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URAISE: Ultrasound Regional Anaesthesia Interpretation Skill Evaluation

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Study coordination centre: St Mary's Hospital, Paddington
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Study Management Group
Chief Investigator: Dr Boyne Bellew
Co-investigators: Dr FA Cook, Dr M Murali, Dr S Habib, Dr S Haddad, Dr J Brandreth, Dr Amit Pawa, Dr AJ MacFarlane, Dr Peter Merjavy, Dr Madan Narayanan, Dr Lloyd Turbitt, Dr James Bowness, Prof William Harrop-Griffiths
Statistician Mr Roger A'Hern,
Study Management: Dr Boyne Bellew

Study Coordination Centre
For general queries, supply of study documentation, and collection of data, please contact:
Study Coordinator: Dr Boyne Bellew
Address: Department of Anaesthesia & Critical Care,
St Mary's Hospital, Paddington
Anaesthesia / Critical Care / Theatres, Specialist Services - CPG 3
4th Floor, QEQM Building, St Mary's Hospital, Praed Street,
London W2 1NY
Registration: GMC 7000811
Tel: 07710787321 E-mail: boyne.bellew@nhs.net

Clinical Queries
Clinical queries should be directed to Dr Boyne Bellew who will direct the query to the appropriate person.

Sponsor
Imperial College Healthcare NHS Trust is the main research sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Research Governance and Integrity Team
Imperial College London and Imperial College Healthcare NHS Trust
Room 215, Level 2, Medical School Building
Norfolk Place
London, W2 1PG
Tel: **0207 594 9459/ 0207 594 1862**
http://www3.imperial.ac.uk/clinicalresearchgovernanceoffice

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This protocol describes the **URAISE: Ultrasound Regional Anaesthesia Interpretation Skill Evaluation study** and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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Glossary of Abbreviations

RCoA	**Royal College of Anaesthetists**
CRQ	**Constructed response questions**

Keywords: Regional Anaesthesia, Sonoanatomy

Study Summary

Title	URAISE: Ultrasound Regional Anaesthesia Interpretation Skill Evaluation
Design	Prospective study based on psychometric principles
Aims	To generate a validated test of ultrasound guided regional anaesthesia that can used to differentiate reliably between users of different skill levels.
Outcomes	Primary outcome: Development of a validated, reliable and defensible tool to test ultrasound guided regional anaesthesia image interpretation skills. Secondary outcomes: Development a validated, reliable and defensible assessment tool assessing anatomical, clinical knowledge and the performance of ultrasound guided regional anaesthesia: Assessment of anatomical knowledge relevant to performing a local anaesthetic injection around peripheral nerves Assessment of clinical knowledge relevant to regional anaesthesia required to perform a local anaesthetic injection around peripheral nerves Assessment of knowledge relating to the performance of an ultrasound-guided local anaesthetic injection around peripheral nerve
Population	UK anaesthetic trainees and consultants
Eligibility	Participants must be registered in an approved UK anaesthetic training programme, or anaesthetic consultants on the GMC register
Duration	12 months

1. Introduction

1.1 Background

There is a drive for trainee anaesthetists to be competent in a number of common ultrasound guided blocks[1] and proficiency is considered an important part of the anaesthetic curriculum laid out by the RCoA[2]. Ultrasound improves the safety, efficacy and efficiency of peripheral nerve blocks[3-6]. It is now the accepted standard of practice in most institutions. However, one challenge for trainers and trainees is that there is a lack of simple, readily available, evidence-based and validated methods to assess the anaesthetists' ability to identify structures using ultrasound. The development of a validated tool to evaluate proficiency in ultrasound-guided regional anaesthesia (UGRA) interpretation would improve the uniformity and consistency of assessment in the UK.

Validated tools for assessment of ultrasound may be even more valuable with the recognised advantages and increased use of regional anaesthetic techniques during the COVID-19 pandemic. Possible advantages to anaesthetists and hospitals include reduced risk of transmission to staff, and preservation of drugs and personal protective equipment required during critical care of COVID-19 patients. These patients may also benefit from avoiding the further cardiorespiratory strain of undergoing a general anaesthetic. All patients may also experience improved postoperative pain relief (thereby also minimising direct contact with care givers), reduced time in recovery and earlier hospital discharge[7].

Legal defensibility is a concept that is central to any assessment tool. There needs to be confidence in the processes used to construct the assessment tool and that the outcomes of the test reflect the participant's ability. The application of rigorous **psychometric principles** is essential to achieving the high standard of **validity** and **reliability** of an assessment required by educational institutions. Anaesthetists seeking certification that is not based on a validated assessment method could give rise to the question of ethical injustice and possibly expose an organisation to legal challenges[8]. On the other hand, anaesthetists that are inappropriately certified may risk patient safety.

The assessment tool must measure what it is supposed to measure. Firstly, **face validity** will be ensured by our participants judging the questions as easy to understand and the ultrasound video quality as representative of clinical practice. The **content validity** of the assessment tool will be verified by a panel of experts who will be asked to assess its relevance to regional anaesthesia by matching it to the RCoA curriculum. Next, the **construct** validity of the assessment will be evidenced by anaesthetists with more regional anaesthesia experience achieving higher ultrasound interpretation scores. The stages of training in our assessment tool will include consultants and will also be based on the new 2021 RCoA curriculum that is

divided into Stage 1 (CT1-3), Stage 2 (ST4-5) and Stage 3 (ST6-ST7) in a spiral curriculum that is both competency and time-based. This is also a proxy outcome measure in that advancement through these competency-based stages of training already include forms of assessment of proficiency in UGRA. Demographic information will be gathered from the participants to demonstrate their prior regional anaesthesia experience. This will factor in additional courses, qualifications and fellowships in relevant areas to account for inconsistencies in clinical exposure to ultrasound throughout training and as a practising anaesthetist (specifically, training level, courses attended, regional anaesthesia fellowships completed, and ultrasound-based fellowships completed).

Consistency of measurement or **reliability** is essential in the assessment tool. **Cronbach's alpha method** is commonly used to assess internal consistency reliability. We will use also use a **"split-half"** method of comparison in the final version of the test wherein the performance of the same participant in the first half is compared to their performance in the second half. The optimal test length is a balance. Using more test items produces more measurements of the construct and therefore result in higher reliability. This must be set against potential cognitive fatigue and participant drop out with longer test times. Statistical analysis of the pilot testing will allow items with higher discrimination to be kept in the final version of the test and lower discrimination, or lower measurement value, to be removed. Inter-rater or marker variability can be minimised by a system of automatic computer marking. However, the marking will also be corroborated by manual checking by investigators blinded to the participant's training level and experience.

Several studies have conducted psychometric evaluations of assessment tools for the development of regional anaesthesia knowledge and skills[9]. These include measuring hand-motion analysis[10, 11], visuospatial and psychomotor screening[12, 13, 14], checklists[15] and global rating scales[16]. In particular, Woodworth *et al* showed the validity and reliability of a 47-item multiple-choice online test of ultrasound interpretation skills for regional anaesthesia that can be used as an assessment of competence milestone in anaesthesia training for a training programme in the USA[17]. There has not been a study to create such an assessment tool in the UK, where the training programme differs from that in the USA. The UK has a seven year specialist anaesthetic training programme compared to the American four year residency in anaesthesiology. There is evidence that "constructed response questions" (CRQs) with free text answers require a higher degree of understanding and are considered higher on Bloom's taxonomy[15] (knows, comprehends, applies, analyses, synthesises, evaluates) in terms of the complexity of skills demonstrated by the learner. This is also in line with the changing curriculum of the RCoA that has recently moved towards using CRQs in their Final Fellowship of the Royal College of Anaesthetists (FRCA) examinations. These CRQs challenge trainees to

apply, justify or compare information to arrive at solutions to clinical questions, thereby better reflecting daily clinical practice[18]. We therefore aim to create a well-validated assessment tool that uses CRQs to assess ultrasound interpretation skills, which is grounded in the psychometric principles of validity, reliability and defensibility.

2. Study Objectives

The primary objective of the study is the development of a validated, reliable and defensible assessment tool to test ultrasound-guided regional anaesthesia image interpretation skills.

The secondary objectives are development a validated, reliable and defensible assessment tool assessing anatomical and clinical knowledge relevant to regional anaesthesia; as well as assessing knowledge pertaining to the performance of ultrasound guided regional anaesthesia:

- Assessment of anatomical knowledge relevant to performing a local anaesthetic injection around peripheral nerves
- Assessment of clinical regional anaesthesia knowledge relevant to performing a local anaesthetic injection around peripheral nerves
- Assessment of the performance of an ultrasound-guided local anaesthetic injection around peripheral nerve

This will support training and assessment in UGRA by UK anaesthetists by enabling trainers to track educational progress. This in turn will support performance of UGRA, improving patient experience, enhancing patient safety by reducing complications associated with these blocks, and increasing the pool of skilled UGRA practitioners.

3. Study Design

This is a prospective, multi-centre study leading to the identification of a validated, reliable and defensible assessment tool for assessing UGRA image interpretation.

Study population	Anaesthetists in the UK
Inclusion	Registered in an approved UK anaesthetic training programme Anaesthetic consultants on the GMC register
Exclusion(s)	Staff grade, associate specialist and specialty doctors not enrolled in a UK anaesthetic training programme
Sample size	Pilot phase: 35-50 Study phase: 250
Duration	12 months
Study centres	Imperial College Healthcare NHS Trust, London Royal Gwent Hospital, Aneurin Bevan University Health Board, Wales Southern Health and Social Care Trust, Northern Ireland, UK Belfast Health and Social Care Trust, Northern Ireland, UK NHS Greater Glasgow & Clyde, Scotland, UK Guy's & St Thomas NHS Foundation Trust, London, UK Frimley Health NHS Foundation Trust, UK
Primary outcome	A validated, reliable and defensible assessment tool to test ultrasound-guided regional anaesthesia image interpretation skills
Secondary outcome(s)	The secondary outcomes are development a validated, reliable and defensible assessment tool assessing anatomical, clinical knowledge and the performance of ultrasound guided regional anaesthesia:

- Assessment of anatomical knowledge relevant to performing a local anaesthetic injection around peripheral nerves
- Assessment of clinical regional anaesthesia knowledge relevant to performing a local anaesthetic injection around peripheral nerves• Assessment of the performance of an ultrasound-guided local anaesthetic injection around peripheral nerve

This study will have 5 Phases:

3.1 Phase 1 – Nerve block identification

A panel of academic experts in regional anaesthesia will extensively review published evidence from UGRA international consensus guidelines. This first step will determine which UGRA nerve blocks are relevant to clinical practice and anaesthetic training in the UK, in particular their relevance to the new RCoA curriculum. The anatomical and clinical knowledge that is relevant to these nerve blocks will also be listed.

3.2 Phase 2 – Content and question generation

A panel of experts in regional anaesthesia will review UGRA nerve blocks and their relevant anatomical structures. The anatomical structures that must be identified on ultrasound for the safe and effective performance of these blocks will be agreed upon using the Delphi method. It will help determine whether these are structures are essential for block performance, desirable, expert or not relevant. The experts in the panel will be defined by their experience – they will all be recognised nationally or internationally for their involvement in regional anaesthesia societies and publications. This information will be collated by the Primary and co-investigators to generate a pilot test of UGRA interpretation content and questions.

3.3 Phase 3 – Preliminary testing

The pilot test will be administered by local investigators via a computer-based application (https://www.classmarker.com/) to 35-50 trainees and consultants, recruited by email and flyers sent to schools of anaesthesia across the UK. The cohorts will include an equal number of trainees and consultants of varying experience, based on the new RCOA curriculum and the extent of their regional experience (stage 1 (CT1-3); stage 2 (ST4-5); stage 3 (ST6-7); stage 3 + regional fellowship trained; consultant; consultant with special interest in regional; consultant + regional fellowship trained). The pilot test will contain short video clips and images of ultrasound guided regional anaesthesia with questions in a constructed response question (CRQ) format to identify relevant structures, anatomy and clinical knowledge. It is important to recognise that due to the change in the RCoA curriculum, some participants will be familiar with the CRQ format while others might be more familiar with MCQ-based format, or other forms of assessment question. Participants in the pilot and main study will be provided with sample questions and answers prior to the test to familiarise themselves with the question format.

Face validity of the test will also be assessed by asking participants to comment on the ease of understanding and to identify terms that appear ambiguous. Participants will be able to comment in a text box after each item in the questionnaire. They will also be asked to comment on how they would improve the test and any relevant anatomy or clinical

knowledge missing from the questions. The format of the test will be amended based on the comments.

A difficulty index of each item will be calculated by dividing the number of correct responses by the total number of responses, as detailed in Abubakar *et al*'s study[19, 20], and thus a higher value suggests a question is easier to answer. Any item with a difficulty index of < 50% will be considered too difficult to answer by the respondents and will be considered for removal. This will be compared to the information gathered from the panel of experts on test items, for example whether the anatomical structure is essential, desirable, expert or not relevant to the specific ultrasound guided nerve block.

One important step in establishing construct validity is to use the pilot study to identify how well the answers for each test item discriminate between the participant's level of ultrasound experience. Differences in ultrasound interpretation skills between study groups will be analysed using one-way analysis of variance (ANOVA)/Rasch modelling. Items that discriminate well will be retained and those that discriminate poorly will be removed from the main test.

Reliability of the test will be improved by presenting the pilot test items in a random order to minimise any effect of cognitive fatigue diminishing performance on subsequent items. The average time taken for participants to complete each item in the pilot test will also be recorded to guide the optimal final study test length. It is important to balance the maximum number of test items whilst minimising the risk of cognitive fatigue and participant drop out. While the pilot test will necessarily have more items than the final test, pilot test participants will be asked to comment on the point at which they felt fatigued to guide this balance. It will also be important to understand whether level of regional anaesthesia experience affects fatiguability.

3.4 Phase 4 – Testing for content validity

To ensure all items in the assessment tool have the content that tests the domain we intend to test, following the pilot the amended test will be presented to the panel of 5 experts in regional anaesthesia, who will be asked to rate the suitability of ultrasound images and questions to performance of the block. This will be on a 4-point Likert scale (1 = definitely not suitable, 2 = probably not suitable, 3 = probably suitable, 4 = definitely suitable).

The content validity of each item will be calculated by dividing the number of experts who rated the item as suitable and very suitable (3 and 4 on the scale) by the total number of experts. Items found to be appropriate by a sufficiently high percentage of participants will be selected. For example, if 26 out of 40 (65%) participants rate an item as suitable or very

suitable then the lower 95% confidence limit for this proportion is 51%, indicating that more than 50% of experts are likely to find it appropriate.

3.5 Phase 5 – Psychometric main study testing

The main study assessment tool will be administered to trainees of all levels and consultants, aiming to recruit an equal number across different stages of the RCoA curriculum and of varying regional anaesthesia experience (stage 1; stage 2; stage 3; stage 3 + regional fellowship trained; consultant; consultant with special interest in regional; consultant + regional fellowship trained). Participants will be recruited using emails and flyers sent to schools of anaesthesia across the UK. Each participant will answer a series of demographic questions, including age, gender, handedness, as well as level of training and practical experience in UGRA to account for inconsistencies in clinical exposure at different stages of training.

The exam will consist of constructed response questions (CRQs), which will require the participant to write free-text responses to questions, in line with RCoA examinations. Participants will be provided with sample questions and answers before the test to familiarise themselves with the question format.

The construct validity of the tool will be tested by comparing the scores of anaesthetists with their level of experience specifically in regional anaesthesia. The level of experience is a proxy outcome measure for their proficiency in ultrasound-guided regional anaesthesia. Differences in ultrasound interpretation skills between study groups will be analysed using one-way analysis of variance (ANOVA)/ Rasch modelling. At the end of the assessment, there will be a short questionnaire to allow for participant feedback regarding ease of understanding and suitability of ultrasound images to support the face validity of the test.

The internal reliability of the item responses will be assessed using Cronbach's alpha. An alpha value of 0.70 will be considered sufficient and acceptable for the questions. A split-test method will also be used for each participant to compare the first half of their assessment with the second half to ensure internal consistency of their item responses. The difficulty index calculated for items in the pilot study will be used to ensure a balanced set of test items, in terms of their difficulty, in the first and second halves of the test. All items will be made mandatory. The test will be administered by local investigators via a web-based application. It will have an automatic system of marking to minimise inter-marker differences. It will also be manually checked by investigators who are blinded to the level and identity of the participant. We will aim to recruit a minimum of 250 participants so that there is a stable reliability value, each of whom will be allocated a participant number to pseudonymise the data. The results will be analysed only when recruitment has ended.

4. Study Outcome Measures

4.1 Primary Outcome

The primary outcome will be the development of a validated, reliable and defensible assessment tool to test UGRA interpretation skills.

4.1 Secondary Outcomes

The secondary outcomes are development a validated, reliable and defensible assessment tool assessing anatomical, clinical knowledge and the performance of ultrasound guided regional anaesthesia:

• Assessment of anatomical knowledge relevant to performing a local anaesthetic injection around peripheral nerves

• Assessment of clinical regional anaesthesia knowledge relevant to performing a local anaesthetic injection around peripheral nerves

• Assessment of the performance of an ultrasound-guided local anaesthetic injection around peripheral nerve

5. Participant Entry

5.1 Pre-registration Evaluation

Participants will be required to complete the following tasks to be involved in this research:

- Read a participant information sheet (PIS) about the study.
- Face to face or virtual explanation and consent of the study will be taken by one of the study team members (PI's or co-investigators); written or online consent (digital signature)

5.2 Participant Recruitment

Consultant and trainee anaesthetists across the breadth of the curriculum stages, will be invited to participate by email. All potential participants will be given a PIS (approved by a Research Ethics Committee) describing the study on recruitment. The participant will have time to read the PIS and to discuss their participation with study administrators, as required, before providing written consent.

5..3. Inclusion criteria

Any anaesthetic trainee currently registered with the Royal College of Anaesthetists in a UK-training programme and practising consultant anaesthetists who are registered with the General Medical Council.

5..4. Exclusion criteria

Staff grade, associate specialist and specialty doctors not enrolled in a UK anaesthetic training programme will be excluded because they encompass a wide range of different experience in regional anaesthesia. Co-investigators, local investigators and pilot test participants will be excluded due to prior experience with the assessment tool.

5.5. Participant withdrawal

Each participant has the right to withdraw at any time. The data will be collected in an pseudonymised format. This means that a participant can withdraw from the study. In order to withdraw from the study a participant will need to contact the Chief Investigator. This will be explained in the participant information sheet.

6. Assessment

6.1 Definition of end of trial

The end of the trial will be when the required number of anaesthetists have completed the web-based test for the validation phase of the study. The data will then be locked for analysis.

6.2 Likely rate of loss to follow up

Losses to follow up are expected to be very few, as each participant will be expected to complete the online test in one sitting. However, in the case of individuals failing to complete the test (e.g. registered but did not take the test, attempted too few questions), their scores will be excluded from the final analysis. We will build an expected loss to follow up of 10% when powering the study.

6.3 Expenses

Participants will not be paid expenses for taking part.

7. Statistics and Data Analysis

7.1 Sample Size Calculation

Sample size for the definitive data capture stage, 'Phase 5 – Psychometric main study testing', will be calculated using a power calculation based on data obtained in the pilot work during 'Phase 3 – Preliminary testing'. For example, internal reliability of the item responses is to be assessed using Cronbach's alpha, an alpha value of 0.70 being considered adequate. With 250 participants completing a 50-item questionnaire it would be possible to show that Cronbach's alpha is significantly higher than 0.6 if the true value is 0.7 i.e. there is

a greater than 85% chance (power) that the 95% confidence interval for Cronbach's alpha will exceed 0.6 and include 0.7.

7.2 Trial Methods

7.2.1 Blinding

The investigators will be blinded to the level of training when checking the automatic marking of the test answers.

7.2.2 Measures taken to avoid bias

All tests will be anonymised and marked automatically by the web-based application to avoid bias. Answers will be checked by local investigators, who will be blinded to the identity of the participant.

It is important to recognise that due to the change in the RCoA curriculum, some participants will be familiar with the CRQ format while others might be more familiar with MCQ-based format, or other forms of assessment question. Participants in the pilot and main study will be provided with sample questions and answers prior to the test to familiarise themselves with the question format.

7.3 Plan of Analysis

We have taken advice from the Imperial College statistician, Mr Roger A'Hern.

The primary outcome will be analysed using a series of calculated indices and statistical tests. A difficulty index will be calculated by dividing the number of correct responses by the total number of responses, with a difficulty index <50% considered sufficient to exclude an item from the test. Content validity will be calculated by asking an expert panel to rate items in the test on a 4-point scale as definitely not suitable, probably not suitable, probably suitable and definitely suitable. A validity index of > 0.78 will be considered sufficient to include a question. Construct validity will be measured using a one-way analysis of variance (ANOVA)/ Rasch modelling, internal reliability using Cronbach's alpha (with a value of 0.70 considered sufficient), and internal consistency using a split-test method.

7.3.1 Frequency of analyses

The primary analysis will take place when the pilot study recruitment is complete in phase 3. This will be used to guide the generation of the final version used in the next phase. Then the analysis of the phase 5 validation study will take place when recruitment for this test is complete. No interim analysis is planned.

7.3.2 Criteria for the termination of the trial

The study may be terminated early if the results of another study make it redundant, or on safety grounds.

7.3.3 Economic issues

There will be no formal economic analysis.

7.3.4 Data storage

All data will be stored in anonymised form and analysed on NHS Trust computers.

Data and all appropriate documentation will be stored for a minimum of 5 years after the completion of the study.

8. Regulatory Issues

8.1 Ethics Approval

The Study Coordination Centre has obtained approval from the xxx Research Ethics Committee (REC) and Health Regulator Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 Consent

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons will be respected. All participants are free to withdraw at any time from the protocol without giving reasons.

8.3 Confidentiality

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act. Data will be pseudonymised.

Each participant will be identified by a unique sequential number identifier allocated to them and this information and all data collected will be stored in the master file in the Primary Investigator's locked office on the hospital site.

8.4 Indemnity

Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Resolution for NHS Trusts in England, which apply to this study.

8.5 Sponsor

Imperial College Healthcare NHS Trust will act as the main Sponsor for this study.

8.6 Funding

This study is unfunded

8.7 Audits

The study may be subject to inspection and audit by Imperial College Healthcare NHS Trust under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

9. Study Management

The trial will be managed by a Trial Management Group (TMG). The TMG will be chaired by a Chief Investigator and will include all members of the named research team (see Chief Investigators & Research Team Contact Details).

A study principal investigator will be responsible for identifying potential participants, seeking informed consent, collecting trial data and ensuring adherence to the trial protocol.

10. Publication Policy

We anticipate that the results will be published in a peer-reviewed journal and may be presented at a national and international conferences.

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12. Appendix

The following link allows you to view sample question(s) that would be posed to the participants

https://1drv.ms/u/s!AoKOa_qdcBwN7xRgYp6889QRs-qh?e=4pd9f2

All ultrasound images are taken from voluntary study team members or NHS patients. These images are fully anonymised and contain no staff and/or patient information and cannot be identified by anyone even study team members. Verbal consent has been gained from all volunteers and NHS patients explaining these images are used for educational purposes as is the nature of this assessment tool being developed.