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Authors: Beverly Snaith, Martine A. Harris, Bethany Shinkins, Michael Messenger, Andrew Lewington, Marieke Jordaan, Nicholas Spencer

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POINT OF CARE CREATININE TESTING IN DIAGNOSTIC IMAGING: A FEASIBILITY STUDY WITHIN THE OUTPATIENT COMPUTED TOMOGRAPHY SETTING.

Beverly Snaith,[1, 2] Martine A Harris,[1] Bethany Shinkins,[3] Michael Messenger,[3] Andrew Lewington,[4] Marieke Jordaan,[1] Nicholas Spencer[1]

1. Mid Yorkshire NHS Hospitals Trust, Wakefield, UK

2. University of Bradford, Bradford, UK

3. University of Leeds, Leeds, UK

4. Leeds Teaching Hospitals NHS Trust, Leeds, UK

Correspondence to: Professor Beverly Snaith

Address: Faculty of Health Studies, University of Bradford, Richmond Road, Bradford, BD7 1DP

Tel: +44 1274 232175

e-Mail: b.snaith@bradford.ac.uk

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The funding agency had no role in: the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; nor decision to submit the manuscript for publication.

Highlights:

1. Screening questionnaires can identify risk factors for post-contrast AKI
2. Scan day changes in kidney function were evident compared to previous results
3. Kidney function screening is easily undertaken on the day of contrast administration
4. Point of care testing correctly identified risk categories in outpatients
5. Screening and testing for kidney function is feasible in the radiology setting

INTRODUCTION[1]

With imaging demand ever increasing and the expectation for rapid access to imaging growing, opportunities to streamline processes are of interest to both health professionals and administrators. As with all investigations, radiologists and radiographers retain the responsibility to ensure that patient safety is not compromised as a result of quicker turnaround, both from a radiation perspective and drug administration. With computed tomography (CT) being one of the highest demand areas, contrast administration safety is one key consideration [1]. Although the risks associated with the use of low and iso-osmolar iodinated contrast media are considered marginal [2-8], there is a recognised causal link. The development of post contrast acute kidney injury (PC-AKI), defined as, an increase in serum creatinine of 1.5 times baseline, within 48-72 hours of intravascular administration of a contrast agent [9], is of particular relevance to patients with pre-existing kidney disease [10,11]. Despite the ongoing controversy, international guidelines still recommend the screening and risk stratification of patients prior to intravascular contrast administration [9,12-14].

Although the screening of kidney function by blood test is only advocated in those patients with risk factors, many organisations undertake a blanket screening or 'test all' strategy [15]. Within the outpatient radiology setting, Point of Care (PoC) blood testing has been suggested as a mechanism for kidney function testing prior to intravascular iodinated contrast media administration and these devices have been found to be a valid alternative to laboratory testing [16-25]. Although theoretically rapid laboratory result turnaround is possible, this depends on local provision and in practice is usually more than one hour and may not complement CT operations. PoC testing, therefore potentially offers opportunities to reduce unnecessary investigations, reduce patient waits, speed up medical decision-making and can promote improved operational efficiency and patient safety [1,16]. PoC analysis can be undertaken using a portable hand-held device. However, a range of alternatives are available on the market including benchtop (mini-lab/blood gas) analysers [25]. These allow testing in the radiology department immediately prior to the examination with the process owned by radiology, rather than the hospital laboratory. The benefits of PoC have been considered to be greatest where a

Abbreviations

CKD-EPI	Chronic kidney disease – epidemiology collaboration equation
CSW	Clinical Support Worker
eGFR	Estimated glomerular filtration rate
PoC	Point of Care
PC-AKI	Post contrast acute kidney injury
QC	Quality control
SCr	Serum creatinine
WBCr	Whole blood creatinine

screening questionnaire is used to identify patients with co-morbidities which may impair kidney function [23,24,26]. However, evaluation of the implementation of such initiatives within UK NHS clinical pathways is limited [15,25].

This feasibility study has evaluated the viability of implementing screening procedures in conjunction with PoC creatinine testing in an outpatient CT service. The objectives included: assessment of individual patient risk factors; the availability of baseline pre-scan day blood test (as mandated locally); comparison of baseline and scan-day kidney function using estimated glomerular filtration rate (eGFR) categorisation; the technical practicalities associated with PoC testing, including failure rates; the clinical concordance of the PoC test against the laboratory gold standard; comparison of serum creatinine (SCr) result pre and post-contrast administration to identify potential PC-AKI.

MATERIALS AND METHODS

Study setting

This study was a prospective single centre (two UK acute hospital sites) feasibility study of PoC kidney function testing within CT.

Study population

Over an eight-week period between February and April 2017 consecutive adult outpatients (≥18 years) attending for a contrast-enhanced CT scan were approached (CT pathway including study specific procedures see Supplementary Figure 1). In advance, patients identified as potentially eligible from the radiology information system by a member of the research team, had been sent a study participant information sheet prior to their appointment. No upper age limit was adopted, but pregnant females and those unable to consent were excluded. As per local protocol at the time of the study, patients with a baseline eGFR below 60mL/min/1.73m^2 followed the standard risk reduction regimen of oral hydration (1L at home) prior to the scan appointment, and all patients were advised to maintain hydration following discharge. Those who declined to participate proceeded straight to scan and followed the standard CT pathway.

Study procedures

Following written consent, all participants completed a screening questionnaire based on previous studies [23,24,27-29], as is the local standard of care. The questionnaire sought details of known kidney disease, diabetes, heart failure, hypertension, plus history of current/recent acute illness (in

the last week, defined as diarrhoea and vomiting; flu; infection requiring antibiotic treatment or acute hospital admission). For the purposes of this feasibility study, the PoC test was performed as an adjunct to the local standard laboratory results (SCr and eGFR), which should have been obtained less than 3 months prior to the CT appointment, to comply with international guidelines [9]. Participants consented to have an additional PoC whole blood creatinine (WBCr) test and a standard laboratory SCr test performed on the day of the CT appointment. Contrast CT scan procedures followed standard clinical practice, utilising a standard or weight-based volume of intravenous contrast (iohexol; Omnipaque 350; GE Healthcare, Cork, Ireland) appropriate to the anatomy under investigation. All participants were also invited to attend for follow-up bloods tests analysed with the PoC device and in the hospital laboratory at 48-72 hours. PC-AKI was defined as an increase in baseline creatinine level of more than 50% (≥1.5 times baseline) [9]. Additionally we reviewed all cases where there was a relative increase in WBCr greater than 25% above baseline, enabling us to explore the characteristics of any patient with acute deterioration in kidney function. Where appropriate, individuals meeting this lower threshold were reviewed by the medical team prior to discharge on the day of follow up.

Blood sampling

All patients were cannulated by a CT radiographer or clinical support worker (CSW) following local standard operating procedures and two whole blood samples were collected. One sample (S-Monovette Lithium Heparin 2.7ml tube, Ref 05.1553, Sarstedt) was transported to the hospital laboratory for routine analysis. The other sample (1ml BD Plastipak syringe, Ref 303172, Becton Dickinson, San Agustin del Guadalix) was immediately tested on the PoC device within the CT scan suite.

Test methods

Laboratory serum samples were processed using Roche Modular IDMS calibrated enzymatic creatinine analysis on a Cobas8000 platform (Roche, Inc.). The CE-marked PoC analyser was the i-STAT (Abbott Laboratories), a handheld device in current use in UK imaging departments [14]. The device utilises an analytic cartridge system (i-STAT Crea, whole blood sample size 65µl) to reduce the risk of sample contamination. To avoid inter-device variation, a single analyser was used for the duration of the study at each site. To ensure the PoC device operated within the limits of acceptability for imprecision, daily quality assurance was performed during the research using the manufacturers' quality control (QC) materials at two levels of creatinine concentration. Staff training for PoC device operation was provided and competency assessed through collaboration with the local PoC management team, the pathology department and manufacturer representative.

Blood test results management

Following cannulation and PoC testing patients proceeded straight to scan with CT contrast injection as appropriate for their examination. The exception being where the PoC test result identified a decline in kidney function from their baseline result, which prompted a requirement to wait for laboratory confirmation (detailed in the participant information sheet and consent procedure).

The laboratory generated SCr and eGFR result were accessed from the hospital order communication system. The Abbot i-STAT does not provide an eGFR calculation and therefore, for consistency, both laboratory and PoC eGFR values were derived from the creatinine measurements using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation [30].

Statistical Analysis

Data were transcribed into the EDGE research management system (University of Southampton) and exported to Microsoft Excel® for descriptive analysis.

Scan-day creatinine and eGFR measures and the associated risk category (high risk =eGFR≤30; Moderate=eGFR31-44; Low≥45) [13] were compared and the results were also reviewed against the pre-scan (baseline) kidney function test. The clinical concordance between the baseline and scan-day results was evaluated through a modified Clarke Error Grid Analysis, a scatter plot of laboratory overlaid with eGFR results categorised into clinically relevant areas.

Scan-day and follow up PoC WBCr measurements and the relevant laboratory SCr results were compared using Bland Altman analysis. Passing-Bablok regression was used to explore the presence of proportional and constant error (from the slope and intercept co-efficient, respectively). This approach does not assume that any measurement error in either the laboratory or PoC measurements is normally distributed. These were generated in R (The R Foundation) using the packages 'mcr' and 'BlandAltmanLeh'.

RESULTS

Following exclusions 300 participant samples were obtained for PoC and laboratory analysis (Figure 1). Of these, 102 patients voluntarily returned for a follow up blood test within the specified time

frame. Additionally, a further 19 outpatients underwent a clinically required kidney function test through follow up clinics within one week of contrast administration.

Participant characteristics

The sample comprised 155 males (51.6%) and the mean age of participants was 65 years (range 23-91 years). The cohort was predominantly Caucasian with only 1 (0.3%) Afro-Caribbean participant. The CT referrals originated from a number of different clinical specialities, including general surgery (n=82; 27.3%), urology (n=52; 17.3%), oncology (n=49; 16.3%) and respiratory medicine (n=19; 6.3%). The majority of examinations related to the thorax and/or abdomen, with only 2 (0.7%) examinations restricted to the head and/or neck.

Baseline blood test availability

Although baseline blood tests were expected to be carried out within the 3 months prior to the scan appointment the actual timing varied, with a mean of 3.7 weeks (range 0 – 59.6 weeks), with 54.0% (n=162) of patients tested on the day of referral for the scan. Importantly, 12.3% (n=37) of blood tests referrals had to be initiated by the radiology department to ensure compliance with local screening procedures and to enable the scan to be performed within clinical pathway timescales. Despite these measures, 4 patients still presented for their scan appointment with no recent kidney function results available. All consented to study participation with 3 patients waiting for the laboratory result, the other patient was eventually scanned without contrast, as they could not wait for the laboratory test result.

Scan day kidney function

Only 14 patients (4.7%) had a scan-day laboratory eGFR below 45mL/min/1.73m^2, with a single case meeting the high risk threshold of 30mL/min/1.73m^2 (PoC test result 28mL/min/1.73m^2). Importantly, this patient had a baseline laboratory eGFR of 70mL/min/1.73m^2 performed seventeen days earlier but declared an acute illness in the preceding week on the screening questionnaire.

The screening questionnaire identified all patients with an eGFR of <45mL/min/1.73m, although half of patients indicated at least 1 risk factor, with the most common being hypertension, followed by

acute illness and diabetes (Figure 2). Due to the small number of high and moderate risk cases (eGFR ≤30 or <45mL/min/1.73m) logistic regression was not performed.

Comparison of the scan-day and baseline laboratory eGFR results confirmed that the majority of patients (n=281/300; 93.7%) fell in the same risk category (Figure 3 and Table 1). For those 19 patients demonstrating a change in category, there was no significant difference in time interval between baseline and scan-day blood tests (whole cohort mean 29 days vs change 26 days; p=0.888).

In 8 cases an increased risk was identified, with the scan-day eGFR result suggesting a moderate (or high) risk of PC-AKI, rather than low risk. In 11 cases the risk was considered to have reduced, including one whose kidney function was noted to have improved from 38mL/min/1.73m to 64mL/min/1.73m, supporting the decision to administer contrast. In one patient with known chronic kidney disease, the decision to withhold contrast was upheld despite a scan-day eGFR of 34mL/min/1.73m^2 (PoC result 32mL/min/1.73m^2), the previous eGFR result being 29mL/min/1.73m^2 obtained five days earlier.

Follow up blood test results

The characteristics of the patients attending for follow up blood tests were similar to those observed in the whole cohort, with no significant difference in gender (p=0.644), age (p=0.533) and scan-day clinical risk category (p=0.602) based on laboratory eGFR result. Of the 121 patients who had a follow up blood test undertaken (study (n=102) or clinically initiated (n=19)), no instances of PC-AKI were demonstrated. A small number (n=5) of patients had an acute decline in kidney function, with >25% increase from the initial PoC WBCr level (Table 2). All had been administered 95ml of contrast, no other common demographic factors were identified. A number of these patients acknowledged (n=3) not following post-procedural hydration advice, no other attributable cause for the rise in creatinine was identified.

PoC performance

The PoC analysis was performed by radiographers (clinical and/or research based) or support staff (Table 3), depending on staff availability.

Six test failures were recorded on the scan day for the Abbott i-STAT device, of these 2 related to an insufficient sample volume, 2 test cartridges were overfilled and 2 were due to an error with the

cartridge itself. In relation to the follow-up tests, 2 failures were recorded, both due to the test cartridge being overfilled. All tests were successful on the second attempt.

All QC tests fell within the limits set by the manufacturer.

Concordance between the i-STAT and laboratory measures

The average (mean) bias of the PoC device in relation to the laboratory standard was close to zero (Table 4). The constant error between the Abbott i-STAT PoC scan-day measurements and the laboratory scan-day measurements was -3.71 (95% CI: -6.41 to -0.50) and the proportional error was 1.036 (95% CI: 1.00 to 1.07).

DISCUSSION

Kidney function testing prior to intravascular contrast administration is only advocated for patients with identified risk factors [9,12-14]. However, the limited clinical history available to radiology, activity volumes and complex workflows mean pre-scan assessment of eGFR is the most common risk assessment technique [1,15,31]. Importantly, for centres which mandate a local pre-scan blood test screening procedure, a patient presenting without a current eGFR result may need to be rebooked, reducing scanner capacity and more importantly introducing a further delay to diagnosis and treatment.

There is no consensus on the optimal time interval between eGFR result and contrast media administration for stable outpatients; rather this should, in practice, be guided by clinical judgement based on the likelihood that kidney function has deteriorated significantly [25]. Patient safety remains of paramount concern and our results suggest that for a small number of patients a blood test result obtained in the weeks or months prior to contrast administration is not reliable. An appropriate decision may only be possible with scan-day screening and kidney function assessment; the implications of not considering a potential change in eGFR has already been highlighted in a UK Coroner's inquest [32]. Our study has confirmed the validity of such a screening questionnaire to identify acute illness and co-morbidities linked to the increased risk of PC-AKI, similar to previous studies [23,26-29]. The high sensitivity, but relatively poor specificity of the tool to identify the small number of patients with radiology relevant kidney dysfunction is likely a factor of the broad questions used during this research study, and supports further modification to the questionnaire. Although screening promotes the identification of risk factors, without access to immediate blood test results

this information is limited in its usefulness [26]. The results do confirm the potential for reducing inappropriate testing of patients with no risk factors.

There remains controversy around the incidence of PC-AKI. However, it is widely acknowledged that the greatest risk is in patients with an eGFR ≤30mL/min/1.73m^2, with 45mL/min/1.73m^{2}consistently cited as a level above which the risk is very low or non-existent [4,11,13,14]. In our study there were no instances of PC-AKI, with only 5% demonstrating a rise in WBCr of greater than 25%. It is key to note that this small cohort of patients was not identified as high risk in pre-procedure screening, and although dehydration during the post-scan period was identified as an anecdotal contributor, it cannot be confirmed. This raises further questions as to whether centres are, or should be, advocating the maintenance of fluid intake, particularly post procedure. Although there is no strong evidence for the use of peri-procedural oral hydration in patients with a moderate risk of PC-AKI, this remains a common strategy in practice [15]. For centres where scan-day risk screening is in place and who opt for an oral hydration strategy for certain risk categories, it may be easier to provide hydration advice to all patients, where there are no contra-indications. Hydration prior to their CT scan appointment could avoid insufficient prophylaxis, or delays, at the appointment. In the absence of evidence, this may not be the most cost-effective approach, but does enable efficient workflow and maintenance of patient safety.

The concordance of the study PoC device with the laboratory gold standard is consistent with other evaluations [16,17,23,24,34] and provides reassurance around the test results. Following appropriate training radiographers and support staff were able to undertake sample testing with a relatively low failure rate, which appears to reduce with experience. These outcomes confirm that it is feasible to utilise a PoC device for kidney function screening in a radiology setting.

Strengths

This study has explored the clinical utility of a screening questionnaire in combination with PoC for risk stratification and evaluation of kidney function prior to intravenous contrast media administration. Additionally, monitoring for AKI post contrast administration (follow up) was offered to all participants and not restricted to patients with a baseline (pre-scan) reduced kidney function, a criticism of previous research.

Limitations

The low number of patients with pre-existing kidney dysfunction is in line with previous studies [17,26] and the stable out-patient population. This does however reinforce the need for a re-examination of the clinical pathway based on over-testing of patients. The study was limited to the review of a single

PoC device in relation to test performance and failures, no other assessment of the practicalities associated with PoC use in clinical practice was evaluated. In this study PoC testing utilised a single portable hand-held device however, a range of alternatives are available on the market.

The need for efficient workflow and rapid turn-around of referrals for contrast-enhanced imaging studies supports the introduction of PoC creatinine testing. However, due to previous concerns around the accuracy of the PoC creatinine technology, it is yet to make its way into mainstream use. This study has demonstrated that PoC creatinine testing is feasible within CT clinical pathways. Further evidence is required of the feasibility and practicality of embedding PoC technology into clinical practice through multi-centre evaluation on a much larger population.

Conflict of interest

The authors have no conflicts of interest to declare

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Figure 1: Recruitment flow chart
Figure 2. Risk factors (single and multiple) identified through the screening questionnaire

Figure 3. Error grid comparing baseline (pre-scan) eGFR laboratory result to scan-day eGFR laboratory result (see table 1 for key)

Figures 4A & B: Bland-Altman plots demonstrating the average bias of the Abbott i-STAT compared to laboratory measured serum creatinine measured on scan day (4A) and follow up (4B), including 95% levels of agreement.

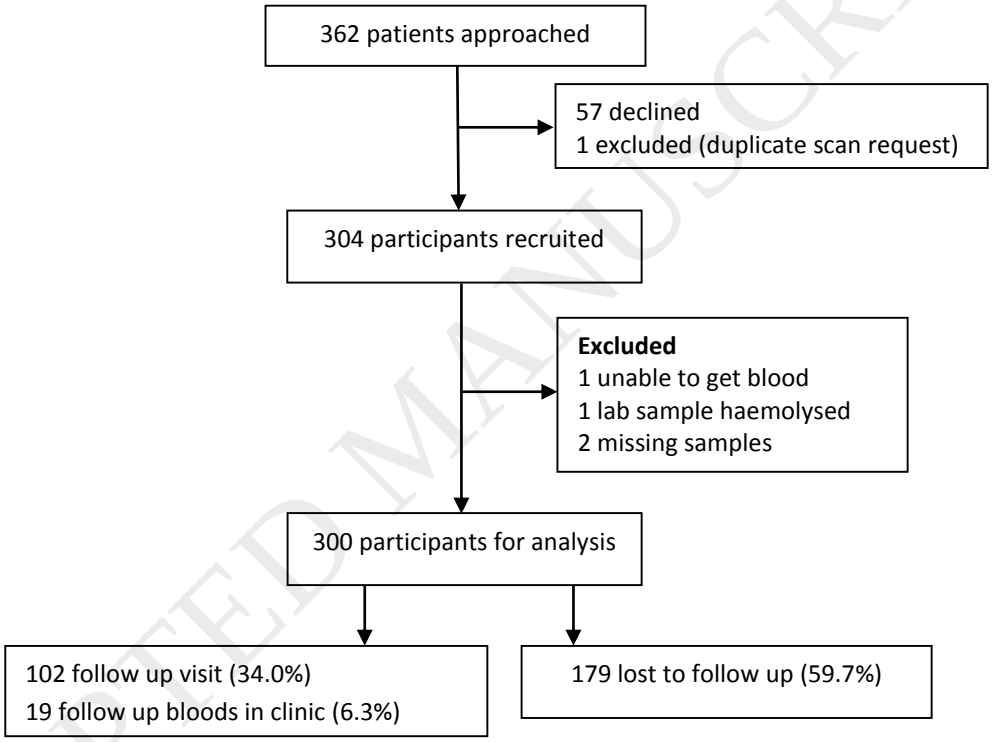
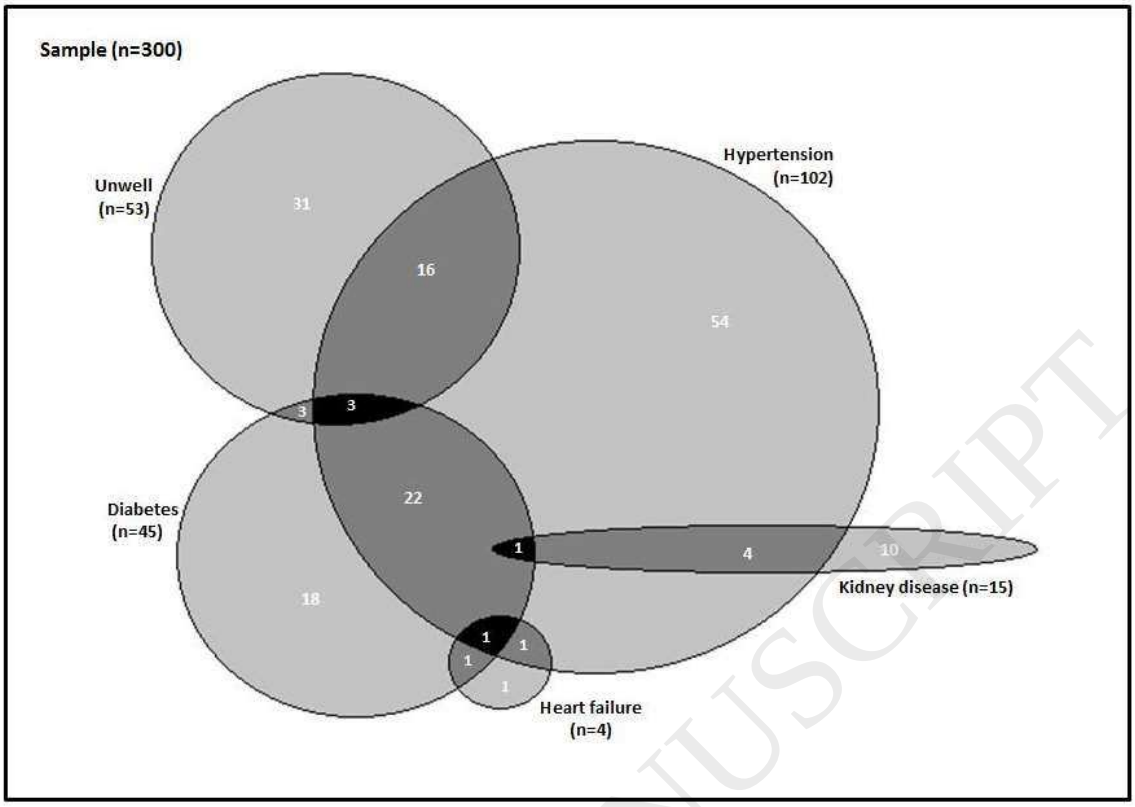
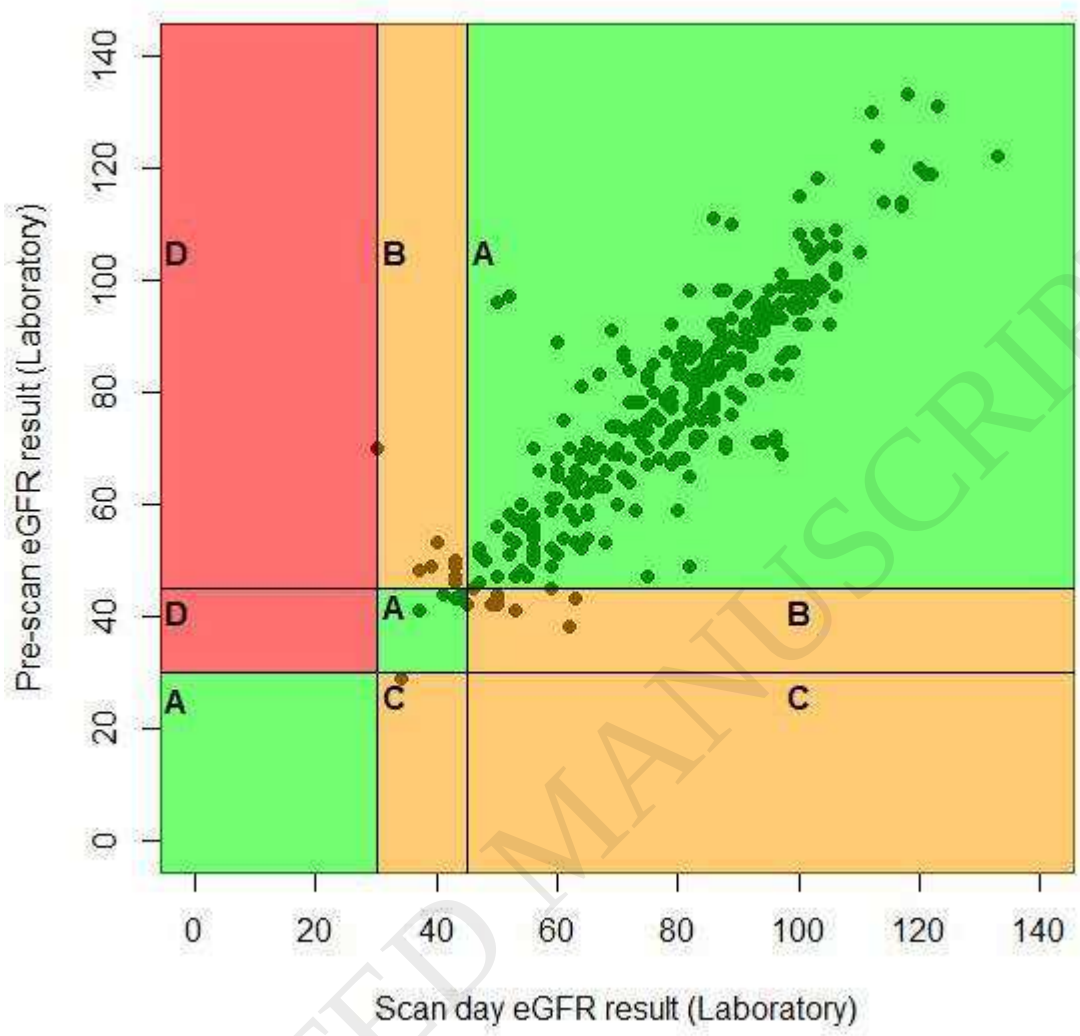
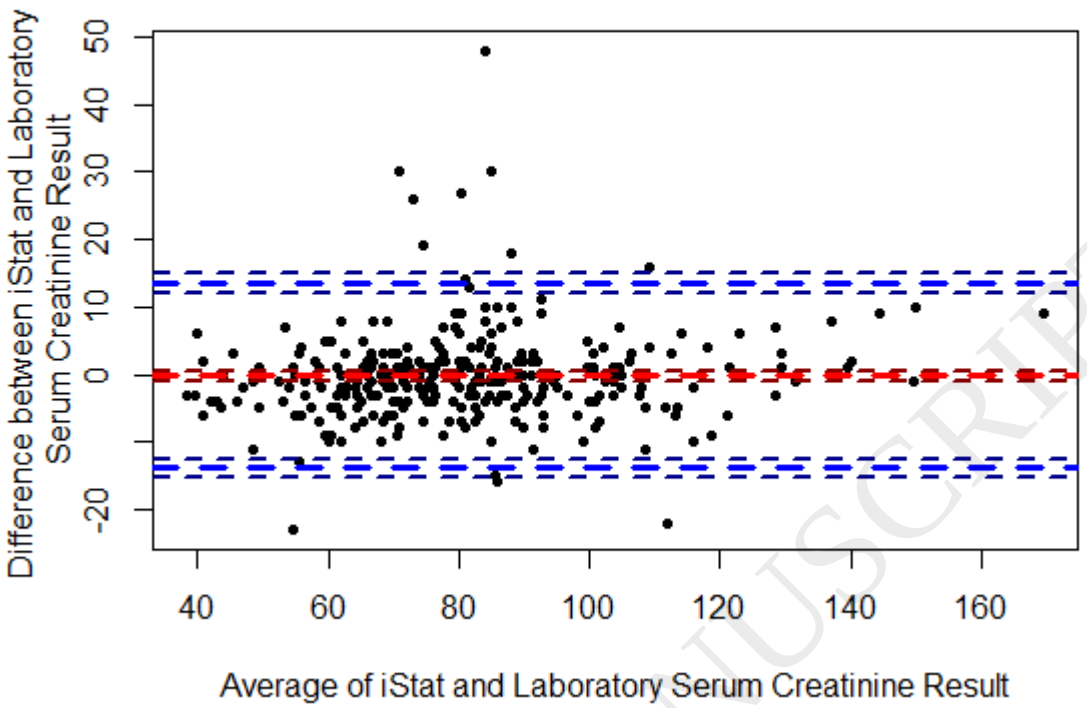


Figure 1: Recruitment flow chart







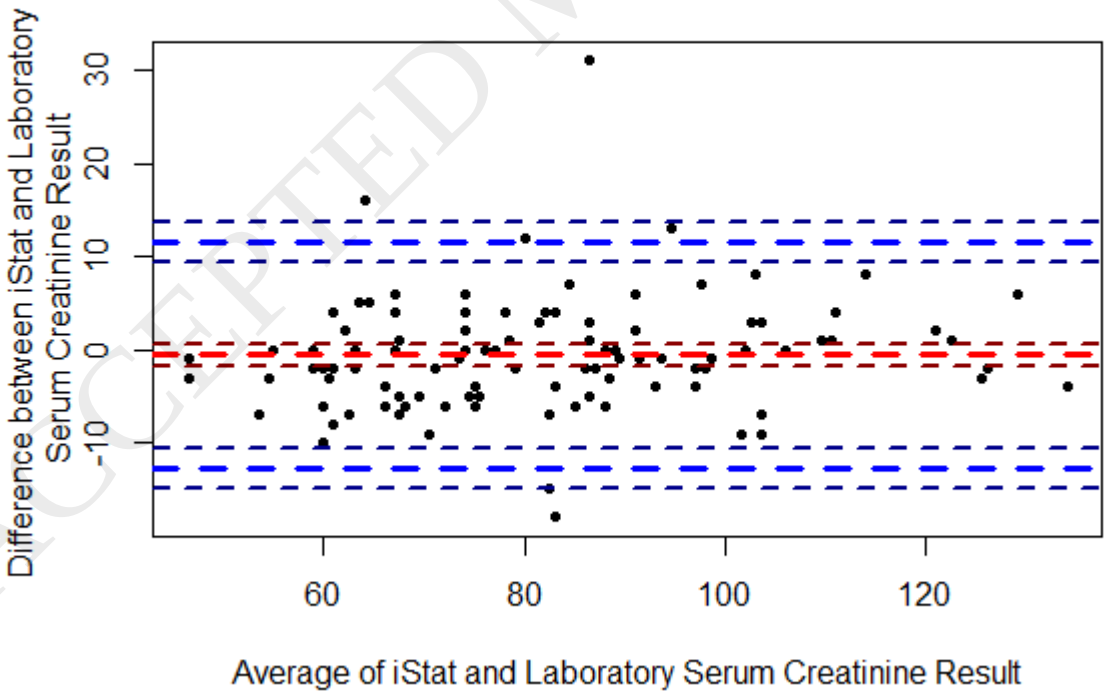


Table 1. Patient management implications of concordance between baseline (pre-scan) eGFR laboratory result and scan-day eGFR laboratory result

Zone	Implication if management based on pre-scan eGFR result	No (%)
A	Same risk category – appropriate management	281 (93.7)
B	Changed from low risk to moderate risk, or vice versa. No impact on management (if all patients orally pre-hydrated as standard).	17 (5.7)
C	Changed from being at high risk to either moderate or low risk, potential for unnecessary prophylaxis or withholding of contrast	1 (0.3)
D	Incorrect classification and potential for increased risk of PC-AKI due to insufficient prophylaxis	1 (0.3)

Table 2. – Characteristics of the patients identified with an increased level (>25%) of PoC whole blood creatinine (WBCr) post contrast administration.

Age (years)/ gender	Scan day WBCr (eGFR)	Follow up WBCr (eGFR)	% change in WBCr	Interval (hrs)	Examination performed
68F*	75 (71)	101 (49)	34.7	48.5	CT head, chest, liver
74F*	101 (47)	132 (34)	30.7	49.5	CT neck, chest, abdomen, pelvis
74F*	82 (62)	107 (45)	30.5	75.5	CT colonography (inc. CT abdomen, pelvis)
53F	41 (113)	55 (103)	34.1	72.5	CT Chest, abdomen, pelvis
45M*	89 (90)	132 (56)	48.3	48.0	CT urogram

Gender M=male; F=female

*Patients referred to Ambulatory Care Unit, advised hydration and return (3 at 24hrs; 1 at 24 + 48hrs), kidney function improved on follow up bloods and patients discharged from hospital care.

Table 3: Roles of the individuals performing the point of care analysis and number of test failures

Role	Scan day	Follow up	Total	Number of failures n (%)
Clinical Support Worker (CSW) (n=5)	43	32	75	1 (1.3)
Radiographer (n=2)	24	19	43	3 (7.0)
Researcher (n=3)	233	51	284	4 (1.4)
Total	**300**	**102**	**402**	**8 (2.0)**

Table 4. Analysis for the Abbott i-STAT PoC device compared to the laboratory reference standard on scan day and at follow up

	Average Bias (95% CI)	95% Limits of Agreement (95% CI)	Correlation Coefficient (95% CI)
Scan-day (n=300)	-0.21 (-1.01 to 0.58)	-13.94 (-15.32 to -12.56) to 13.51 (12.14 to 14.89)	0.948 (0.935 to 0.958)
Follow up (n=102)	-0.59 (-1.81 to 0.63)	-12.77 (-14.88 to -10.65) to 11.59 (9.48 to 13.70)	0.949 (0.926 to 0.966)