Study Title: Simulation Training for Emergency Department Imaging 2

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Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. SYNOPSIS

Study Title	Simulation Training in Emergency Department Imaging Phase 2	
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Study Design	Prospective interventional cohort study	
Study Participants	Emergency Department Clinicians who request CT head scans as part of their clinical practice	
Planned Sample Size	180 staff from Oxford University Hospitals NHS Foundation Trust (2 hospitals), Royal Berkshire NHS Trust, Milton Keynes NHS Trust, Buckinghamshire Healthcare NHS Trust and Frimley Health NHS Foundation Trust.	
Planned Study Period	18 Months	
	Objectives	**Outcome Measures**
Primary	To determine the improvement in image interpretation accuracy of the trial participants after undergoing simulation training.	Sensitivity, specificity pre and post assessment.
Secondary	To measure potential reduction in time to diagnostic report	Compare time of ED clinician interpretation and final radiology report
Secondary	Measure real-world accuracy of ED staff at interpreting medical imaging	Sensitivity and specificity
Secondary	To compare the change in image interpretation accuracy of ED staff with and without online training	Sensitivity and specificity

2. ABBREVIATIONS

AI	Artificial Intelligence
CI	Chief Investigator
CQC	Care Quality Commision
CRF	Case Report Form

CTRG	Clinical Trials & Research Governance, University of Oxford
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
NHS	National Health Service
NRES	National Research Ethics Service
OXTREC	Oxford Tropical Research Ethics Committee
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SOP	Standard Operating Procedure

3. BACKGROUND AND RATIONALE

Diagnostic imaging plays a critical role in the management of Emergency Department (ED) patients and delays related to imaging are associated with longer hospital stays. Early imaging has been shown to reduce admissions by up to 50% for some common conditions, and reduce unnecessary surgery by 15%, with significant cost savings to the NHS.[1-2]

As demand for acute care has risen and imaging equipment becomes more readily available, there has been a sustained rise in the demand for acute imaging. An independent review of the NHS England diagnostic service conducted by Sir Mike Richards has recommended doubling the number of scanners to reduce delay.[3]

Currently, most scans are interpreted by radiologists, but the Royal College of Radiologists (RCR) are predicting a shortage of 2000 NHS radiologists by 2023.[4] Image reporting turnaround times are now a major bottleneck for EDs. An RCR national audit showed <50% of ED patients receive their scan reports within the recommended time[5] and only 2% of radiology departments are able to fulfil their reporting requirements within contracted hours.[4] The CQC and NICE guidelines recommend that only appropriately trained clinicians report on imaging but currently, there is no standardised training or assessment process. This has been recognised as a key concern by Health Education England, the Society of Radiographers and the RCR.[7] A CQC inspection at Portsmouth University Hospitals found that junior doctors were reviewing images without appropriate training resulting in significant harm.[8]

The advent of AI-enhanced imaging offers a potential solution to this shortfall in allowing clinicians to interpret unfamiliar modalities such as CT, however most AI readouts are based around a location map for the finding of interest accompanied by a probability score, rather than a diagnosis per se. As such, clinicians are likely to remain responsible for diagnostic interpretation, meaning that some degree of skill in reporting CTs is likely to be essential in order to realise the full impact of the technology.

Training ED clinicians to reliably interpret CT scans may therefore yield significant future benefit to the NHS.[7] The new Royal College of Emergency Medicine training curriculum requires trainees to be able to appropriately use imaging investigations and ED clinicians are also looking to expand their practice into new areas of imaging, such as point of care ultrasound.[6] Reporting and Imaging Quality Control (RAIQC) Ltd has developed a web-based clinical simulation platform for medical image interpretation (www.raiqc.com).This mimics real-world clinical practice and allows users to be taught and assessed for different imaging modalities, ranging from X-rays to CT and MRI scans. This platform was developed by radiologists at Oxford University Hospitals and already hosts a large databank of anonymised medical scans which were acquired at Oxford University Hospitals as part of routine clinical care, and authorised for use in training healthcare professionals via a data sharing agreement.

We have recently explored this potential in a pilot study in which 30 ED staff at varying levels of seniority underwent online training in CT head interpretation then compared their reporting against that of radiologists in their routine clinical practice. The sensitivity of ED staff for detecting stroke and brain haemorrhage improved by 24% and 16% respectively, with an overall accuracy for detecting an acute abnormality in routine cases of 97% - clinician reporting took place on average 52 minutes sooner than the radiology report (unpublished data). We now propose to undertake a larger scale study to further investigate these findings.

4. OBJECTIVES AND OUTCOME MEASURES

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
To assess the impact of online simulation training/clinical reporting on the accuracy of ED clinicians in reporting non-contrast CT head scans.	Sensitivity, specificity pre and post assessment.	pre/post training, 3 months, 6 months post training
To assess the impact of online simulation training/clinical reporting on the confidence of ED clinicians in reporting non-contrast CT head scans	Self-reported confidence scores	pre/post training, 3 months, 6 months post training
To measure potential impact on time to diagnostic report	Compare time of ED clinician interpretation and final radiology report	at 3 months post training
Measure real-world accuracy of ED staff at interpreting medical imaging	Sensitivity and specificity	at 3 months post training

To assess the ability of clinicians to retain newly acquired CT reporting skills		At 6 months post training
To explore which imaging factors influence clinicians' reporting accuracy	Abnormal finding, size of abnormality, image quality, rotation/position, other abnormalities present	Pre and post training
To explore factors affecting the uptake of new image reporting roles in the ED clinical population		At 6 months post training
To explore the potential clinical and health economic impact of introducing CT head reporting into ED clinical practice		At 6 months post training
To compare the change in clinicians interpretation accuracy with and without undergoing online training	Sensitivity, specificity	Pre-training/clinical phase, 3 months, 6 months post start of study

5. STUDY DESIGN

This is a prospective observational cohort study to assess the improvement in the image interpretation accuracy and confidence of reporters using online simulation training for CT head scan interpretation.

Using the RAIQC online platform (www.raiqc.com), the trial participants will be required to complete a baseline assessment where users will review and interpret a pre-existing set of CT scans, which have been curated and reported by senior radiologists. They will be asked to record their interpretation, which will be subsequently compared against that of the radiologists. The participants will be blinded to both original reports for the images, and their overall performance results. After completing the baseline assessment, users will be given access to an online training package. After completing the training, the users will complete a further assessment. The improvement in diagnostic accuracy pre- and post-training will be measured.

Once the ED staff have been trained, they will each be asked to evaluate a minimum total of 30 CT scans during clinical shifts spread over a 3-month period. For each CT scan included they will be asked to record their scan interpretation, the time the scan was performed, the time they reviewed the scan and the time the radiology report was issued. The radiology report

will be considered the gold-standard diagnosis. Online assessments will be repeated at the end of the 3 month period and at 6months post training, to monitor changes in performance over time.

Subsequent comparison and analysis will allow us to measure the real-world accuracy of ED staff at interpreting CT head scans. In addition, we will also be able to measure potential time saving by ED staff interpreting the scans compared with the radiology report being issued.

Setting:

- 6 hospitals comprising the Thames Valley Emergency Medicine Research Network (TaVERN):
  i. John Radcliffe Hospital (Oxford University Hospitals NHS Foundation Trust)
  ii. Horton General Hospital (Oxford University Hospitals NHS Foundation Trust)
  iii. Royal Berkshire Hospital (Royal Berkshire Hospital NHS Foundation Trust)
  iv. Milton Keynes University Hospital (Milton Keynes University Hospital NHS Foundation Trust)
  v. Wexham Park Hospital (Frimley Health NHS Foundation Trust)
  vi. Stoke Mandeville Hospital (Buckinghamshire Healthcare NHS Trust)

Population:

- 180 Emergency Department clinicians (30 per site) of varying grades who routinely interpret images as part of their usual role, including:
  i. Junior Doctors (F1-ST2)
  ii. Registrars (ST3-ST6)
  iii. Consultants
  iv. Radiographers
  v. Nursing and Allied Health Professionals (NMAHPs) – Advanced Nurse Practitioners, Physician Associates

Methods:

1. The trial participants will each be assigned a unique study number

2. Participants will be randomised to control (see section below – no online training, 30 clinicians, 6 from each site) versus intervention (online training – 150 clinicians) groups. Prior to the start of the study, each participant ID will be randomised to either group in a 1:5 ratio via simple randomisation using an online number generator – the outcome of this allocation will be recorded on a linkage document held by the central study team in Oxford. To minimise bias in recruiting, site Principal Investigators will be unaware of their overall site allocations, but as each participant at their site is enrolled, they will contact the central study team to find out to which group the participant has been allocated.

3. Intervention Group:

- All intervention group participants will first be required to complete a baseline online assessment during their non-clinical time, which will consist of CT head images with a clinical vignette of varying difficulty and pathology where users will review a set of scans and provide a diagnosis and confidence score (5 point Likert scale) before submitting the case. Time taken to complete each individual case will be recorded by the RAIQC platform. Participants will be blinded to the results.

- Participants will be given access to an existing bespoke online training module on the RAIQC platform (www.raiqc.com) which takes approximately 2-4hours to complete, with a post-training assessment consisting of a different set of cases

- Participants will then be required to evaluate a minimum of 30 CT Head scans each - encountered during their clinical shifts over a 3-month period. They will be asked to record results in real time on a standardised eCRF, including:
    - date/time at which CT scan was performed
    - date/time of participant review
    - participant interpretation and confidence score
    - date/time of radiology report
    - radiology report findings (reference-standard)

  NB: Participants will be instructed to base their subsequent clinical decision making based on the formal radiology report as per standard clinical practice, not their own interpretation.

- This will result in a large pooled group of logged CT head interpretations for subsequent analysis

- Participants will then each repeat a 50-case assessment at the end of the 3-month period and again at 6 months post-training (to assess skill retention)

- Qualitative surveys will be completed by participants prior to each assessment module to obtain feedback and comment regarding their experiences of the project and monitor any changes over the course of the study. Participants will be issued with a certificate to recognise that they have undergone imaging training for Continuous Professional Development purposes

4. Controls:

- To provide a control for comparison as to the relative benefits of the online training phase and the clinical interpretation phase in terms of improving reporting performance, 30 participants (6 clinicians from each site) will be randomised to undertake the clinical interpretation phase prior to the training module, i.e.:

  i. Complete an online baseline assessment of CT interpretation accuracy
  ii. Interpret and record findings from 30 CT images encountered in clinical practice over a three month period
  iii. After the clinical phase (at approximately 3 months after the start of the study) they will proceed to undertake an online assessment followed by the training module and a post-training assessment (as undertaken by the intervention group initially)

iv. A further online assessment will be undertaken at 6 months after the start of the study as per the intervention group
v. Qualitative surveys will be completed by participants prior to each assessment module to obtain feedback and comment regarding their experiences of the project and monitor any changes over the course of the study. Participants will be issued with a certificate to recognise that they have undergone imaging training for Continuous Professional Development purposes

- Baseline accuracy statistics from each participant will be compared to subsequent results from each stage of the study

- Accuracy statistics will be compared with those of Radiology Consultants and Registrars

Analysis:

- Training:

  i. Changes in reporting accuracy (sensitivity/specificity), confidence and speed will be calculated in a pooled analysis for all readers at all sites, as well as for the following subgroups:
     - Clinical role
     - Level of seniority
     - Pathological finding
     - Difficulty of image

  ii. These will be repeated for each of the four sequential assessments

- Clinical Interpretation:

  i. Accuracy (sensitivity/specificity), confidence and speed will be calculated for all pooled data, and the following subgroups:
     - Clinical role
     - Level of seniority
     - Pathological finding

  ii. Total and mean potential time saving will be calculated by comparing time of participant interpretation versus time of radiology report, and will be used to calculate potential cost benefit of clinician reporting versus radiology reporting

  iii. Results from the qualitative surveys will be collated and used to explore the experiences and factors affecting the uptake of new image reporting roles in the ED clinical population

Delivery:

- Each hospital site will nominate a designated site study Principal Investigator who will be responsible for implementing and delivering the trial at that site

6. PARTICIPANT IDENTIFICATION

6.1. Study Participants

Emergency Department staff of varying grades of seniority who review CT head scans as part of their routine clinical practice

6.2. Inclusion Criteria

- ED clinicians who review CT head scans as part of their clinical practice
- Working in the relevant ED during the clinical phase of the project

6.3. Exclusion Criteria

- Previous formal postgraduate CT reporting training
- Previous career to registrar level in radiology/neurosurgery
- Staff in Emergency Department post for less than four months

7. STUDY PROCEDURES

7.1. Recruitment

Each participating site will have a study lead who will be responsible for the implementation and delivery of the study at that site, including recruitment and progress of clinicians.

7.1. Screening and Eligibility Assessment

Participants will be approached via email advertisement and asked to contact the site Principal Investigator, who will assess their eligibility for the study.

7.2. Informed Consent

Participants will be provided with an electronic copy of the PIS via email. They will express an interest in participating in the study to the site Principal Investigator, who will discuss the study further with them and answer any questions. Consent will be sought from participants to participate in the study and for their anonymised results to be used for analysis and publication purposes. If they agree to the study, they will then be asked to complete the consent form online and return it to the site Principal Investigator.

7.3. Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with training regimen or study requirements
- Withdrawal of Consent
- Loss to follow up

All data obtained to that point will be retained for analysis

Withdrawn participants will not be replaced.

The reason for withdrawal will be recorded in the CRF.

7.4. Definition of End of Study

The end of the study will be defined as being when all clinicians have either completed all parts of the study process or dropped out of the study.

8. STATISTICS AND ANALYSIS

1.1. Sample Size

During the pilot study, the diagnostic accuracy of participants in detecting acute intracranial abnormality improved by a mean of 8% (SD15%). We calculated a sample size of 30 participants using a power of 80% and a level of significance of 5% (two sided). This was a realistically and practically achievable target for each of the six sites, and 180 clinicians was, therefore, chosen as the overall target for the current study.

1.2. Statistical Analyses

- Training Assessments:

    1) Changes in reporting accuracy/sensitivity/specificity/inter-reader variability/confidence/speed will be calculated in a pooled analysis for all readers at all sites, as well as for the following subgroups:
        - Clinical role
        - Level of seniority
        - Pathological finding
        - Difficulty of image

    2) These will be repeated for each of the four sequential assessments

- Clinical Interpretation Phase:

    1) Accuracy/sensitivity/specificity/inter-reader variability/confidence will calculated for all pooled data, and the following subgroups:
        - Clinical role
        - Level of seniority
        - Pathological finding

    2) Total and mean potential time saving will by calculated by comparing time of participant interpretation versus time of radiology report, and will be used to calculate potential cost benefit of clinician reporting versus radiology reporting

    3) Results from the qualitative surveys will be collated and used explore the experiences and factors affecting the uptake of new image reporting roles in the ED clinical population

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9. DATA MANAGEMENT

9.1. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

The RAIQC platform already hosts a large databank of anonymised CT head scans obtained from Oxford University Hospitals NHS Foundation Trust to create the training and assessment content. Approval from the OUH Caldicott Guardian has already been sought and received for use of this anonymised data for the training of healthcare professionals. No further images will be required to undertake this study or will be acquired as part of its implementation.

Individual participant accuracy scores will be anonymised and the study team will not have access to the identifying link between the participants' personal details and the data. Data about the participants' seniority level and professional group (e.g. junior doctor, consultant, nurse practitioner) will be retained to allow group comparisons.

9.2. Data Recording and Record Keeping

All study data will be entered into a password-protected and secure database. The participants will only be identified by study-specific participant number. The name and any other identifying detail will not be included in the main study dataset as transferred to the central study team. Names will, however, be on consent records, but these are not shared with the central study team.

Data will be stored securely from the end of the study for five years. Data storage and transmission will comply with each individual Trust policy.

10. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

11. ETHICAL AND REGULATORY CONSIDERATIONS

11.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

11.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

11.3. Approvals

The HRA online tool (http://www.hra-decisiontools.org.uk/, Accessed 12/11/21) indicates that the study does not require Research Ethics Committee (REC) approval from an NHS ethics Committee. A copy is provided in appendix 1. However, as this study relates to hospital staff, we will follow internal OUH policy and also seek approval from a subcommittee of the Oxford University Central University Research Ethics Committee (CUREC).

11.4. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the Medical Sciences Interdivisional Research Ethics Committee (MS IDREC), HRA, host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

11.5. Participant Confidentiality

The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by a participant ID number on all study documents (other than consent forms and linkage document) and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act 2018, which requires data to be anonymised as soon as it is practical to do so. All personal study data relating to participants (e.g. signed consent forms) will be transferred to Oxford University Hospitals via secure file transfer. We will store any identifiable data (contact details) of the participants for 12 months in a separate secure file, along with the document linking names to study ID numbers, following which time these files will be deleted. All other study data (including consent forms) will be stored in a similar manner for 7 years.

11.6. Expenses and Benefits

£500 will be paid to each participant on completion of the study.

12. FINANCE AND INSURANCE

12.1. Funding

Funding has been secured from NHS England's Small Business Research Initiative (SBRI) Healthcare programme

12.2. Insurance

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical research study 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.

13. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the Small Business Research Initiative (SBRI). Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

14. REFERENCES

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15. APPENDIX A: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made