PARTICIPANT INFORMATION SHEET

EDITH: Early Detection using Information Technology in Health

This information sheet explains what the EDITH study is, why the research is being done and what it will mean for women attending breast screening.

What is the purpose of the study?

Artificial Intelligence (AI) is being used more commonly in the NHS. The EDITH study is looking to see how well AI could support the breast screening programme in the UK. It will test how AI can help NHS trained experts to look for cancer in mammograms.

AI is a computer programme that can undertake tasks that usually require human intelligence. The AI used in this trial has been trained by using lots of breast x-rays (mammograms) to be able to find cancer. The AI has been tested and found to be accurate at finding cancer in a mammogram. AI is being used to assist a human expert to detect cancer.

As part of the study, women will be randomly allocated to one of three groups:

- Women in group one will receive standard breast screening, where two NHS experts look at the breast images for signs of cancer.
- Women in groups two and three will receive AI-assisted breast screening, where the AI helps the NHS expert(s) by also looking for signs of cancer. In the two groups we will try out two different ways of using AI in breast screening.

- The first way of using AI is after the NHS expert has looked for cancer and the AI will look for cancers that they might have missed.
- The second way AI is used is before NHS experts look at the mammogram to say whether there is a high or low likelihood of cancer. This information is then used by the NHS expert. If the likelihood is low, one NHS expert will check the images. If the likelihood is high, two experts will check the images before a decision is made whether to recall women for further tests.

All images will be looked at by at least one human expert.

What is being tested?

We want to test whether NHS experts working with AI are better than without. We will look at the results from the three groups to see how well human experts combined with AI assistance works compared to the human readers alone, and the costs and benefits of this.

Things we will look at:

- The number, size and type of cancers found.
- The number of women asked to come back for more tests.
- How well each AI system works for different groups of women.
- Cancers found by women between screening rounds (interval cancers).
- NHS workload.
- How women feel about the use of AI in screening.
- How the screening workforce feel about the use of the AI.

Why have I received the link to the information in my invitation letter?

You have received the link to the information about the EDITH study because you have been invited to attend one of the breast screening centres taking part in the study.

Who will take part?

We plan to have 660,000 women take part in the study from approximately 30 breast screening centres in England, Scotland, Wales and Northern Ireland. Women

will be informed about the study when they get their screening (mammogram) invitation letter.

Do I have to take part?

All women who attend participating screening centres may be included in the study. If you prefer that your images are not looked at with the help of AI, you can let the screening centre know. You can do that by either:

- Phone/email the breast screening centre using the information on your invitation letter
- Tell them when you make your appointment to attend screening
- Tell the screening staff at your screening appointment

If you decide to opt out of the study before or during your screening appointment, your images will be looked at by two NHS experts without the help of AI and your data will not be used in the trial results. If you opt out after your screening appointment, AI may have already been used to help look at your images. If AI has already been used, this cannot be undone but your data will not be included in the trial results.

We are very keen to learn why some people object to the use of AI. If you opt out and are happy to discuss this, please let the screening centre staff know or contact the research team directly by emailing: edith@warwick.ac.uk.

What will happen if I have registered with the National Data Opt-out?

If you have opted out of data from your health records being shared for healthcare research and planning, via the National Data Opt-Out, you will still be randomly allocated to one of the three groups and your images may be looked at with the help of AI but your data will not be collected for the purposes of the study results. If you prefer that your images are not looked at with the help of AI, you can let the screening centre know.

What will happen to me if I take part?

Your mammograms will be taken in the standard way. Your mammograms will then be either read by two NHS experts without AI or by at least one NHS expert using AI. This is decided randomly and you will not know which. You will hear about your screening results in the usual way.

For a short period of time when your screening centre initially begins taking part in the study, your mammograms may be looked at in the standard way by two NHS experts but in addition the AI may look at your images. During this period, the AI result may be considered by the experts, alongside their clinical opinion, when making their decision whether to ask you to come back for further tests. The purposes of this phase are to check everything is working as we would expect when the AI is first set-up at the centre and enable experts to become familiar with looking at AI results.

What are the possible disadvantages and risks of taking part?

AI may highlight more areas as high likelihood of cancer than human experts. Some of these may not be cancer. This may mean more women are recalled for additional testing than if AI is not used. Some women may feel anxious and/or worried if they are asked to attend additional follow-up tests.

The mammography and any further testing are part of your routine care and helps the experts examine the breast more thoroughly. In most cases there is no abnormality to be found. If you are feeling anxious about additional testing, your recall letter will provide details on where you can seek further support.

These procedures use ionising radiation to form images of the breast and provide NHS trained experts with clinical information. Ionising radiation may cause cancer many years or decades after the exposure. The majority of participants in this study will not undergo any additional procedures. For those participants the chance of this happening is the same whether they take part in the study or not. Participants who may not have been recalled for additional testing, but are recalled due to participation in the study, will undergo additional exposure to ionising radiation. The risk arising from these additional exposures is extremely small.

What are the possible benefits of taking part?

There is a possible benefit in taking part in the EDITH study as some studies have shown increased cancer findings when AI is used. The information gained from this study should help improve the screening service offered to women in the future.

Have patients been involved in designing the study?

Yes, patients have been involved from the beginning and will continue to help us make sure that the study is done well and for the benefit of patients. This is called Patient and Public Involvement (PPI).

What happens when the research study stops?

We will continue to collect available information on your health for several years via the screening database to identify the number of women (if any) who had a cancer missed in any of the three groups. This helps us to learn whether NHS experts working with AI detect more cancer or not.

What if there is a problem?

If you have any concerns about any aspect of this study, you should ask to speak to the research team who will do their best to answer your questions. If you are still concerned and wish to discuss your concerns with someone else or make a complaint, please address your complaint to a senior University or hospital Official, entirely independent of this study. Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed.

Associate Director Research Culture,
Governance and Compliance
Research and Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Tel: 02476 575733
Email: researchgovernance@warwick.ac.uk

Patient Advice and Liaison Service
Cambridge University Hospitals
NHS Foundation Trust
Hills Road
Cambridge
CB2 0QQ
Tel: 01223 216756
Email: Cuh.pals@nhs.net

The sponsors take out appropriate insurance cover for this study.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: infocompliance@warwick.ac.uk. Or you can contact the Independent Advice Service/Patient Advice Liaison Service (PALS) at your participating site.

What will happen to the results of the research study?

The results will be published in a scientific journal after a number of years and presented at professional and academic conferences. We will share the results with the UK Government and breast screening services so they can make decisions on adopting AI in national screening programmes. They will also be shared with the wider population through media coverage and breast cancer charities so that breast cancer patients can have access to them. We will ensure that results are displayed in breast screening clinics through posters and leaflets, as well as on the publicly accessible study website. You will never be identified in person in any report about the study or in the study results.

Who is organising and funding the research?

The study is organised by a research team at the University of Warwick and Cambridge University Hospitals NHS Foundation Trust. This research is funded by the UK Department of Health funding body; the National Institute of Health Research Health Technology Assessment Programme (NIHR HTA 162840).

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee. This committee is there to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by East of England - Cambridge East Research Ethics Committee. It has also been approved by patient and carer representatives.

The application was reviewed by the Confidentiality Advisory Group (CAG). CAG is an independent group of lay people and professionals which provides expert advice on the use of confidential patient information without consent. CAG recommended that

our application should be supported and the Decision Maker within the Health Research Authority approved this.

How will we use information about you?

We will need to use information from your medical records for this research project. This information will include your:

- name
- NHS number
- hospital number
- date of birth
- mammogram images
- breast screening history
- outcome of your breast screening mammogram and any further investigations done as a result
- gender
- ethnicity
- socio-economic status
- postcode

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 Warwick and Cambridge University Hospitals NHS Foundation Trust are co-sponsors of this research. The University of Warwick is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- A company called CIMAR (UK) Ltd providing a secure online cloud environment where mammograms can be read by AI
- DICOM Systems, a company that provides some of the software used by CIMAR to allow mammograms to be read by AI

- AI providers
- The National Breast Screening Service
- NHS organisations involved in this study
- Other Universities involved in this study

Confidential patient information will be disclosed to a third party – CIMAR (UK) Ltd – to allow mammograms to be read by AI. CIMAR will hold this information for a maximum of 30 days before the information is permanently deleted. CIMAR are a trusted company who are already used by the NHS for the lung screening programme and have all of the security in place to undertake work for the NHS.

Individuals from the co-sponsors, the organisations listed above and regulatory organisations may look at your medical and research records to check the accuracy of data collected.

We will keep all information about you safe and secure:

- All information we collect about you during the study will be kept strictly confidential and will only be accessible to authorised people.
- Information about you will be held on a trusted and secure database and cloud-based storage at the University of Warwick, University of Cambridge, and the Royal Surrey NHS Foundation Trust. This will not include your name and contact details.

International transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- Allow the companies that developed the AI being used in this trial, access for the purpose of ensuring their product is working accurately and effectively.

- Allow DICOM Systems, a technology owner that provides some of the software used by CIMAR to allow mammograms to be read by AI, access for the purpose of ensuring their software is working correctly.
- These companies will not be able to take data outside of the UK-based secure CIMAR environment and they will not be able to keep the data or use it for their own purposes.

We will make sure your data is protected. Anyone who accesses your data from outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe when being accessed from outside the UK by doing the following:

- some of the countries your data may be accessed from will have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

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 twenty years after the study has finished. The study data will then be fully anonymised and securely archived or destroyed.

Some of the information we collect about you including mammogram images may be used to support future research and may be shared anonymously with other researchers. Other researchers who want to use this data will need to make a formal request, which will be assessed by the research team.

What are your choices about how your information is used?

- You can opt out of the study at any time, without giving a reason.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study.
- If you opt out of the study after your screening appointment, AI may have already been used to help look at your images. If AI has already been used, this cannot be undone but your data will be deleted before analysis and will not be included in the trial results.
- It will not be possible to delete your data once it has been analysed and the results published because trial data is required to be retained to ensure research is reliable, reproducible and compliant with legal and ethical rules.

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

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

- www.hra.nhs.uk/patientdataandresearch
- University of Warwick privacy statement: https://warwick.ac.uk/services/legalandcomplianceservices/dataprotection/otherprivacynotices/research/
- CIMAR (UK) Ltd privacy policy: https://www.cimar.co.uk/privacy-policy/
- By sending an email to the research team: edith@warwick.ac.uk

Thank you for taking time to read this information sheet.

If you would like any independent information about taking part in research, you may find it useful to contact one of the following organisations:

- Breast Cancer Care: **Tel: 0808 800 6000** (Free phone)
  http://www.breastcancercare.org.uk
- Cancer Research UK **Tel: 0808 800 4040** (Free phone)
  http://www.cancerhelp.org.uk
- PALS (Patient Advice and Liaison Service)
  Ask your GP or Phone NHS 111 for details of your nearest PALS

This study is funded by the NIHR Health Technology Assessment (HTA) programme (NIHR 162840). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.