.

Visit our website for more information: imabqi.org

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