Evaluating the integration of a guided 3D ultrasound imaging system (CUS) operated by non-specialist staff in a community urology setting

Version: V1.3, 04/11/2026
IRAS 374406

Study Management Group

Chief Investigator: Jade Dougoud, Biomedical Researcher
Co-investigator: Jason Carrier, Sonographer and CUS Engineer, Technical Lead
Co-investigator: Matthew Liew, Consultant Urological Surgeon, Clinical Lead

Sponsor
CarrierTech Ltd is the research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Chief Investigator.

Funder
This study is funded by the National Institute for Health and Care Research (NIHR) Invention for Innovation (i4i) FAST programme (award NIHR521955).

This protocol describes the urology CUS community integration 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 Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act 2018 and UK General Data Protection Regulation (UK GDPR), and other regulatory requirements as appropriate. The Medicines and Healthcare products Regulatory Agency (MHRA) has confirmed in writing that, in its current use as evaluated in this study, CUS does not meet the definition of a medical device.

© CarrierTech Ltd

TABLE OF CONTENTS

1. INTRODUCTION **3**
1.1 Background 3
1.2 Study Rationale 3
2. STUDY OBJECTIVES **4**
3. STUDY DESIGN **5**
3.1 Methodology 5
3.2 Outcomes, pre-specified criteria and analysis 6
3.3 Quantitative sample size 8
3.4 Qualitative sample size and analysis (operator and clinician interviews) **9**
3.5 Gantt chart 10
4. PARTICIPANT RECRUITMENT **10**
4.1 Pre-recruitment evaluations 10
4.2 Inclusion Criteria 10
4.3 Exclusion Criteria 11
4.4 Withdrawal Criteria 11
5. ADVERSE EVENTS **11**
5.1 Reporting Procedures 12
6. ASSESSMENT AND FOLLOW UP **13**
7. REGULATORY **14**
7.1 Ethics approval 14
7.2 Consent 14
7.3 Confidentiality 14
7.4 Document handling, pseudonymisation and transfer of records**Error! Bookmark not defined.**
7.5 Indemnity 16
7.6 Sponsor 16
7.7 Funding 16
7.8 Audits 16
8. PUBLICATION POLICY **16**
9. REFERENCES **17**

© CarrierTech Ltd

1. INTRODUCTION

1.1 Background

Diagnostic ultrasound is among the most frequently requested investigations in UK primary and community care, but access is constrained by a national shortage of trained sonographers, averaging 24% [1]. Patients referred for bladder, prostate, or pelvic ultrasound commonly wait six to twelve weeks for a hospital-based appointment [1]. For older adults, people with limited mobility, and those living in deprived or geographically isolated communities, the wait is compounded by the burden of travelling to a hospital site. Diagnostic access correlates inversely with deprivation [2]. The consequence is that conditions which are readily treatable when identified early, such as prostate cancer, are diagnosed later in the populations least able to absorb the delay.

CUS (Computed Ultrasound) is a portable, handheld imaging system developed by CarrierTech Ltd that can be operated by a trained healthcare assistant (HCA), nurse, or clinician at the point of care, without specialist sonography skills or fixed imaging infrastructure. The system uses on-screen prompts during acquisition, automatically verifies that the whole organ has been captured, and reconstructs a three-dimensional anatomical volume in under three minutes. Outputs are produced in standard NIfTI/DICOM formats for remote review through existing picture archiving and communication system (PACS) infrastructure. Three clinical modules are commercially available: Prostate; Kidney, Ureter and Bladder (KUB); and Trans-abdominal Pelvic.

An independent clinical evaluation of 88 patients in a community clinic setting demonstrated high concordance between CUS and conventional hospital ultrasound across these pathways [3]. What has not yet been assessed is whether CUS can be operationally integrated into a real community clinic workflow: whether non-specialist staff can deliver it autonomously within routine clinic activity, whether patients and clinicians accept it as part of a community-first diagnostic pathway, and the impact on the clinic's activities. This evidence is a main requirement for adoption decisions by Integrated Care System (ICS) commissioners and community providers [4].

1.2 Study Rationale

Aims:

- This project aims to assess whether CUS can be embedded into the routine workflow of a community urology clinic, in the hands of non-specialist staff, in a manner that is feasible, acceptable to patients and clinicians, and capable of informing clinical management.

Research question:

- Can CUS be successfully embedded into a community clinic setting, operated by non-specialist staff, in a manner that integrates into the clinic workflow and is accepted by both clinicians and patients as part of a community-first diagnostic pathway?

Hypothesis:

- CUS scanning delivered by trained non-specialist staff will integrate into the existing clinic workflow without prohibitive operational burden, and will be acceptable to patients and operators.

© CarrierTech Ltd

2. STUDY OBJECTIVES

The primary study objective is to assess whether CUS can be operationally integrated into a community urology pathway when operated by non-specialist staff. The primary outcome is Operational Integration, evaluated through the following pre-specified primary process metrics:

- Scan completion / adequacy rate: the proportion of scans performed by trained healthcare assistants judged adequate for reporting (target ≥90%). Image adequacy is rated pass / fail by the independent sonographer.
- Operator usability: measured using a validated instrument (System Usability Scale), supplemented by semi-structured operator interviews.
- Clinic operational feedback: semi-structured interviews with operators, clinicians, and supporting staff, to identify any prohibitive operational burden and to report added cost and benefit at clinic level.
- Time-to-result: time from the CUS scan to an available report, and, where the participant is also referred for conventional ultrasound, compared with that conventional referral-to-report interval.
- Patient acceptability and experience: satisfaction and acceptability questionnaire completed by every participant.
- Healthcare assistant competency sign-off rate.
- Upstream and downstream resource impact: operating / reporting time per CUS scan, and urology nurse and consultant appointments avoided or generated, derived from clinic activity data, semi-structured interviews and broad estimates.

The secondary study objectives are:

- Pathway integration: the proportion of CUS findings judged sufficient to inform clinical management without onward imaging referral.
- Landmark clarity rating of CUS acquisitions.
- Uptake, completion and attrition data, and competency data across operators and sites.

This study is additionally designed to generate the input parameters required for a subsequent health-economic analysis: reporting time per CUS scan, onward-referral rate, and the effect of the pathway on urology appointment demand. The health-economic modelling itself sits outside the scope and budget of this award and is not undertaken here; however a health economist co-produced the intended study outputs, which are intended to support the future health-economic modelling and to inform the commissioner implementation guide.

The study is an operational-integration and implementation study and is not designed as a diagnostic-accuracy study; concordance with conventional ultrasound has been established previously and is examined here only to confirm that diagnostic quality is retained in a different community setting. The sample size is determined by the precision required for the primary process metric and the operational exposure required to characterise integration; this is specified in Section 3.3.

© CarrierTech Ltd

3. STUDY DESIGN

3.1 Methodology

The study design is a multi-site, prospective, observational study of the integration of CUS into urology clinics. Participation does not alter standard care: patients attending the clinic for a urology or prostate-related concern who would benefit from an ultrasound will be offered a CUS scan alongside, and in addition to, their standard care pathway. Participant feedback will be collected following the scan. Eligibility includes individuals who would benefit from an ultrasound but do not receive a referral: in several areas, waits for conventional ultrasound of a year or more mean that patients who would benefit are not referred, or are directed elsewhere, and this group would benefit from inclusion in this study to encourage future adoption by clinics in similar position. Where a participant is also referred for conventional ultrasound as part of standard care, that referral proceeds unchanged whether or not they take part, and, with the participant's separate consent, the resulting ultrasound image and report are transferred to the study, anonymised to study number by the site, to serve as the paired comparator. This design generates integration evidence, with minimal disruption to the existing care pathway. As a contingency where a single practice cannot generate sufficient throughput to meet the per-site minimum of 34 evaluable scans, adjoining practices may refer eligible patients to a designated hub site for scanning. The hub is the participating site: it holds the enrolment log, takes consent, and acts as data controller. Referring-practice origin is recorded as a covariate. Data collection will run simultaneously or sequentially at multiple sites depending on site output and hardware availability.

CUS scans will be performed by operators employed at the host site, who will have completed a structured training programme delivered by a qualified sonographer and achieved documented competency sign-off before any participant is scanned. Real-time AI guidance and automated image completeness checks operate during every acquisition. Final image quality assessment is made by the reviewing clinician. Reconstructed volumes will be uploaded to PACS in standard NIfTI/DICOM format and reported remotely. An independent sonographer with no affiliation to CarrierTech will perform the blinded scan reports, and, for the subset of participants who are also referred for conventional ultrasound and consent to its transfer, randomised paired review against that ultrasound, providing the reference standard for the secondary concordance outcome.

Operator usability data will be collected across the scanning period. Semi-structured interviews with the operators, and with the clinicians receiving CUS reports, will be conducted towards the end of the scanning period; these are expected to last approximately 30 minutes, will be audio recorded with consent, and transcribed. Recordings will be deleted once transcribed, and all personal identifiable information will be removed from transcripts. Transcribed data will be analysed using thematic analysis, with the initial coding framework developed independently by two researchers and refined by the team. Patient acceptability will be collected by structured questionnaire at the study visit; they will not be interviewed.

A Patient and Practitioner Advisory Group (PPAG), containing no CarrierTech employees or affiliates, will be established at study start, Month 1. The PPAG will review the AI-guidance interface; review patient-facing materials, the consent process, the satisfaction questionnaire

© CarrierTech Ltd

and the post-study participant report; and review all data-collection instruments before deployment.

Consent forms and patient leaflets will be professionally translated into the three most common non-English languages spoken at the study site.

Each participating site is issued a block of study numbers in the format “SXX-nnn”, where the prefix SXX denotes the site. A study number is allocated to each participant at the point of consent by a member of the site team delegated for this task, and recorded in the site enrolment log against the participant's name.

Each participating site maintains its own enrolment log, the sole record linking participant identity to study number, comprising participant name, contact details, study number, consent status and withdrawal status. The enrolment log is held only at the site that created it, under that site's controllership and access controls, and is never transferred to CarrierTech. CarrierTech Ltd holds no master identity store and no participant identifiers; it receives and holds only study-number-keyed research data. Clinicians receiving standard-care ultrasound reports anonymise those reports to study number, using the site's own enrolment log, before transfer to the research team. All research data (imaging, questionnaire, interview and operational data) are recorded, transferred, stored and analysed against the study number only. Because CarrierTech cannot access the site enrolment logs, its copy of the research dataset is pseudonymised in its hands and becomes anonymous once those logs are destroyed (Section 7.3).

Site-held custody of identifiers is adopted so that the ability to re-identify a participant rests only with that participant's own site and can be extinguished at study close. CarrierTech, as Sponsor, retains the study-number research dataset for the archival period but holds no means of re-identification. Participants exercise withdrawal and other data subject rights through their site, which alone can locate their records; retention and destruction of the enrolment logs and consent forms are set out in Section 7.3.

The study will be conducted over 12 months, with planned: months 1-2 for governance, site agreements and equipment; months 2-4 for operator training, competency sign-off and PACS integration testing; months 3-9 for participant recruitment, scanning and data collection; and months 10-12 for analysis, reporting and dissemination.

3.2 Outcomes, pre-specified criteria and analysis

Outcome	Definition and pre-specified criterion	Analysis

© CarrierTech Ltd

Scan adequacy (primary)	Proportion of operator-performed scans judged adequate for reporting, rated pass/fail by the independent sonographer against image quality and image completeness. Pre-specified benchmark ≥90%.	Proportion reported per operator and per site with bilateral Wilson 95% CI (primary presentation); the design-adjusted pooled proportion (§4.5) is the primary estimand against which the pre-specified ≥90% benchmark is reported.
Operator usability	System Usability Scale (SUS) score per operator, feedback questions.	Median (IQR); descriptive.
Clinic operational feedback	Semi-structured interview themes (prohibitive burden, added cost/benefit). Questionnaires.	Thematic analysis (§4.7). Median (IQR); descriptive.
Time-to-result	Interval from CUS scan to available report, compared with the conventional referral-to-report interval. Where the scan is on a different day from the clinic appointment, the interval from appointment to report is also recorded.	Median (IQR); descriptive paired comparison.
Patient acceptability	Satisfaction/acceptability questionnaire.	If ordinal: median (IQR) and category distribution with simultaneous 95% CIs (Sison–Glaz). If binary: proportions with bilateral Wilson 95% CI. Descriptive.
Competency sign-off	Supervised scans to sign-off, per operator; sign-off rate across operators.	Descriptive; training-phase output (§4.6).
Upstream/downstream resource impact	Reporting time per CUS scan; onward-imaging referral rate; urology appointments avoided/generated.	Descriptive (means/medians, proportions); from clinic activity data, interviews and broad estimates.

© CarrierTech Ltd

Workflow-efficiency curve	Scan and setup time against cumulative scans per operator; plateau defined as the point beyond which the moving estimate remains within 10% of the fitted asymptote.	Pre-specified model, e.g. negative-exponential to asymptote; descriptive, per operator. Contingent on §4.6.
Pathway integration	Proportion of CUS findings sufficient to inform management without onward imaging referral.	Proportion with Wilson 95% CI; descriptive.
Concordance	Cohen's κ, CUS vs conventional scan, on the subset with a reported conventional scan.	κ with 95% CI; descriptive (§4.5, and subset caveat below).
Landmark clarity	Sonographer clarity rating per scan.	Median (IQR) and category distribution with simultaneous 95% CIs (Sison–Glaz); descriptive.

Quantitative measures are analysed descriptively: continuous measures as means (SD) or medians (IQR); proportions with Wilson 95% CIs. Where a conventional ultrasound is performed, time-to-result for the CUS pathway is compared descriptively with the participant's conventional referral-to-report interval. Completeness is reported as an outcome.

3.3 Quantitative sample size

As an operational-integration study, the sample size is determined by the precision required for the primary process metric and by the operational exposure required to characterise workflow integration. Because one operator is trained per site, operator and site coincide and observations are clustered within site; all sample-size and precision statements below are therefore design-adjusted and no unadjusted pooled interval is used.

Primary threshold metric: the primary metric is the scan adequacy rate (pass/fail, independent sonographer, benchmark ≥90%), estimated overall across sites. For $p = 0.90$ and a two-sided 95% Wilson interval, $n = 141$ gives a half-width of ±5.0%.

Adjustment for clustering: one operator is trained and competency-signed per site, so operator, site and cluster coincide. The requirement is inflated by $DEFF = 1 + (\bar{m} - 1)\cdot ICC$, with ICC assumed 0.02. At $\bar{m} = 34$ scans per site, $DEFF = 1.66$ and the requirement is 141 ×

© CarrierTech Ltd

1.66 ≈ 234 evaluable scans. No unadjusted pooled interval is reported. The ICC is an assumption; the realised ICC, mean cluster size and recalculated design effect are reported alongside the final estimate.

Target: Seven sites are targeted, giving a planned **238 evaluable scans (7 × 34)**, n_eff = 143 and a design-adjusted 95% interval of 84.0–93.9% at an observed adequacy of 90%. Up to **262 participants** are recruited to allow for withdrawal and non-evaluable scans. Per-site adequacy is presented descriptively (per-site half-width ±10.4%); the threshold comparison is made on the pooled adjusted estimate.

Should additional sites beyond seven be secured, the **per-site minimum of 38** evaluable scans and scanning window of two weeks is maintained, for the results to be representative of the integration of a new system in a clinic's operations. The additional data improve pooled precision, the reliability of the ICC estimate and generalisability across operators, and the realised precision is reported as achieved.

Per-site exposure: each site scans for a minimum of two weeks of routine operation and until 38 evaluable scans are obtained, whichever occurs later. At the predicted minimum throughput of ≥7 evaluable scans per week, 38 scans corresponds to approximately six weeks of operation.

A count-based stopping rule would allow a higher-throughput site to complete recruitment within the initial adoption phase, during which the device is still being consciously accommodated into clinic activity rather than used as settled routine; integration, the outcome of interest, is by definition the state reached after this novelty phase has normalised. A minimum window of two weeks ensures every site is observed through the transition into habituated use, equalises exposure-to-normalisation across sites of differing volume, and provides the sustained exposure required to observe the workflow-efficiency curve as the operator settles into routine use.

Contingency for fewer sites: the attainable half-width is bounded below by $z \cdot \sqrt{(p(1-p)/n_eff)}$. At five sites the ±5.0% target requires approximately 38 scans per site and is met; at four it is not (±6.6%). Where fewer than seven sites are secured, the precision target is revised to the value attainable at the realised configuration and reported as realised rather than met. At two sites the primary operational-integration outcomes remain estimable, but pooled precision and generalisability are reduced and reported as limitations.

3.4 Qualitative sample size and analysis (operator and clinician interviews)

Semi-structured interviews with operators and referring / receiving clinicians; expected total no more than 20 individuals. The sample size is justified by information power [9] rather than

© CarrierTech Ltd

by statistical precision or a fixed saturation count. Four considerations indicate that a small sample carries adequate information power here:

- Narrow aim: whether CUS embeds into clinic workflow and is acceptable to operators and clinicians, not broad theory development.
- Dense, specific sample: participants are the actual operators delivering CUS and the referring clinicians / clinicians receiving its reports, i.e. maximally relevant informants.
- Bounded population: with one operator per site, interviewing all operators is a near-census; the cap accommodates receiving clinicians.
- Focused analysis: thematic analysis with an a priori framework aligned to the integration constructs, supporting adequacy at lower N than exploratory grounded-theory work.

Thematic saturation is expected within this range; recruitment of clinician interviewees may be extended modestly toward the cap if new operational themes are still emerging. Transcripts are analysed by thematic analysis, with the initial coding framework developed independently by two researchers and refined by the team (NVivo).

3.5 Gantt chart

NIHR i4i FAST 2026/387 : Project Timeline (Gantt Chart)

CarrierTech : Evaluating Usability of AI-Guided 3D Ultrasound in Community Settings

WP	Task / Activity	Start	End	Sep 26	Oct 26	Nov 26	Dec 26	Jan 27	Feb 27	Mar 27	Apr 27	May 27	Jun 27	Jul 27	Aug 27
WP1	**Ethics & governance**	1	2												
	Site agreements & setup	1	2												
	Equipment procurement	1	2												
WP2	**HCA training**	2	4												
	PACS/DICOM integration	2	3												
WP3	**Patient recruitment & scanning**	3	9												
	Usability & satisfaction data collection	3	9												
	Concordance data (secondary outcome)	3	9												
WP4	**Statistical analysis**	10	11												
	Publication & write-up	10	12												
	Implementation guide	11	12												
WP5	**Knowledge mobilisation framework**	1	12												
	Patient and Professional Advisory Group	1	12												

KEY MILESTONES

- HRA/REC submitted
- REC approval / recruitment
- Recruitment complete
- Final report & publication submitted

4. PARTICIPANT RECRUITMENT

4.1 Pre-recruitment evaluations

All participants will be screened against the inclusion and exclusion criteria below before recruitment into the study. Potential participants will be identified by the clinic team from

© CarrierTech Ltd

patients booked-in to attend a urology appointment for a urology or prostate-related problem. They will be introduced to the study by a member of the clinical team, in person or via text. They will be given a Participant Information Sheet (PIS), and given the opportunity to ask questions. The CUS scan is offered alongside standard care. No study procedure will take place before written informed consent has been obtained.

Operator and clinician participants (for usability data and interviews) will be approached directly by the research team, given the relevant PIS, and given 72 hours in which to consider participation; if they wish to participate within a shorter time frame after reading the PIS, they will be allowed to do so. They may choose to participate in the written questionnaire, the semi-structured interview, or both. Data collection will take place during the next convenient time for both the participant and the researcher following participant consent.

4.2 Inclusion Criteria

Urology patient participants:

- Adults aged 18 or over
- Seeking clinical care for a urology or prostate concern
- Referred for a pelvic, prostate, or bladder ultrasound, or would benefit from an ultrasound referral (according to NICE guidelines [6-8])
- Willing and able to give informed consent

Operator and clinician participants:

- HCA, nurse or clinician involved in delivering CUS scanning or receiving CUS reports
- For operators: completion of the study training programme and competency sign-off
- Willing and able to give informed consent

4.3 Exclusion Criteria

Patient participants:

- Unable to give informed consent
- Unable to tolerate a trans-abdominal ultrasound scan
- Broken or infected skin over the scanning area, or known allergy or sensitivity to water-based ultrasound gel
- Clinical presentation requiring urgent or emergency imaging, as judged by the treating clinician

Operator and clinician participants:

- Unable to give informed consent

4.4 Withdrawal

It will be made clear to participants during the consent process that they are free to withdraw from the study at any time by contacting their site, without giving any reason, and that this will have no effect on their clinical care or on their involvement in future studies. Should a participant withdraw, the site identifies their records from its enrolment log and their study-number data are deleted from the study database and any paper records destroyed, except where analysis using their data has already taken place and cannot be undone; this is

© CarrierTech Ltd

explained in the PIS. Because only the site can re-identify a participant, withdrawal requests are made to the site, which notifies CarrierTech by study number only and provides written confirmation to the participant. Withdrawal of already-collected data is possible up to the point at which the site enrolment log is destroyed (Section 7.3), after which the data are anonymous and can no longer be identified or withdrawn; this cut-off is explained in the PIS and consent form.

5. ADVERSE EVENTS

Trans-abdominal ultrasound is a non-ionising, non-invasive investigation in routine clinical use, and the CUS scan performed in this study is of the same nature as a standard-of-care ultrasound scan, using off-the-shelf CE marked ultrasound hardware. The anticipated risks are minimal: transient discomfort from probe pressure or coldness of the gel, and skin irritation in individuals sensitive to water-based ultrasound gel (excluded at screening). Participants may ask for the scan to be stopped at any point, and it will be stopped immediately on request or if the participant shows any distress. The scan is expected to last under a minute. The host clinic is a staffed clinical environment with clinicians present during all scanning sessions.

Incidental or clinically significant findings: all CUS volumes are reported by a radiologist or sonographer. Any finding requiring clinical action will be communicated to the participant's referring clinician through the clinic's standard results pathway, and the participant informed by their clinical team in the usual way. The study does not remove, replace or delay any element of standard care, including any conventional ultrasound referral the participant may have.

CUS reports are research outputs and are not diagnostic reports, in this context. Every report carries a standard notice to this effect. Where the participant is referred for a standard-of-care ultrasound, that referral proceeds unchanged and is neither replaced nor delayed by participation. Clinical management remains at all times the responsibility of the participant's referring clinician within usual care.

Notwithstanding this, the study team does not withhold findings of potential clinical significance. All CUS acquisitions are reviewed by a qualified sonographer. Where a finding of potential clinical significance is identified, the sonographer notifies the referring clinician and the Site Principal Investigator within one working day making the report, by the agreed route, in addition to the routine report. The notification records the finding and states that it is a research finding requiring clinical interpretation. The referring clinician determines what, if any, clinical action follows, within usual care and on the standard-of-care pathway. Notifications and the resulting action are logged. Where a finding suggests an urgent condition, the escalation is immediate and by direct contact rather than by written report.

Where the participant has a standard-of-care ultrasound that has not yet been performed at the time of escalation, the referring clinician is reminded that it remains outstanding.

© CarrierTech Ltd

5.1 Reporting Procedures

All adverse events (AEs) should be reported. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

5.1.1 Non serious AEs

All such events, whether expected or not, should be recorded in the study file.

5.1.2 Serious AEs

A Serious Adverse Event (SAE) form should be completed and emailed to the Chief Investigator within 24 hours. All SAEs should be reported to the reviewing Research Ethics Committee where the Chief Investigator believes the event was:

- ‘related’, i.e. resulted from the administration of any of the research procedures; and
- ‘unexpected’, i.e. an event that is not listed in the protocol as an expected occurrence

SAEs will additionally be reported to the study Sponsor and, as a condition of the award, notified to the NIHR through routine progress reporting.

6. ASSESSMENT AND FOLLOW UP

Patient participants attend a single study visit; there is no study follow-up visit. Participants who attend a separate study clinic session, rather than having the scan alongside a routine appointment, will be offered reimbursement of reasonable travel expenses (up to £20 per visit, on receipt), paid by the site and recharged to the Sponsor. Reimbursement is not offered for visits combined with routine care. Payment details are handled by the site only and are not shared with the Sponsor.

The visit is not expected to add more than 30 minutes to the participant’s attendance and comprises:

- Confirmation of eligibility and written informed consent, including, where applicable, optional consent to transfer of any subsequent conventional ultrasound image and report
- Brief demographics (age, weight, ethnicity, height, and postcode), recorded against study number only
- CUS scan of the relevant pathway (prostate, KUB or trans-abdominal pelvic) indicated by the presenting problem, performed by a trained operator
- Patient acceptability and satisfaction questionnaire (paper or electronic), completed immediately after the scan

Operational data recorded at each scan will include:

- setup time, scan duration, and the number of acquisition attempts;
- first-pass image capture success and upload success;
- time-to-result, defined as the interval from the CUS scan to an available report, and, where the participant is also referred for conventional ultrasound, recorded alongside that referral-to-report interval for the same participant's standard-care pathway;

© CarrierTech Ltd

- any interruption to, or displacement of, routine clinic activity attributable to the scan.

Operator competency sign-off will be recorded per operator, including the date of sign-off, the number of supervised scans required to reach competency, and the competency sign-off rate across the operators trained. Operator SUS scores will be collected at defined intervals across the scanning period. Semi-structured interviews with operators and receiving clinicians will be conducted as described in Section 3; transcripts will be managed using NVivo software and analysed using thematic analysis.

All CUS acquisitions are reviewed by the independent sonographer, who records a pass / fail image adequacy rating and a landmark clarity rating for each scan. Scan completion and adequacy rates will be reported per operator and per site against the target of ≥90%.

Appointments avoided or generated will be derived from clinic activity data, from the semi-structured interviews, and, where activity data are incomplete, from broad estimates agreed with the site.

For the secondary concordance outcome, where a participant's standard-of-care ultrasound is subsequently performed and reported, the independent image reviewer will conduct a randomised paired review of the CUS volume against the conventional study. Agreement will be summarised descriptively and using appropriate agreement statistics (e.g. Cohen's kappa for categorical findings).

Quantitative data will be analysed descriptively: continuous measures as means (SD) or medians (IQR), proportions with 95% confidence intervals. Time-to-result for the CUS pathway will be compared descriptively with the participant's conventional pathway. Data will be reported in aggregate and graphically and, where numbers permit, disaggregated by site and by operator to describe variation across the clinic environments and the trained operators. Uptake, completion and attrition rates will be reported to inform subsequent study design. No imputation of missing data will be performed; completeness will itself be reported as an outcome.

7. REGULATORY

7.1 Ethics approval

The Chief Investigator will obtain a favourable opinion from an NHS Research Ethics Committee before any participant is approached. The study involves NHS patients, staff, and premises, and a SoECAT was therefore approved by an AcoRD specialist. 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. The MHRA has confirmed in writing that CUS, in the use evaluated in this study, does not meet the definition of a medical device; the study is accordingly not a clinical investigation of a medical device and does not require MHRA notification.

7.2 Consent

© CarrierTech Ltd

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information sheet offered, and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected, and declining will have no effect on the participant's clinical care. All participants are free to withdraw at any time. Because the study can offer a same-day scan alongside a clinic attendance the participant has already made, patients may consent on the day; the consent discussion will make explicit that taking part is optional, additional to their standard care, and of no direct clinical benefit to them. Translated consent forms and information sheets will be available in the three most common non-English languages spoken at the study site, and a web-based consent interface will be available as an alternative to paper.

7.3 Confidentiality

The Chief Investigator will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the UK GDPR for health and care research. Each participating site is the Controller of the identifiable study records it holds, namely its enrolment log and the signed consent forms of its participants; these are held at the site and are not transferred to CarrierTech. CarrierTech Ltd is the Controller of the study-number research dataset and, as Sponsor, is custodian of that dataset; it holds, and can access, no participant identifiers. This controllership split will be confirmed in the Data Protection Impact Assessment and reflected in the site agreements.

The study-number research dataset is held on access-controlled CarrierTech systems, encrypted at rest and in transit, with role-based permissions and audit logging. Each site maintains its own enrolment log, linking only that site's participants to their study numbers; access is limited to the delegated site staff and the responsible clinicians at that site, for enrolment, for returning results, and for anonymising standard-care reports before transfer. The enrolment log is held securely at the site (an encrypted electronic store, or a locked cabinet in a restricted-access area) and is never shared with CarrierTech. CarrierTech and each site will meet the requirements of the NHS Data Security and Protection Toolkit, or an equivalent standard of information governance, under the site agreements. Personal data breaches are managed under the relevant Controller's breach procedure and notified within 72 hours where the threshold is met.

Retention and destruction are as follows. The site enrolment log, the only record linking identity to study number, is retained by the site solely until study close-out and completion of final data reconciliation, and is securely destroyed no later than 6 months after the end of the study; on its destruction the study-number research dataset becomes anonymous and no participant can thereafter be re-identified. Signed consent forms are retained by the site, in the Investigator Site File, for 5 years after the end of the study as the record that valid consent was obtained, and are then securely destroyed. CarrierTech retains the study-number research dataset and associated study documentation for a minimum of 10 years after the end of the study, after which they are securely destroyed in accordance with the study retention and destruction schedule. All destruction is documented, and the site issues a certificate of destruction for the enrolment log.

© CarrierTech Ltd

7.4 Document handling, pseudonymisation and transfer of records

Electronic capture is the default. The patient acceptability and satisfaction questionnaire and the operational forms are completed through the study web interface wherever practicable, entered against study number only, and transmitted directly to CarrierTech. The consent form is completed and held at the site and is not transmitted to CarrierTech. Paper completion is a documented fallback where electronic capture is not practicable at a site or where a participant prefers it.

Where paper is used, two streams are distinguished.

Signed consent forms are identifiable by nature and cannot be pseudonymised; they carry the participant's name but no study number, so a consent form cannot itself be used to link a participant to their study data. They are held only at the site and are not transferred to CarrierTech. Consent forms are held in the Investigator Site File in a locked cabinet in a restricted-access area, retained for the period specified in Section 7.3, and are not scanned, uploaded or couriered to CarrierTech.

Questionnaires and operational forms carry a study number field only and no name field. The study number is entered on the form by the delegated site staff member before the form is given to the participant, and participants are asked, verbally and in writing on the form, not to write their name or any other identifying detail on it. These forms are the source data and are transferred by scan and secure upload as above, with originals retained at the site until closeout.

Completed forms are not left unattended in clinical areas and are placed directly into an opaque study folder held in a locked cabinet in a restricted-access area at the site.

At monthly intervals and at site closeout, each site reconciles its own records: the number of signed consent forms held and the number of enrolment-log entries must correspond to the number of participants enrolled at that site. In parallel, CarrierTech confirms that the count of study-number records it has received matches the enrolment count reported by the site, by study number and totals only, with no identifiers exchanged. Discrepancies are investigated and documented.

CUS acquisitions are labelled with the study number at the point of acquisition. The reported findings are returned to the participant's site under study number; the site re-identifies the participant from its own enrolment log and passes the result to the responsible clinician through the site's standard results process. Re-identification and clinical follow-up remain the site's responsibility, and CarrierTech takes no part in de-pseudonymisation.

Staff participants are allocated study numbers on the same basis. Interview recordings are made under study number only, transcripts are checked and identifiers removed before analysis, and recordings are deleted once transcription is verified.

© CarrierTech Ltd

7.5 Indemnity

CarrierTech Ltd holds professional and public liability insurance policies which apply to this study.

7.6 Sponsor

CarrierTech Ltd will act as the main Sponsor for this study.

7.7 Funding

This study is funded by the NIHR i4i FAST programme (award NIHR521955). Jason Carrier and Jade Dougoud are founders of CarrierTech Ltd, the company that developed CUS, and therefore have a direct commercial interest in its successful evaluation. This interest is declared transparently, and the following safeguards are built into the study design: co-investigator and clinical lead with no affiliation to CarrierTech; independent blinded or randomised (as appropriate) radiological review by a sonographer with no affiliation to CarrierTech; independent review of the statistical analysis by a statistician with no affiliation to CarrierTech; a PPAG containing no CarrierTech employees or affiliates; and publication of all findings regardless of outcome.

7.8 Audits

The study may be subject to inspection and audit by CarrierTech Ltd under its remit as Sponsor, and to the monitoring and reporting requirements of the NIHR as funder.

8. PUBLICATION POLICY

Findings from this study will be published in a peer-reviewed open-access journal in accordance with the NIHR Open Access policy, and presented at a relevant UK clinical conference (e.g. the British Medical Ultrasound Society, BMUS). A plain-language summary and a short-form implementation guide will be shared directly with Greater Manchester ICS and community provider networks, and made publicly available. All results will be published regardless of outcome. No identifiable data will be used. Participants will be sent a summary of the aggregate findings at the end of the study.

9. REFERENCES

1 NHS England. Diagnostic Waiting Times and Activity Data, November 2024. https://www.england.nhs.uk/statistics/statistical-work-areas/diagnostics-waiting-times-and-activity/

2 NIHR Health and Social Care Delivery Research. Diagnostic services and socioeconomic deprivation. https://www.journalslibrary.nihr.ac.uk/hsdr/published-articles/GJBB0820

3 Dougoud J, Carrier J . : Comparing AI-assisted acquisition computed ultrasound (CUS) of prostate, KUB and pelvis in the community to conventional ultrasound; 2026 *Manuscript.*

4 Greater Manchester Integrated Care Partnership. Strategy 2023–2028. https://gmintegratedcare.org.uk/wp-content/uploads/2023/04/gm-icp-strategy-190423.pdf

© CarrierTech Ltd

5 Brooke J. SUS: a ‘quick and dirty’ usability scale. In: Jordan PW, Thomas B, Weerdmeester BA, McClelland IL, eds. Usability Evaluation in Industry. London: Taylor & Francis; 1996.

6 National Institute for Health and Care Excellence. Suspected cancer: recognition and referral. NICE guideline NG12, June 2015 (updated October 2023). https://www.nice.org.uk/guidance/ng12

7 National Institute for Health and Care Excellence. Lower urinary tract symptoms in men: management. NICE guideline CG97, May 2010 (updated June 2015). https://www.nice.org.uk/guidance/cg97

8 National Institute for Health and Care Excellence. Prostate cancer: diagnosis and management. NICE guideline NG131, May 2019 (updated December 2021). https://www.nice.org.uk/guidance/ng131

9 Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. *Qualitative Health Research.* 2016;26(13):1753–1760. doi:10.1177/1049732315617444

© CarrierTech Ltd