Oxford University Hospitals
NHS Foundation Trust

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PARTICIPANT INFORMATION SHEET

STEDI: Simulation Training for Emergency Department Imaging (Phase 2)

University of Oxford Central University Research Ethics Committee Reference R80145/RE001

We would like to invite you to take part in the STEDI study, which aims to assess the improvement in the image interpretation accuracy and confidence of Emergency Department doctors using online simulation training for CT head scan interpretation.

What is the purpose of the study?

The purpose of this study is to see if simulated training can make improvements to interpretation accuracy, confidence of ED clinicians and the length of time from imaging to availability of results when reported by ED clinicians compared with radiologist's reports.

Why have I been invited?

We are aiming to recruit 180 participants from Emergency Departments across the Thames Valley. You have been invited to participate in this study because you are an Emergency Department clinician in one of the five participating Trusts in the Thames Valley

Do I have to take part?

No, you do not have to participate in the study. This completely voluntary, and you can change your mind at any time.

What will happen to me if I decide to take part?

If you decide to take part in the STEDI study, you will be offered the chance to discuss the study with the Principal Investigator who will be able to answer any questions you may have pertaining to the study. If you are still happy to participate you will be asked to sign a consent form online provided by the Principal Investigator, giving permission for the use of your pseudonymised information to be stored and used for the study.

If you take part in the study, you will first be randomly allocated to one of two groups: the intervention and control groups:

Intervention Group:

If you are allocated to the intervention group, you will be given access to an online teaching platform, where you will first be asked to review a set of CT Head scans (50), record your diagnosis and some additional information. Once this is completed, you will be given access to training cases, where you will be given the correct diagnosis once you have attempted the case yourself. It is expected that this training could take 2-4 hours of your time, outside your clinical hours, and can be accessed remotely using an online web-based platform on any laptop or desktop with internet access. After the training is complete you will be asked to undertake a further 50-case assessment.

Following this, you will be asked to evaluate a minimum of 30 CT Heads encountered during your clinical practice in the three months following your training, and record information about your review and the radiology reported results. You should continue to base your clinical decisions on the radiologist report rather than their assessments of the scans for this study, so this process should not directly affect patient care. At the end of this 3 month period, you will be required to repeat a 50-case online assessment, and again at 6 months to assess the retention of the training provided.

You will be asked to complete a survey before each assessment module (at the start and again at 6 months) about your experience of the project.

Control Group:

If you are allocated to the control group, you will not receive the training at this stage, but will be asked to complete an online assessment, then evaluate a minimum of 30 CT Heads encountered during your clinical practice over the next three months, and record information about your review and the radiology reported results. You should continue to base your clinical decisions on the radiologist report rather than their assessments of the scans for this study, so this process should not directly affect patient care. At the end of this 3 month period, you will be required to undertake a 50-case online assessment, then will undertake the online training module with a further 50-case online assessment at the end of the module, and again at 6 months after the start of the study to assess the retention of the training provided.

In either group you will be asked to complete a survey before each assessment module (at the start and again at 6 months) about your experience of the project.

What should I consider?

You will not be able to participate in the STEDI study if you have previously undergone CT Head scan reporting training, worked as a registrar in Radiology or Neurosurgery, or have worked less than four months in the Emergency Department.
The total time required to participate in this study is estimated at 10-12 hours over 6 months

Are there any possible disadvantages or risks from taking part?

There are no anticipated risks to taking part in the study.
We would expect the time taken to complete the surveys and review the scans to take roughly 10-12 hours of your time over a six month period.

What are the possible benefits of taking part?

By taking part in the STEDI study you will gain experience and training in reporting CT Head scans.

Will my taking part in the study be kept confidential?

All information provided to the study team at Oxford will be anonymised before transfer, and only the lead at your hospital will be able to link your details to the study number you will be allocated.

All anonymous information will be stored securely on Oxford University Hospitals NHS Foundation Trust servers, and access limited to specific individuals. Study data will be stored for seven years after the study finishes, and will then be securely disposed of.

Responsible members of the Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

Yes, there is a compensatory payment of £500 for completing the study, including all assessments and training

What will happen to my data?

- We will be using information from the assessments and forms you complete in order to undertake this study. You will be assigned an individual study ID, and your personal details (e.g. name) will be held on a separate list which links them to the ID – this list will only be available to your local study PI, and will not be seen by the central Oxford team analysing the data. Research is a task that we perform in the public interest. Oxford University Hospitals NHS Foundation Trust, as sponsor, is the data controller. This means that we, as Oxford University Hospitals NHS Foundation Trust researchers, are responsible for looking after your information and using it properly. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the Oxford University Hospitals NHS Foundation Trust for 7 years after the end of the study. Data will be emailed from sites in a password-protected file once the study has closed.
- Your local NHS Trust study team will keep identifiable information such as your name and contact details from this study for a maximum of one year after the study has finished. A copy of your consent form will also be held.
- Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://www.ouh.nhs.uk/privacy/default.aspx
- *You can find out more about how we use your information by contacting the Chief Investigator Dr Alex Novak via his email address alex.novak@ouh.nhs.uk*

What will happen if I don't want to carry on with the study?

- Participation is voluntary and participants may change their minds at any stage.
- If you decide to withdraw from, or stop participating in the STEDI study, information already collected will be used in the analysis
- So that we can learn for future studies, we may ask if you would be happy to provide us with a reason as to why you have chosen to withdraw. You are not obliged to give a reason.

What will happen to the results of this study?

The results of the study will be shared in journal articles and conference presentations/posters.

How have patients and the public been involved in this study?

This study was developed in conjunction with member of the AcuteCare Public and Patient Involvement group. The study has also been sponsored by Oxford University Hospitals NHS Foundation Trust

Who is organising and funding the study?

The STEDI study is organised by a group of clinicians working in Emergency Medicine and radiology at the Oxford University Hospitals NHS Foundation Trust, with the help of RAIQ, and is funded by a grant from the Small Business Research Initiative (SBRI)

Who has reviewed the study?

All research involving staff in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by a subcommittee of the University of Oxford Central University Research Ethics Committee (CUREC).

What if there is a problem?

if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should contact <name of investigator><contact details (phone number & email)

There are no special compensation arrangements. Oxford University Hospitals NHS Foundation Trust will provide indemnity for this study. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it.

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

Further information and contact details:

For further information about the study, please contact the local investigator at your site:
Dr……..
Telephone number: ……
Email:……

If your questions are not adequately resolved, please contact the Chief Investigator, Dr Alex Novak
Phone: 07944 653970
Email: alex.novak@ouh.nhs.uk
Thank you for considering taking part.