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Assessing the effectiveness of artificial intelligence (AI) in prioritising CT head interpretation: study protocol for a stepped-wedge cluster randomised trial (ACCEPT-AI)

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ABSTRACT

Introduction Diagnostic imaging is vital in emergency departments (EDs). Accessibility and reporting impacts ED workflow and patient care. With radiology workforce shortages, reporting capacity is limited, leading to image interpretation delays. Turnaround times for image reporting are an ED bottleneck. Artificial intelligence (AI) algorithms can improve productivity, efficiency and accuracy in diagnostic radiology, contingent on their clinical efficacy. This includes positively impacting patient care and improving clinical workflow. The ACCEPT-AI study will evaluate Qure.ai's qER software in identifying and prioritising patients with critical findings from AI analysis of non-contrast head CT (NCCT) scans.

Methods and analysis This is a multicentre trial, spanning four diverse sites, over 13 months. It will include all individuals above the age of 18 years who present to the ED, referred for an NCCT. The project will be divided into three consecutive phases (pre-implementation, implementation and post-implementation of the qER solution) in a stepped-wedge design to control for adoption bias and adjust for time-based changes in the background patient characteristics. Pre-implementation involves baseline data for standard care to support the primary and secondary outcomes. The implementation phase includes staff training and qER solution threshold adjustments in detecting target abnormalities adjusted, if necessary. The post-implementation phase will introduce a notification (prioritised flag) in the radiology information system. The radiologist can choose to agree with the qER findings or ignore it according to their clinical judgement before writing and signing off the report. Non-qER processed scans will be handled as per standard care.

Ethics and dissemination The study will be conducted in accordance with the principles of Good Clinical Practice. The protocol was approved by the Research Ethics Committee of East Midlands (Leicester Central), in May 2023 (REC (Research Ethics Committee) 23/EM/0108). Results will be published in peer-reviewed journals and disseminated in scientific findings (ClinicalTrials.gov: NCT06027411)

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The ACCEPT-artificial intelligence (AI) trial is a prospective, multicentre trial evaluating an AI algorithm in improving the reporting turnaround times for non-contrast head CT scans in patients presenting to the emergency department (ED).
⇒ The study adopts a stepped-wedge design for implementation, controlling for adoption bias and accounting for any time-based changes in patient characteristics ensuring a more robust evaluation of the AI algorithm's impact on ED workflow and patient care.
⇒ The study will include a comprehensive health economic evaluation in addition to generating evidence for evaluating the safety and technical performance of the AI algorithm in routine National Health Service clinical practice.
⇒ The study leverages the radiologist's discretion to agree with or ignore the AI findings and adherence to the prioritisation. This nuanced interplay between the AI system and radiologists' clinical judgement is a pivotal aspect of this study.

Trial registration number NCT06027411.

INTRODUCTION

Background

A non-contrast head CT (NCCT) is the first-line imaging investigation for patients presenting to the emergency department (ED) for a range of indications including head injuries, abnormal neurological presentations and strokes.[1] These scans are predominantly interpreted by a radiologist to guide management. Prompt diagnosis not only results in earlier treatment, reducing brain injury, mortality and illness but also expedites discharge times from the ED.[2] Rising ED

attendances and concurrent radiologist shortages have resulted in increased wait times and workload.[3 4] This has led to an operational and clinical imperative for shorter report turnaround time (TAT) in an effort to streamline throughput and decrease healthcare expenditures.[5] Furthermore, for time-critical diagnoses like head injuries and strokes, an artificial intelligence (AI) tool which prioritises certain patients' NCCT for earlier attention, could improve abnormality detection, optimise clinical pathways and improve patient outcomes.

The pressures on radiology departments

Diagnostic imaging plays a critical role in the management of ED patients and delays related to imaging are associated with longer hospital stays.[5–7] As demand for acute care has risen and imaging equipment has become more readily available, there has been a sustained rise in the demand for diagnostic imaging.[8] An independent review of the National Health Service (NHS) England diagnostic service conducted by Sir Mike Richards has recommended doubling the number of scanners to reduce delays.[9]

Currently, most scans are interpreted by radiologists, but the Royal College of Radiologists (RCR) has reported a shortfall of 30% clinical radiologist consultants in England, forecasted to increase to 39% by 2026.[4 10] Image reporting TAT is now a major bottleneck for EDs, impacting quality of care and exacerbating exit block.[11 12] An RCR national audit showed <50% of ED patients receive their scan reports within the recommended time, and only 2% of radiology departments are able to fulfil their reporting requirements within contracted hours.[13]

Study justification

AI: the opportunity

The use of AI to reduce radiology TAT in the NHS presents a unique opportunity to enhance patient care and outcomes. Potential applications of AI in radiology go beyond image analysis to support diagnostic and prognostic opportunities. AI solutions have the potential to address challenges in productivity, operational efficiency and improving accuracy in diagnostic radiology.[14] These technologies are being developed to aid the radiology workflow addressing multiple points including (a) managing urgent referrals; (b) clinical decision support systems for detection of critical findings; (c) worklist priority adjustment via AI results and (d) reducing TAT through worklist prioritisation and semi-automated reporting.

qER

Qure.ai's emergency room software solution qER (qER EU 2.0) is an AI medical device, developed by training a deep-learning algorithm using over 300 000 scans labelled by expert radiologists.[15 16] qER has been shown to be accurate in identifying a range of abnormalities in NCCT head scans as well as prioritising them for urgent review and radiologist reporting.[15] It is designated as a clinical support tool and, when used with original scans, can assist the clinician to improve efficiency, accuracy and TAT in reading head CTs.[17]

Study motivation

While qER has been found to be accurate, safe and effective when used in other healthcare systems, its use has not been evaluated in the NHS.[15] The adoption of any AI tool is dependent on the demonstration of impact on patient care and evident improvement in clinical workflow. The National Institute for Health and Care Excellence (NICE) has developed a digital health technologies (DHTs) framework to evaluate the safety, clinical effectiveness and cost-effectiveness of DHTs, including AI.[18]

In this study, we aim to assess whether real-world implementation of qER, which augments the worklist priority could affect TAT, in line with the DHT framework[18] and SPIRIT-AI guidelines.[19] This protocol will involve collaboration with healthcare providers, technology developers, patients and other stakeholders to develop the evidence to meet the current evaluation requirements.

Hypothesis

Implementation of the qER product will reduce time to reporting of prioritised NCCT head findings within the ED and improve radiology reporting workflow, enabling improved clinical pathways for patients requiring NCCT imaging.

Objectives

Primary objective

To assess if qER tool-based reporting and triage significantly reduces report TAT of prioritised NCCT scans for patients attending the ED.

Secondary objectives

1. To assess the utility of qER to support ED pathways for patients requiring NCCTs and the radiology reporting workflow.
2. To assess the safety of qER in identifying patients with critical findings on NCCTs.
3. To evaluate the technical performance of qER.
4. To conduct a health economics and cost–utility analysis of qER.

METHODS

Study design

This is a multicentre stepped-wedge cluster-randomised study following the SPIRIT-AI framework. The study will run over a 13-month period in three phases (pre-implementation, implementation and post-implementation of the qER tool) (figure 1). Identified hospitals will be initiated into the qER solution with a 30-day implementation period. The order in which the sites will receive the qER intervention will be determined by computer-based randomisation.

An independent statistician will perform randomisation of the sites with one trust to receive the intervention

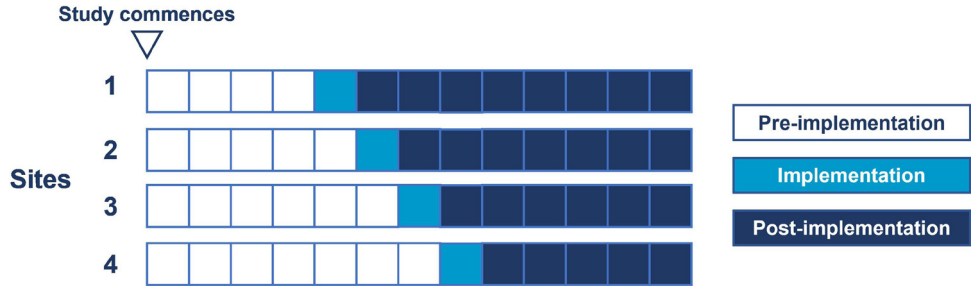

Figure 1 Proposed multicentre stepped wedge cluster randomised study design.

in each of the time periods. At each participating site, we will identify all patients referred through ED for an NCCT head.

Study setting

The study will be conducted in four NHS hospitals that undertake a substantial number of NCCT heads within the ED per annum. Specialty leads from radiology and ED will be identified with support from their NHS Trust to participate in the deployment of qER. Hospitals that have already deployed qER of similar AI-enhanced NCCT will be excluded. The identified sites (table 1) will provide a good representation of potential heterogeneity (geographical, population and ethnicity).

Equipment

qER is a CE Class IIb approved, and FDA cleared medical device which detects and localises the presence of six target abnormalities in NCCT head scans.[15] For the purpose of this study, there are consensus definitions and terms have been created to conduct the analysis. These terms will be used throughout the protocol. The table below lists these terms and the corresponding definitions (table 2).

Study protocol

This study will assess the clinical effectiveness of qER to prioritise patients' reporting of NCCT scans that have prioritised findings (identified from the AI analysis of NCCT). The study period will be divided into three phases: a pre-implementation phase (baseline/standard-of-care phase), an implementation phase (qER installation phase) and a post-implementation phase (AI assistance phase).

Pre-implementation

During the pre-implementation phase, we will be gathering data around the technical requirements for integrating qER into the radiology workflow. A random sample of 500 scans per site will be sent for the ground-truthing process for the purpose of technical evaluation.

We will also be collecting data on the baseline status of all the endpoints including TAT. The reporting of NCCT scans will follow the same workflow as the current standard of care (i.e., the images/cases will appear in the radiology information system (RIS) chronologically and the radiologist either follows this order or prioritises some cases based on communication from ED).

Implementation

Structured training and support will be provided to the end-users on qER. The thresholds for detecting target abnormalities will be adjusted, if necessary, during the implementation phase as per the deployment standard operating procedure for the qER tool. Technical integration with local workflow systems, in particular the prioritisation system (figure 2) will also be tested.

Pos-timplementation (trial Intervention)

In the post-implementation phase, there will be a notification (prioritised flag) in RIS. The order of the cases in RIS will not be altered. When the radiologist clicks a case in RIS, a secondary capture of qER along with the original images will be available in the picture archiving and communication system (PACS). This secondary capture (figure 3) will have a contour showing the algorithm's attention point for a specific abnormality. The radiologist can then choose to agree with qER findings as it is or

Table 1 Participating sites in the ACCEPT-AI clinical trial

Location	Type of NHS site	Neurosurgical cover	Number of consultant radiologists	Number of ED attendances per annum
Queen Elizabeth University Hospital, Glasgow	Major Trauma Centre	Yes	82	110 000
St Thomas' Hospital, London	Central London Teaching Hospital	No	60	186 000
John Radcliffe Hospital, Oxford	Major Trauma Centre	Yes	60	155 000
Northumbria Specialist Emergency Care Hospital, Northumberland	Purpose Built Specialist Emergency Care Teaching Hospital	No	12	250 000

AI, artificial intelligence; ED, emergency department; NHS, National Health Service.

Table 2 Custom terms differentiating findings in these four categories: prioritised, non-prioritised, no findings and no interpretation

Term	Definition
Target abnormality	This refers to the list of all target abnormalities that qER can detect in an NCCT head scan: ► Intracranial haemorrhage ► Midline shift ► Mass effect ► Cranial fracture ► Atrophy ► Hypodensities suggestive of infarct
qER prioritised findings	A subset of target abnormalities which when identified in an NCCT head scan by qER, will lead to the prioritisation of such scans in the radiology worklist: ► Intracranial haemorrhage ► Midline shift ► Mass effect ► Cranial fracture
qER non-prioritised findings	A subset of target abnormalities which are detected by qER but not in the list of qER-prioritised findings: ► Atrophy ► Hypodensities suggestive of infarct These scans will not get prioritised in the radiology worklist for interpretation by the radiologist but will still be available for interpretation in the worklist in a non-prioritised manner.
qER no findings	Any NCCT head scans where none of the target abnormalities are identified by qER. These scans will be classified as scans where no qER findings are identified
qER not interpreted	NCCT head scans which were not processed by qER and thus have no AI outputs.

NCCT, non-contrast head CT.

modify or ignore it according to their clinical judgement, writing and finally signing off the report. For scans which were not processed by qER the radiologist can prioritise and report as per the standard of care.

In the prioritised, non-prioritised and no-finding categories, all cases where the radiologist did not agree with qER findings will be sent for ground truthing (see online supplemental figure 1). The final categorisation of a scan into prioritised, non-prioritised and no-findings categories will be determined either by the original radiological report for concordant scans or by a panel of radiologists (ground truthing) for discordant scans. The ground truthing will be done by using two radiologists independently reviewing the discordant scans blinded to the original radiological report and original request. If there is a disagreement between the two radiologists, then an additional radiologist will interpret the scans and adjudicate. All disagreements (inter-reader disagreement during ground truthing) and discordances (between qER output and original radiological report) will be based on the level of categorisation of scans and not at individual target abnormality level. For example, if the qER flagged an NCCT head scan as a prioritised scan, but the original radiological report did not mention any prioritised findings in the scan, then this will be considered as a discordant scan.

Eligibility criteria

Inclusion criteria

1. Individuals undergoing an NCCT are referred from the ED.
2. Age above 18 years.
3. Non-contrast axial CT scan series with consistently spaced axial slices.
4. Soft reconstruction kernel covering the complete brain.
5. Maximum slice thickness of 6 mm.

Exclusion criteria

There will be no explicit exclusion criteria for qER as all scans in the inclusion criteria will be processed by qER.

Figure 2 Mock-up example of a qER prioritised radiology reporting worklist. RIS, radiology information system.

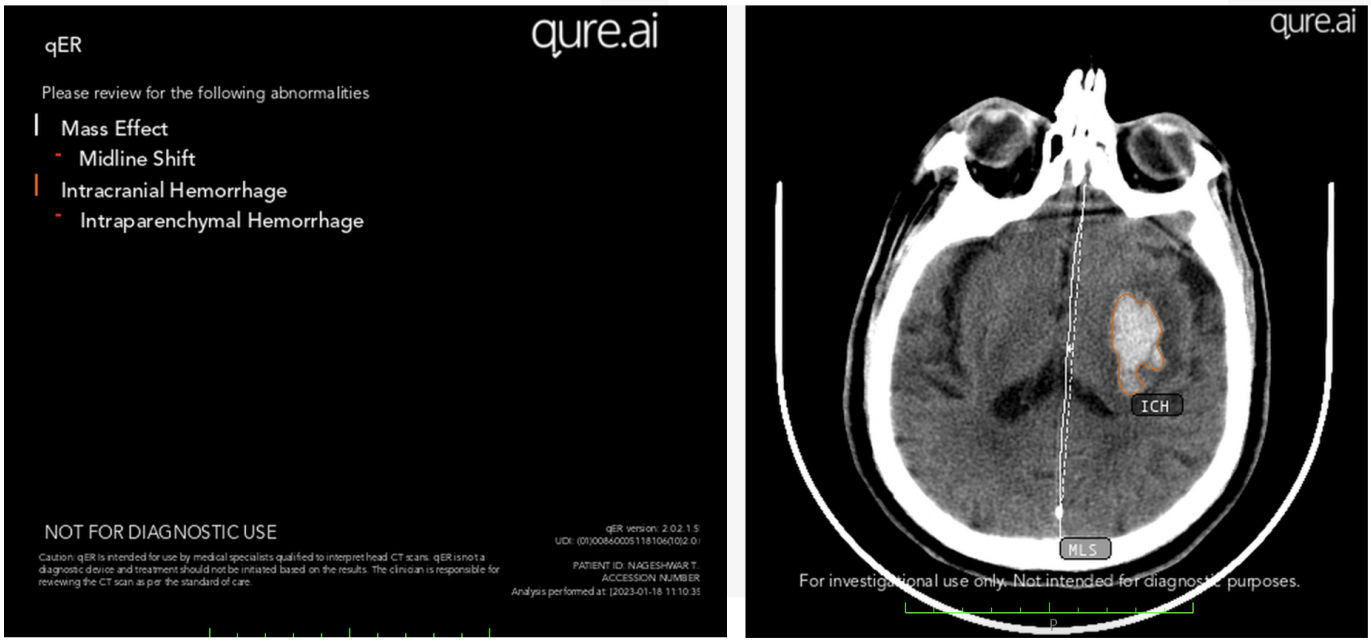

Figure 3 Secondary capture demonstrating a target abnormality.

Outcomes

The primary study outcome measure of this study will be the time from NCCT head acquisition to reporting for patients with prioritised findings in ED compared with standard of care.

Secondary outcome measures will be:

1. Utility of qER compared with standard of care:
   - Time taken from acquisition to report NCCT for patients without prioritised findings in ED.
   - Time taken from acquisition to report NCCT for patients with an absence of findings in ED.
   - To assess the impact of qER on radiology reporting workflow on other requests for CT scans.
   - To assess the impact of qER supported reporting on teleradiology.
   - Time to diagnosis from NCCT acquisition.
   - Time to discharge from NCCT acquisition.
   - Time to referral from NCCT acquisition.
   - Time to initiation of treatment from NCCT acquisition for prioritised scans.
   - Death within 28 days of NCCT head acquisition.
   - Percentage of NCCT heads that qER classifies as prioritised, non-prioritised and absence of findings.
   - Percentage of qER non-prioritised scans but identified by the radiologist as prioritised.
   - Percentage of qER non-prioritised scans but identified by the radiologist as absence of finding.
2. Technical evaluation of product performance:
   - Sensitivity, specificity, positive and negative predictive values of qER in detecting scans with prioritised findings overall and stratified by all six target abnormalities.
   - Percentage of CT scans that could not be processed by qER due to technical factors.
3. Safety of qER
   - Percentage incorrectly qER reported non-prioritised NCCT head among patients with scans confirmed with prioritised findings.
4. Health economic assessment
   - Compare costs and health benefits between preimplementation and postimplementation of qER, including cost evaluation of fully automatic diagnosis of high confidence normal triage.

Statistical analysis

Sample size and power calculation

Power calculations were derived for the primary outcome measure based on the number of hospitals taking part in the study and the number of patients attending the ED modelled to require NCCT during the study period.

The number of prioritised NCCT head scans varies from 120 to 600 scans per site per year. Assuming type I statistical error at the α=0.05 level and the total duration of the study 12 months (excluding the implementation period) the generalised linear mixed-effect regression model with expected distribution of the outcome variable Gamma, the total sample size of 1680 prioritised scans (35 per site per month; total yearly per site 420) ensures satisfactory level of statistical power exceeding 80% for detecting reduction in TAT by 20%.

Our modelling has been estimated for scans with prioritised findings which is our primary endpoint. Therefore, assuming that prioritised cases are only ~10% of all NCCT head scans performed at sites it can be expected that the total number of available scans in this study will be 16 800. Within our modelling process, we will be controlling for study centre, intervention, calendar month, after-hours reporting, individual patient diagnosis (ground truth indicating bleed, infarct, presence/ absence of midline-shift,

mass-effect and cranial fracture). Simulations have been performed in R V.4.1.0.

Data collection and management

Throughout all three phases of the study, clinical data will be collected by a clinical trial assistant, supervised by the principal investigators. Every patient from ED undergoing an NCCT head will be assigned a unique identifier as a key to match their demographic information, NCCT head report outcomes and TAT. The key to the identification code will only be accessible to the local research team during the study. The anonymised data set will then be uploaded to a non-publicly available repository on a secure cloud storage system, through which the central research site will have access to the data (see online supplemental figure 2). The chief investigator and clinical AI fellow at the central research site will manage and protect the data.

DISCUSSION

Diagnostic imaging is indispensable in patient management within the ED, and AI algorithms hold the potential to significantly streamline radiology workflow and improve patient care.[20] Recently, guidelines for AI trials have been put forward by the SPIRIT-AI and Consolidated Standards of Reporting Trials-AI steering groups,[19] offering roadmaps for routine use of AI in clinical practice.[21] However, the application of AI in radiology is limited by the lack of evidence showcasing its impact on patient outcomes and radiologist workflow.[20] The ACCEPT-AI study aims to address these issues by evaluating the clinical effectiveness of qER, an AI algorithm, in enhancing the prioritisation and identification of critical findings in NCCT scans, with the goal of improving radiology reporting workflow and patient management within the ED.

This study has incorporated a strategic approach to the design and execution of its protocol that is in line with the requirements of the NICE DHT.[18] This not only enhances its adherence to the Evidence Standards Frameworks but also strengthens its potential to provide robust evidence that supports future adoption decision-making. A key strength of the study is the multicentre randomised design, which allows for a diverse population. The diversity broadens the external validity of the results and the potential adaptability of the qER solution in different settings. Furthermore, the study's stepped-wedge design allows for the control of adoption bias and the adjustment for temporal changes in patient characteristics.

Limitations

The study's limitation lies in the radiologist's discretion to agree with or ignore the qER findings and adherence to the prioritisation code, which might influence the interpretation of results. Nevertheless, this nuanced interplay between the AI system and radiologists' clinical judgement is a pivotal aspect of this study. The exercise of professional discretion by radiologists reflects standard clinical practice. Particularly, in scenarios where diagnostic ambiguity exists, there is often a collaborative review of scans representing a rigorous approach to ensuring diagnostic accuracy, The ACCEPT-AI study aspires to underscore the complementary role of AI in supporting, not supplanting, the rich tapestry of clinical decision-making.

Furthermore, ED clinicians will also have the capacity to act on their independent interpretation of critical scans. To mitigate this, the study will follow a rigorous protocol, with ED clinicians and radiologists undergoing comprehensive training during the implementation phase. Additionally, the RIS will feature a prioritised flagging system for qER-processed scans, enabling the radiologist to objectively consider the AI's findings during the reporting process. Finally, the study's robustness could be significantly enhanced by triangulating with further acceptability data by collecting feedback from all stakeholders including referring clinicians and radiologists. This will ensure the proposed system is not only technically competent but also user-friendly and practicable in a real-world clinical setting.[22]

We anticipate that the ACCEPT-AI study is poised to provide valuable insights into the role of AI in improving diagnostic imaging efficiency, enhancing the quality of patient care within EDs and addressing the anticipated shortage of NHS radiologists. It is our belief that this study will provide the necessary foundation for the wider integration of AI into the realm of radiology.

Patient and public involvement

Patient representatives have contributed to the design of the protocol and patient facing materials (posters and leaflets) and will continue to be integral members of the team for wider dissemination. The patient and public involvement leads will also be part of the trial management group.

ETHICS AND DISSEMINATION

Research ethics committee approval

This study has ethical approval from Research Ethics Committee of East Midlands (Leicester Central), in May 2023 (REC 23/EM/0108) and will be conducted in accordance with the principles of Good Clinical Practice. Patient data will be anonymised, and no personal information will be included in the data set. Sites will develop data processing impact assessments and system security protocols gaining local information governance approvals.

Intended publications and research dissemination

Datasets created and/or processed during the current research, aimed at improving the TAT for reporting of NCCT heads in the UK, will not be accessible to the public due to privacy agreements with data administrators. The findings produced by the study will be disclosed in a summarised form to the public. Research papers discussing the objectives of the study will be published in peer-reviewed medical and radiology journals. The

results will also be presented at national and international conferences relevant to AI application in healthcare. Outcomes of the study will be shared with stakeholders involved in UK's radiology departments and policymakers in healthcare AI, to guide future assessment and policy dialogues regarding the potential integration of AI into radiology reporting processes.

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Contributors KV, DR, HS and DJL conceived the protocol and were responsible for the final version of the manuscript. SK and HS wrote the initial grant for the AI Award. KV, DR, AK, MG, HS and DJL finalised the statistical analysis plan. MN, RD, MHarrison, SA, AN, MHall and DJL are principal investigators for the trial. HS is the chief investigator for the trial. JG and NW were part of the PPI group.

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Competing interests DR, AK and SK are Qure.ai employees. DJL receives funding from Qure.ai for an additional investigator-led grant.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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