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CLINICAL RESEARCH

Patient Self-Testing of Kidney Function at Home, a Prospective Clinical Feasibility Study in Kidney Transplant Recipients

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Introduction: People with long-term health conditions often attend clinics for kidney function tests. The Self-Testing Own Kidneys (STOK) study assessed feasibility of kidney transplant recipients using handheld devices to self-test kidney function at home and investigated agreement between home self-test and standard clinic test results.

Methods: A prospective, observational, single-center, clinical feasibility study (TRN: ISRCTN68116915), with $N = 15$ stable kidney transplant recipients, investigated blood potassium and creatinine results agreement between index self-tests at home (patient self-testing of capillary blood, using Abbott i-STAT Alinity analyzers [i-STAT]) and reference tests in clinic (staff sampled venous blood, analyzed with laboratory Siemens Advia Chemistry XPT analyzer) using Bland-Altman and error grid analysis.

Results: The mean within-patient difference between index and reference test in creatinine was 2.25 μmol/l (95% confidence interval [CI]: −12.13, 16.81 μmol/l) and in potassium was 0.66 mmol/l (95% CI: −1.47, 2.79 mmol/l). All creatinine pairs and 27 of 40 (67.5%) potassium pairs were judged clinically equivalent. Planned follow-up analysis suggests that biochemical variables associated with potassium measurement in capillary blood were predominant sources of paired test result differences. Paired patient and nurse i-STAT capillary blood test potassium results were not statistically significantly different.

Conclusions: This small feasibility study observed that training selected patients to competently use handheld devices to self-test kidney function at home is possible. Self-test creatinine results showed good analytical and clinical agreement with standard clinic test results. Self-test potassium results showed poorer agreement with standard clinic test results; however, patient self-use of i-STATs at home was not a statistically significant source of difference between paired potassium test results.

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Kidney function tests are among the most commonly ordered health care tests.[1] Regular potassium and creatinine tests are essential for many people with long-term health conditions such as heart failure, diabetes mellitus, and chronic kidney disease, to ensure safe monitoring and optimal treatment of their condition. Patients are required to attend health care clinics for such tests when they have no other need to see a health care professional. Unnecessary clinic visits impact negatively on patient experience and health care resources.[2,3]

Enabling patients to self-test kidney function at home could reduce their need to attend health care facilities. Reducing clinic attendance or hospital stay for monitoring of kidney function is an attractive value proposition for health care services. Home self-testing

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could also facilitate personalized care pathways, empowering patients to organize health care monitoring around their daily activities.

Patient use of hand-held technology for home self-testing of kidney function would also align with the National Health Service Long Term Plan.[4] This national, system-wide initiative aims to develop and accelerate models of health that give patients greater control of their care, recognizing that many patients can develop expertise in managing their own health conditions.

The COVID-19 pandemic highlights additional circumstances where self-testing kidney function at home would benefit many patients with long-term health conditions, who frequently require assessment of their kidney function yet are extremely vulnerable to adverse outcomes if they develop COVID-19. Many clinical teams, including our Renal Service, set up virtual clinics to enable the majority of vulnerable patients to be reviewed remotely during the height of the COVID-19 pandemic. Approximately 10% of our patients continue to prefer virtual clinic review, especially those living in rural areas. Although virtual reviews enable many aspects of patient care to be managed remotely, patients must often still attend a clinic for kidney function tests, negating many benefits of virtual clinics. In addition, many patients reattend clinic for repeat kidney function tests if their clinic test result is abnormal or unexpected, or following drug changes.

Many patients who are vulnerable to COVID-19, including those with kidney disease, would especially benefit from initiatives to integrate home self-management into existing health care programs.[5–7] Self-care at home has been demonstrated to be clinically effective and well received by patients across diverse scenarios, including self-monitoring of blood pressure and anticoagulation treatments.[8–10] Home self-care has also been demonstrated to benefit patients with kidney disease; for example, self-care among patients receiving peritoneal dialysis or hemodialysis has the potential to improve clinical outcomes and patient quality of life, by promoting patient engagement with their disease management.[7,11,12]

Current technology, which is designed and approved to assist remote blood testing by patients, only enables patients to self-*sample* capillary blood at home (e.g., Neoteryx). Dried blood samples obtained using such microsampling devices must still be posted to a central laboratory for subsequent analysis, before test results are available. Although such technology has been used to monitor blood creatinine and transplant drug levels in kidney transplant recipients,[13] dried blood samples cannot be used for potassium testing. Therefore, currently licensed technology does not enable real-time patient self-testing at home and does not include potassium testing, which is often a time-sensitive and clinically important test alongside creatinine for many patients with kidney disease and other long-term health conditions.

The STOK study assessed if it is feasible to train a small group of stable kidney transplant recipients to competently use a hand-held, point-of-care test (POCT) to self-test key kidney function parameters at home and produce results that agree with standard clinic test results. We invited such clinically and biochemically stable patients to participate in this study, for the purpose of assessing feasibility. They also represent a group of patients who regularly attend clinic for kidney function tests. Although marked abnormalities in blood potassium or creatinine are rare in stable kidney transplant recipients, we assessed feasibility of self-testing these tests, because both tests are frequently required to enable safe monitoring and optimal treatment for many patients with kidney disease and other common long-term health conditions.

To place our findings within current understanding and use of hand-held POCTs to measure kidney function, we also performed a systematic review of literature evaluating use of POCTs to measure creatinine and potassium. Because current POCTs capable of measuring these analytes are not licensed or designed for self-testing by patients, previous publications identified by our literature review predominantly report *health care professional* use of POCT devices to measure kidney function.

METHODS

Clinical Feasibility, Study Design, and Patients

This was a single-center, prospective, observational, clinical feasibility study of clinically stable kidney transplant recipients registered with the South Tees Hospitals National Health Service Foundation Trust. This Trust serves a population of 1.01 million people, across an area of approximately 80 km^2, including many rural settings far from a central laboratory. The Trust's Renal Service is a non-transplanting center, primarily responsible for the care of 605 kidney transplant recipients, including early follow-up care within 1 to 2 weeks of transplantation.

Fifteen adult kidney transplant recipients were invited to participate. Inclusion criteria required that patients had adequate cognitive and functional ability to enable competency-based training to use hand-held medical devices, were clinically well with stable kidney transplant function, aged 18 years or older, and

had capacity to provide informed, written consent to take part. The exclusion criteria were pregnancy, clinical instability or drug changes within the previous 4 weeks, or current involvement in another research study.

Creatinine and Potassium Sample Collection and Testing

We evaluated patient self-use of the i-STAT. The i-STAT is a portable hand-held *in vitro* analyzer, Conformité Européene (CE)-approved for health care professional use to test arterial, venous, or capillary whole blood samples at the point of consultation.

Licensed use of i-STATs is restricted to health care professionals demonstrating analyzer competency after hands-on training. Users first confirm and record patient, test cartridge, and blood sample details, using the on-board i-STAT scanner or keyboard. Blood sampling is undertaken to enable users to apply 2 to 3 drops (65–95 μl) of whole blood into the test cartridge collection well. Automated quality assurance and blood sample analysis begins immediately after the user inserts the test cartridge into the analyzer, with results displayed on screen within 2 minutes. i-STAT CHEM 8+ cartridges are CE-approved for measuring several blood components,[14-16] including potassium and creatinine.

We obtained advice from the Medicines and Healthcare products Regulatory Agency and secured Health Research Authority and Research Ethical Committee approval, to authorize study participants to use i-STATs off-license to self-test their kidney function at home, only for the purpose and duration of our feasibility study. After providing valid consent, eligible patients completed competency-based training to use i-STATs to self-test potassium and creatinine in fingerprick capillary blood samples (Figure 1).

After completing training, participants self-tested kidney function with i-STATs at home, once a week for 4 weeks. On the same day as each self-test, capillary and venous whole blood samples were taken from participants and tested in clinic by study nurses using i-STATs. The clinic venous whole blood samples were also sent to the hospital laboratory, to obtain clinic standard reference test results. As per standard laboratory practice, the venous whole blood samples were spun to venous serum, before analysis with a central laboratory analyzer (Siemens Advia Chemistry XPT analzser), to produce gold-standard reference test results. This also ensured the study clinical team validated and responded to any abnormal test results the same day. All test results were recorded on study case report forms.

The study was designed to enable follow-up analyses to investigate anticipated potential sources of differences between self-test and standard clinic test results, by measuring test combinations illustrated in Table 1, split by test analyzer, blood type, blood

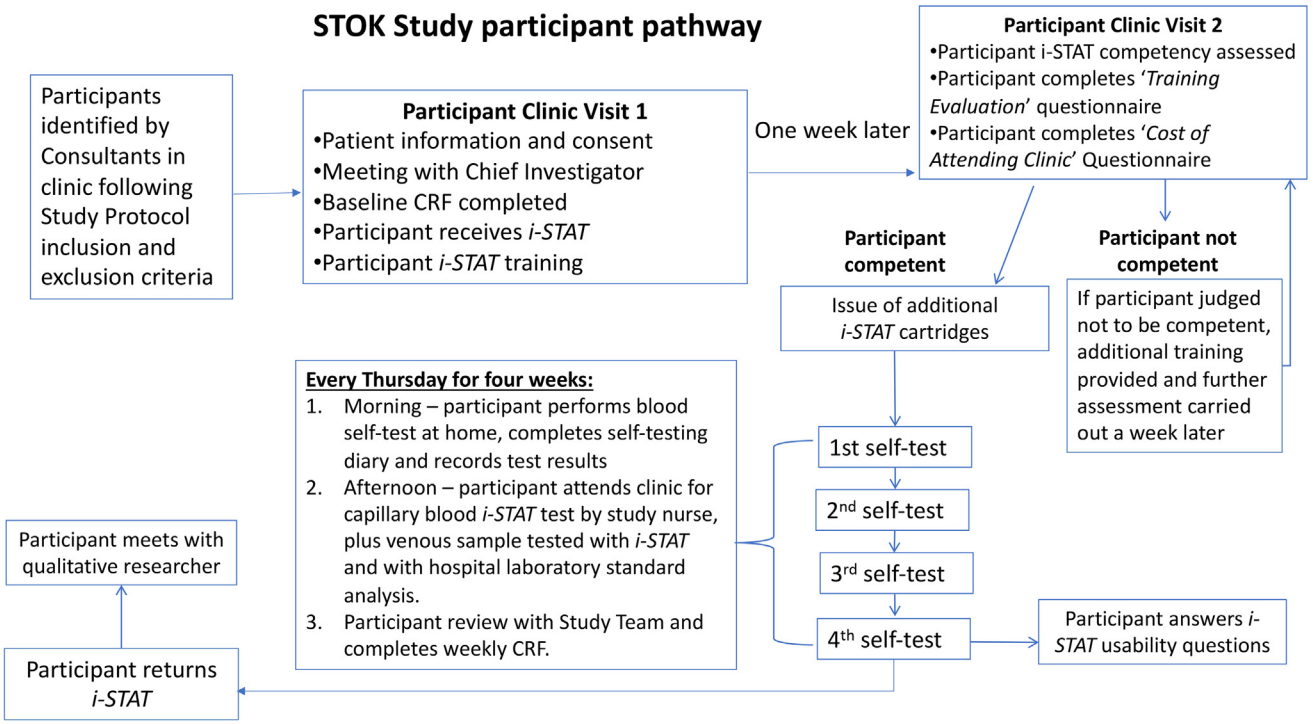

Figure 1. Pathway completed by Self-Testing Own Kidneys (STOK) Study participants, comprising study consent, training, home and clinic testing, and evaluation. CRF, Case Report Form.

Table 1. Showing all possible combinations of experimental conditions and the fraction investigated in the study. Rows not tested are identified in the final column

Analyzer	Blood type	Sampled by	Venue for sampling	Investigated
i-STAT	capillary	Patient	Home	✓
i-STAT	capillary	Study nurse	Clinic	✓
i-STAT	venous (whole)		Home	X
i-STAT	venous (whole)	Study nurse	Clinic	✓
i-STAT	venous (serum)		Home	X
i-STAT	venous (serum)		Clinic	X
Lab standard	capillary		Home	X
Lab standard	capillary		Clinic	X
Lab standard	venous (whole)		Home	X
Lab standard	venous (whole)		Clinic	X
Lab standard	venous (serum)		Home	X
Lab standard	venous (serum)	Study nurse	Clinic	✓

sampler and venue. The combinations that were not assessed during the study are identified in the final column.

Study Outcomes

Primary outcome measures were agreement between potassium and creatinine results produced by index patient self-tests and reference standard tests.

Statistical Analysis

Numerical agreement between index and reference tests was assessed using Bland-Altman and error grid analyses.[17-19] To report the Bland-Altman analysis, we followed the reporting recommendations suggested by Abu-Arafeh *et al*.[20] Standard 95% limits of agreement were generated for Bland-Altman analysis. In addition, see Supplementary Material for the CONSORT statement.

Although technical accuracy of index self-tests can be assessed using mathematically derived Bland-Altman limits of agreement, such numerical analysis does not investigate clinical accuracy, which reflects different medical decisions based on test results. Common or different clinical decisions may be made despite apparent analytical differences between 2 test results, depending on relevant clinical thresholds and contexts. For example, health care staff routinely use capillary blood glucose POCTs to support clinical decision-making on the basis that results are clinically equivalent to laboratory analysis of venous blood glucose test results, even though the 2 tests frequently produce numerically different results.[21]

Considering that there is no consensus on clinically acceptable differences for comparative measurement of creatinine and potassium among stable kidney transplant recipients, we proposed clinical limits of agreement for this patient population in advance of the statistical analysis. If results of index self-test and reference laboratory potassium and creatinine test results were clinically equivalent, both tests would lead to the same clinical decision. The threshold for a clinically acceptable difference between paired index self-test and laboratory standard test creatinine results was ≤25 μmol/l. We proposed paired potassium results clinically equivalent if both returned within the normal reference range (3.5–5.3mmol/l). For potassium test results outside of the normal reference range, we proposed a difference of <0.3 mmol/l as clinically equivalent.

An additional error grid plot was generated for potassium because the clinical acceptability criterion for potassium, discussed above, is nonlinear, and so could not be fully visualized with a Bland-Altman plot. This plot was used to illustrate whether differences between paired potassium results were clinically acceptable or unacceptable. Paired results within the error grid's bounds were sufficiently similar to be deemed useful by clinicians, whereas those outside were deemed too different to be useful in practice.

A planned framework of follow-up analyses was used to investigate sources of differences between index self-test and reference standard test results. The linear mixed effects model takes the form

$$y_{i,j} = \beta_0 + \beta_1 x_{cli,cap} + \beta_2 x_{cli,vw} + \beta_3 x_{lab,vs} + \varepsilon_{setting,blood,j},$$

$$\varepsilon_j \sim N\left(0, \sigma^2_{setting,blood,j}\right)$$

where $y_{i,j}$ is the *i*th potassium reading for patient *j* (Patients 1–15). We denote indicator variables (variable = 1 when the sample has the characteristics, and = 0 otherwise) $x_{s,b}$ where s is the setting of the test (home, clinic, or laboratory) and b is the blood sample type (capillary, venous whole, or venous serum). In this case, the home setting test of capillary blood is considered the baseline and is included in the β_0 parameter. The $\varepsilon_{setting,blood,j}$ parameter represents the error term for patient *j*, in each setting (home, clinic, or laboratory) and for each blood sample type (capillary, venous whole, or venous serum).

Primary analysis was carried out in R[22] using the *tidyverse::ggplot* package[23] to generate the Bland-Altman and error grid plots. The secondary analysis was carried out using the R *lme4Test* package[24] and was validated in SAS JMP (SAS Institute Inc., Cary, NC, 1989–2022).

Rapid Review Search Methods

We conducted a systematic review of the Medline and Embase databases for self-testing creatinine and potassium in kidney disease. We conceptualized the

Table 2. Weeks 1 to 4 (combined) blood measurements of patient kidney function (potassium and creatinine), measured by the patient and clinic use of i-STAT and the laboratory

Variable	Mean	SD±	N-successful	N-drf	N-prf	N-other
Creatinine						
Patient creatinine capillary i-STAT	100.10	17.50	42	9	5	4
Clinic creatinine capillary i-STAT	96.58	17.22	44	12	n/a	4
Clinic creatinine venous whole i-STAT	100.11	17.18	46	10	n/a	4
Lab creatinine venous serum	98.67	14.19	57	1	n/a	2
Potassium						
Patient potassium capillary i-STAT	5.12	0.91	42	9	5	4
Clinic potassium capillary i-STAT	4.97	0.95	44	11	n/a	5
Clinic potassium venous whole i-STAT	4.30	0.44	48	7	n/a	5
Lab potassium venous serum	4.49	0.57	54	1	n/a	4

"N-sucessful" = number of successful measurements made.
"N-drf" = number of device-related failures.
"N-prf" = number of patient related failures.
"N-other" = Number of other types of failures.

searches as follows: A: (test type) AND B: (potassium OR creatinine) AND C: (kidney). For element A, we considered POCTs, self-testing, and the i-STAT device. For element B, we searched for mentions of either potassium or creatinine. For element C, we searched for mentions of kidney. Further details are provided in the Supplementary Data S1. The resulting papers were screened for relevance, to include only those comparing diagnostic test results in human patients for creatinine and/or potassium readings.

RESULTS

Clinical Feasibility Study Results

Demographics and Test Measurements

A total of 15 patients (14 males, 1 female), aged between 35 and 73 years (mean = 54 years, SD ±10.77 years), were recruited to the study.

The mean and SD test results for capillary blood samples analyzed with i-STATs by patients at home and nurses in clinic, alongside mean and SD test results for venous blood samples analyzed with i-STATs by nurses in clinic and by standard laboratory analysis are presented in Table 2.

The number of tests that failed to produce a test result are also presented. Failed capillary blood tests using i-STAT devices were similar, whether undertaken by patients at home (18/60 patient self-tests failed) or study nurses in clinic (16/60 study nurse tests failed). Test failure was lower for i-STAT analysis of venous blood samples by study nurses in clinic (14/60 creatinine and 12/60 potassium study nurse tests failed). Standard clinic tests (venous blood samples taken by study nurses in clinic and analyzed in laboratory) failed least frequently (3/60 creatinine; and 5/59 potassium standard clinic tests failed to produce result, 59 because 1 missing laboratory data). For tests conducted by patients, 5/60 (8.3%) failed because of patient-related reasons, whereas 13/60 (21.6%) failed because of device-related or other reasons.

Creatinine

The creatinine results comparison (Figure 2) between patient self-testing of capillary blood samples using i-STATs at home (Mean = 100.10 μmol/l, SD ±17.50 μmol/l) and standard laboratory testing of venous blood samples taken by nurses in clinic (Mean = 98.67 μmol/l, SD ±14.19 μmol/l) revealed a

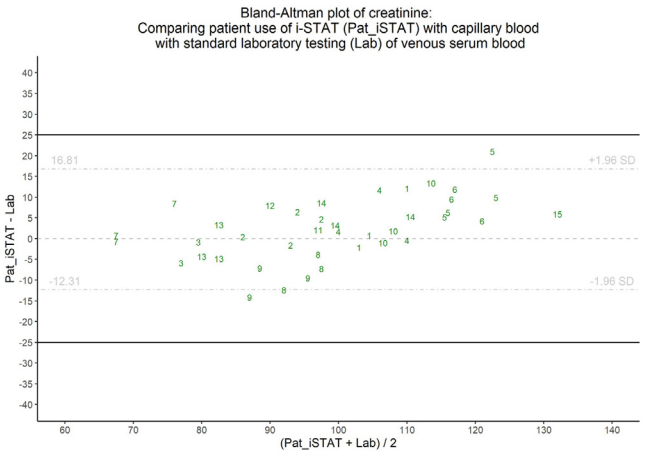

Figure 2. Bland-Altman plot of creatinine (unit = μmol/l) showing the difference for each patient, at each time point, between the i-STAT at home (capillary blood) and standard laboratory testing (venous blood), plotted against the mean of the 2 tests. The dashed reference line (y = 0) represents zero difference between tests (i.e., perfect agreement), the 2 dot-dash lines (y = 16.81, −12.31) represent the 95% confidence interval for differences between pairs of individual measurements, and the 2 solid lines (y = 25, y = −25) represent the clinical acceptability criteria. Participant ID has been used as the data-point symbol. Green symbols represent clinically acceptable differences between measures (i.e., data points located in-between the 2 solid lines), whereas red symbols represent clinically unacceptable differences (i.e., data points located outside the 2 solid lines); there are no clinically unacceptable paired results for creatinine.

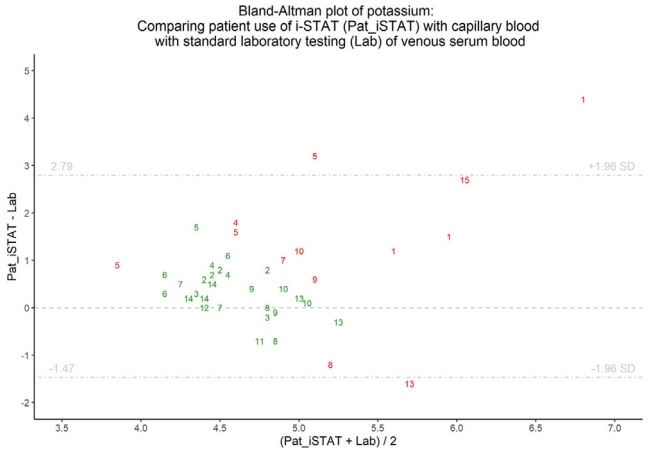

Figure 3. Bland-Altman plot of potassium (unit = mmol/l) showing the difference for each patient, at each time point, between the test result for the i-STAT at home on capillary blood and standard laboratory testing on venous blood (Pat_iSTAT – Lab), plotted against the mean of the 2 tests— (Pat_iSTAT + Lab)/2. The dashed reference line (y = 0) represents zero difference between tests (i.e., perfect agreement), and the 2 dot-dash lines (y = 2.79, y = −1.47) represent the 95% confidence interval for differences between pairs of individual measurements. Participant ID has been used as the data-point symbol. Green symbols represent clinically acceptable differences between paired results, whereas red symbols represent clinically unacceptable differences.

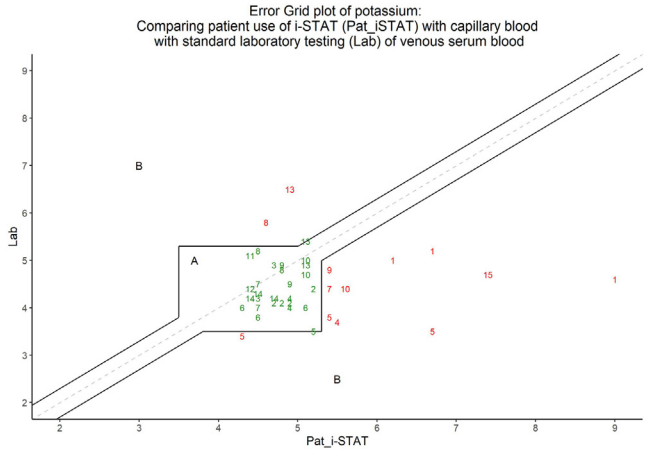

Figure 4. Error grid plot of potassium (unit = mmol/l) showing the result for each patient, at each time point, of standard laboratory testing on venous blood (Lab) plotted against the test result using the i-STAT at home on capillary blood (Pat_i-STAT). The diagonal dashed reference line represents zero difference between tests (i.e., perfect agreement). The data points inside area A, which comprises the rectangular area and the 2 adjoining corridors, represent the clinically acceptable paired results. The data points in area B, which comprises the entire area outside of area A, represent the clinically unacceptable paired results. Participant ID has been used as the data-point symbol. Green symbols represent clinically acceptable differences between paired results, whereas red symbols represent clinically unacceptable differences.

mean within-patient difference between these tests of 2.25 μmol/l, SD ±7.31 μmol/l, with a 95% CI between 16.81 μmol/l (upper) and −12.13 μmol/l (lower). The SD of the difference is consistent with the observed uncertainty in the measurement of the individual tests. Forty out of forty (100%) pairs of results were classified as clinically acceptable. Although a lower SD for the differences between the tests would result in less vertical spread in the Bland-Altman plot, the high level of clinical agreement suggests the agreement between tests is strong enough for practical use. The intraclass correlation for patients was 0.8893, suggesting a good reliability across the different testing scenarios.

Potassium

The potassium results comparison (Figures 3 and 4) between patient self-testing of capillary blood using i-STATs at home (Mean = 5.12 mmol/l, SD ±0.91 mmol/) and standard laboratory testing of venous blood samples taken by nurses in clinic (Mean = 4.49 mmol/l, SD ±0.57 mmol/) revealed a mean within-patient difference of 0.66 mmol/l, SD ±1.10 mmol/l between these tests, with a 95% CI between −1.47 mmol/l (lower) and 2.79 mmol/l (upper). Twenty-seven of forty (67.5%) pairs of results were classified as clinically acceptable. In 11 of 13 (84.6%) of the clinically unacceptable paired results, the patient use of the i-STAT produced a higher potassium result than the standard laboratory test. The intraclass correlation for patients was 0.3247, suggesting some differences in reliability across the testing scenarios.

Follow-up analysis further investigated the difference in potassium measurement. Box plots of the data, comparing readings from different settings are presented in Figure 5. Because there is potentially a difference between potassium readings in capillary and venous blood, we used a linear mixed effects model to investigate for any source of statistically significant difference.

We compared the results of the self-tests at home using capillary blood. Regression output provided in Table 3 shows that the results from the home tests were not significantly different to those produced in the clinic using capillary blood ($P = 0.346$). There was a significant difference found between the results of home capillary blood tests and the tests using venous blood, both i-STAT analysis of venous whole blood in clinic ($P < 0.003$) and laboratory analysis of venous serum ($P < 0.002$).

Expanding on this, the pairwise contrasts between each of the test setting and blood sample combinations are presented in Table 4. This identifies consistently significant differences, irrespective of test setting or user, in the results from capillary blood samples (home or clinic) compared to venous blood samples (whole

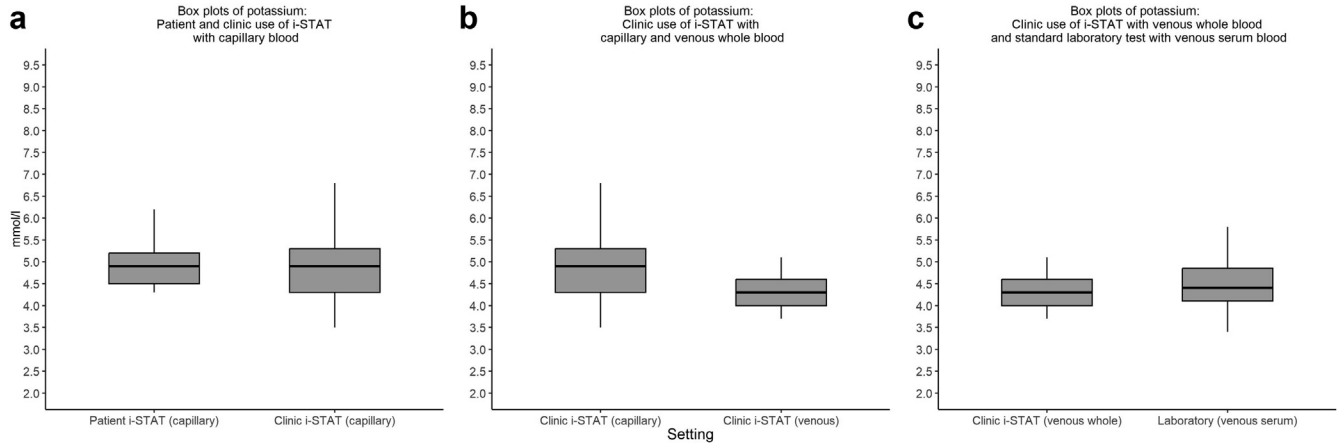

Figure 5. Box plots showing the comparisons in the linear mixed effect modeling, as part of the planned framework of follow-up analyses on potassium (unit = mmol/l). The lower and upper hinges of the boxplots correspond to the first and third quartiles (i.e., the 25th and 75th percentiles). The upper and lower whiskers extend from the hinge to the largest and smallest value, respectively. The bolded, horizontal line inside the boxplot represents the median value. Outliers were determined using the 1.5 × IQR rule ($Q_1 - 1.5 \times IQR$, $Q3 + 1.5 \times IQR$) No outliers were detected. Plot A shows the comparison between the patient use of the i-STAT at home and the clinic use of the i-STAT, both on capillary blood.

blood in clinic, or serum in the laboratory); and no significant differences because of users or test setting (home vs. clinic and clinic vs. laboratory).

Rapid Review Results

Results comparing i-STAT to laboratory methods are summarized in Table 5, with further results provided in the Supplementary data, S1. A total of 320 papers were identified by the systematic review search, which were narrowed down to 46 that compared the performance of POCTs to laboratory methods, 15 of which contained results from the i-STAT test. Fourteen papers compared i-STAT to laboratory analysis evaluating creatinine test results, whereas only 1 compared potassium results. Additional papers comparing other POCTs compared both creatinine and potassium (see Supplementary data, S1). The literature suggests that when used as licensed by healthcare professionals, i-STAT performs well when compared to laboratory methods, though some minor bias between the 2 methods has been reported.

DISCUSSION

Although current POCTs capable of testing kidney function are not authorized or designed for use by patients, there is no other *a priori* reason why selected patients could not be trained to use a POCT to assess kidney function at home. Jacobs *et al.*[39] found that i-STATs were simple for varied health care staff to operate and produced reliable results, concluding that operator technique did not significantly affect i-STAT analytical performance. The STOK study assessed potential wider i-STAT usability by evaluating patient self-testing with this POCT at home.

Our study found that selected patients can be trained to use a POCT safely to self-test kidney function at home. Study participants had a similar test success rate at home (42/60, 70%, tests successful) to nurses in clinic (44/60. 73%, tests successful). Approximately 30% of capillary blood tests failed to produce a test result for creatinine or potassium, even when tests were undertaken by study nurses. Therefore, although patient i-STAT test success at home was comparable to nurse i-STAT test success in clinic, we found overall device usability for capillary blood testing was less successful than for i-STAT testing of venous blood by nurses in clinic (77%–80% test success) and standard laboratory testing of venous blood samples taken in clinic (92%–95% test success). Other POCTs may have better usability characteristics.

Creatinine results obtained by STOK study patient self-testing of capillary blood at home showed good agreement with paired standard reference results. This finding is consistent with the published literature, which predominantly evaluates POCT creatinine measurement by health care staff, as presented in Table 3 and Supplementary Data S1. Most studies found strong agreement between i-STAT and laboratory methods for creatinine measurement. A systematic literature review by Corbett *et al.*[40] found i-STAT

Table 3. Follow-up analysis results for potassium readings, with home as baseline

Model Term	Estimate	SD	*P* value
Intercept	5.16	0.2317	< 0.0001
Clinic (capillary)	−0.21	0.2220	0.346
Clinic (venous whole)	−0.85	0.2410	0.003
Lab (venous serum)	−0.65	0.2561	0.002

Table 4. Contrast differences between each test setting and blood type estimate

Contrast	Estimate	SD	*P* value
Home (patient, i-STAT capillary)–Clinic (nurse, i-STAT capillary)	0.216	0.223	0.348
Home (patient, i-STAT capillary)–Clinic (nurse, i-STAT venous whole)	0.855	0.242	0.003
Home (patient, i-STAT capillary)–Lab (nurse, lab venous serum)	0.648	0.257	0.024
Clinic (nurse, i-STAT capillary)–Clinic (nurse, i-STAT venous whole)	0.639	0.171	0.002
Clinic (nurse, i-STAT capillary–Lab (nurse, lab venous serum)	0.423	0.175	0.027
Clinic (nurse, i-STAT venous whole)–Lab (nurse, lab venous serum)	−0.207	0.101	0.059

Each contrast estimate represents the differences between the 2 groups, with a positive value when the first group has a larger potassium level, and a negative value when the second group has a larger potassium level.

creatinine values demonstrated positive bias in 6 studies, negative bias in 1 and negligible bias in 5, and reported relatively narrow limits of agreement, suggesting biases were generally consistent and predictable (summarized in the CONSORT Statement). This review informed UK National Institute for Health and Clinical Excellence diagnostics guidance, which supports i-STAT use by health care staff to evaluate kidney function for outpatients without a recent creatinine result who require contrast-enhanced computed tomography imaging.[41] An earlier review by Lomakin and Tobar[42] found that concordance between POCTs and laboratory creatinine methods worsened with severe renal impairment.

Potassium results obtained by the STOK study patient self-testing of capillary blood at home showed less good agreement with paired standard reference test results. Unlike creatinine, POCT potassium measurement has not been widely studied, with no published studies evaluating patient self-testing of potassium with POCTs. Potassium results obtained by nurses using i-STATs in our study were comparable to other studies evaluating POCT potassium measurement by health care staff. Performance was similar to that presented by Bingham *et al.*,[38] though worse than that presented for the Nova Stat Profile CC device[43] or the ChemSTAT device,[44] though the latter 2 POCT devices are not hand-held.

We performed planned follow-up analysis to investigate potential sources of clinically unacceptable

Table 5. Systematic review summary of papers comparing i-STAT and other POCT device measurements of creatinine and potassium to laboratory methods

Authors, yr reference	Statistics	Summary
Creatinine		
Batte *et al.*,[25] 2021	$R^2 = 0.95$ Sens = 63.4%	i-STAT underestimated Creatinine in lean Ugandan children <4 yrs of age
Bogaert *et al.*,[26] 2019	$R^2 = 0.997$ Mean difference = −7.0% Imprecision = 0.0% to 3.0%	i-STAT and ABL90 Flex Plus most accurate of POC methods tested (small sample size, n = 5)
Currin *et al.*,[27] 2021	Correlation = 0.92	i-STAT and StatSensor more imprecise than laboratory methods, for both capillary and venous blood
Korpi-Steiner *et al.*,[28] 2009	Sensitivity = 97%	Radiometer ABL800 FLEX performed better than i-STAT, i-STAT had better sensitivity but poorer specificity for lower readings
Lee-Lewandrowski *et al.*,[29] 2012	$R^2 = 0.99$	i-STAT had good agreement with laboratory methods
Mathur *et al.*,[30] 2021	$R^2 = 0.83$	Nova StatSensor and Abbott i-STAT moderately effective compared to laboratory methods
Nichols *et al.*,[31] 2007	Correlation = 0.9977 Mean difference = 14.1 (11.5–16.8)	IRMA TRUpoint performed better than i-STAT, both biased compared to laboratory methods
Obrador *et al.*,[32] 2012	Correlation = 0.93 (capillary) 0.90 (venous) Sensitivity = 100%, Specificity = 99%	i-STAT performed well compared to laboratory methods
Snaith *et al.*,[33] 2018	94% correct risk classification	StatSensor had poor agreement with laboratory methods, Abbott i-STAT and Radiometer ABL800 FLEX had higher correlations
Snaith *et al.*,[34] 2019	93.7% correct risk classification Correlation = 0.948 Average bias = −0.21 (−1.01 to 0.58)	i-STAT agreed with laboratory methods
van der Heijden *et al.*,[35] 2019	Mean bias = −0.09 (−0.14, −0.04)	i-STAT and epoc performed better than StatSensor
Gault *et al.*,[36] 2001	Mean bias = 20.1 μmol/l (−39.9, 79.5)	i-STAT creatinine method showed satisfactory accuracy and precision, though results were on average slightly higher than the laboratory methods
Dimeski *et al.*,[37] 2013	Mean bias = 3–8 μmol/l	The i-STAT offers better analytical imprecision and patient comparison with the laboratory method with the 3 sample types but showed significant interference from dopamine
Potassium		
Bingham *et al.*,[38] 1999	Difference in potassium 0.24 mmol/l ($p = 0.0001$)	i-STAT found a lower potassium reading than the laboratory method

differences observed between 13 of 40 paired self-test and standard reference test potassium results. We found that patient self-testing with hand-held devices at home was not a significant source of difference between paired test results, because results produced by patient self-testing capillary blood at home were not statistically significantly different from results obtained by nurses performing the same tests in clinic. This suggested that variables inherent to capillary blood sampling and measurement of potassium in capillary, venous whole blood and serum, were likely sources of statistically significant differences between paired potassium test results, consistent with established biochemical phenomena.[45]

Capillary blood potassium results were statistically significantly higher than venous whole and serum potassium results, including when capillary and venous whole blood tests were both performed by study nurses using i-STATs in clinic. Several biochemical factors affecting capillary blood potassium concentration likely explain this finding, including membrane stress or hemolysis because of sampling trauma, plus contamination of capillary samples with interstitial fluid and intracellular contents. Venous blood sampling is rarely affected by such factors and as Dalton[46] highlights, the relatively larger blood samples obtained by standard venesection usually mitigate the variation associated with sample contaminants.

We found that i-STAT venous whole blood potassium results obtained by study nurses were lower than the results produced by standard laboratory analysis of paired venous serum samples. Although not statistically significantly different, the magnitude of difference observed in our study aligns with established biochemical phenomena, because intracellular potassium is released from cells when blood is spun to serum, as part of standard laboratory preanalytical preparation of blood samples, before laboratory analysis. The mean magnitude of difference between paired venous whole blood and serum potassium results observed in our study (0.21 mmol/l) was comparable to the findings of Bingham *et al.*,[38] who found that mean venous blood potassium results produced by health care staff using i-STATs were 0.24 mmol/l lower than results of paired serum samples analyzed in their laboratory. The Association for Clinical Biochemistry and Laboratory Medicine also report that whole blood potassium results are typically 0.1 to 0.7mmol/l lower than paired serum potassium results.[47]

These findings suggest that observed clinically unacceptable differences between home self-test and standard clinic test potassium results in our study, were likely because of systematic differences in blood sampling and type (capillary, venous whole, and venous serum) rather than the ability of study patients to obtain and self-test capillary blood samples at home.

Our small feasibility study findings demonstrate that it is possible for selected patients to use hand-held devices to safely and competently self-test kidney function at home. However, further studies are required to validate our findings and to evaluate other devices, with potentially different patient usability characteristics and performance. Future work should also investigate how to overcome variation inherent to potassium measurement in capillary blood samples, and investigate barriers to and enablers of uptake of self-testing kidney function at home within different patient populations and care pathways.

Limitations

The findings of this small study cannot immediately be generalized to clinical practice, especially because i-STAT devices are not licensed for self-use by patients. Before self-testing with any *in vitro* device can be licensed and adopted within clinical practice, it must be thoroughly assessed to demonstrate its safety, performance, and economic viability across large patient populations, which was outside the scope of our small feasibility study, which has several other limitations.

To compare home self-test and standard laboratory results, we needed to develop criteria to determine limits of clinical acceptability between paired test results; this was done by consulting with study clinicians. The magnitude of clinically acceptable difference in clinical practice will vary depending on baseline kidney function, clinical context, and clinician opinion; thus applicability of our study results is limited to similar patient populations and clinical settings.

Patients recruited to this study were all Caucasian and predominantly male; this may further limit generalization of our findings.

The study sample size was low, because the study was only designed to investigate feasibility of self-testing kidney function at home. Limitations associated with our low sample size were compounded by POC test failures by both patients and nurses, which contributed to wide CIs for our study results. Larger scale studies would enable more precise estimate of self-test accuracy.

Coefficients of variance analysis is an important component of analytical validation. The data collected in this study did not allow for coefficients of variance analysis to be performed, because it requires multiple repeated tests on the same sample, which was not part of the study protocol. For follow-up larger studies, all components of analytical validity should be measured to allow a fuller understanding of test performance,

which would be required for CE-marking in this intended use.

Future Research

Future work should systematically and formally establish consensus on limits of clinically acceptable differences between kidney function tests, across different clinical contexts. This could be evaluated using a Delphi survey, with rigorous design to ensure limits are elicited appropriately, incorporating different patient populations, clinical scenarios, and settings.

Because of variables inherent to capillary blood sampling, it is currently unlikely that analysis of capillary blood samples will produce potassium results that consistently agree with venous sample results. Future work should therefore consider developing a normal reference range or actionable limits for capillary potassium results and include development of technology that is designed for patient self-testing at home, that is easier for unselected patients and their carers to use.

The magnitude of difference between venous i-STAT and standard laboratory potassium results observed in this study, was of the order expected when measuring potassium in venous whole blood and serum samples.[47] Future studies investigating POCT and standard clinic test potassium results could investigate this further, by including laboratory analysis of venous whole blood samples alongside standard laboratory analysis of serum samples.

Future work must also evaluate how self-testing of kidney function could be integrated safely and effectively within different patient pathways before such technology could be embedded within routine clinical practice. Factors to consider include the following: which patient-centered and health care professional factors are fundamental barriers to and enablers of uptake of health care technology at home? How are home self-test results displayed alongside routine clinic results within electronic health records in a timely fashion? How to ensure use of healthcare technology does not widen health inequalities. Which patient populations and clinical contexts would benefit most from home self-testing of kidney function? Which patient characteristics are necessary for, and would benefit from, home self-testing of kidney function? When should patients self-test their kidney function, and for how long? Who is responsible for interpreting test results and how is this communicated to the patient? How and when are self-test results actioned, especially if tests are performed outside of routine working hours? What are the health economics associated with technology and changes to patient pathway?

Conclusion

This small feasibility study found that it is possible to train selected patients to use hand-held devices competently at home, to self-test key kidney function parameters. Although i-STATs are not designed for patient self-testing, study patients obtained successful capillary blood test results as frequently as study nurses performing the same tests in clinic. Furthermore, patient use of i-STATs at home was not a significant source of difference between paired self-test and standard clinic test results.

Self-test creatinine results showed good agreement with standard clinic test results and all paired results were judged clinically equivalent for the study population. Self-test potassium results showed less good agreement with standard clinic test results and only two-thirds of paired results were judged clinically equivalent. Planned follow-up analysis suggests that biochemical variables associated with potassium measurement in capillary blood, were predominant sources of paired test result differences observed in one-third of paired potassium test results.

Technological developments should focus on overcoming these variables and design technology that is easier for unselected patients and their carers to use at home. Such technological advances may enable many patients with common long-term health conditions to benefit from the option to self-test potassium and creatinine at home. However, wider clinical evaluation of such technology across different care pathways would also be necessary before it could be implemented within routine clinical practice, including assessment of patient-centered, healthcare system, regulatory and economic barriers to and enablers of uptake of such technology at home.

DISCLOSURE

All the authors declared no competing interests.

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Data Availability Statement

Data underlying the findings described in this manuscript, and the associated R code, are available on reasonable request to one of the corresponding authors.

AUTHOR CONTRIBUTIONS

JSM contributed to the conception and design of the work, the acquisition, analysis, and interpretation of the data, as well as drafting and revising of the manuscript. CJW designed, performed, and analyzed the systematic review, the analysis and interpretation of the data; and contributed to drafting and revising of the manuscript. CL contributed to the design of work, the acquisition, analysis, and interpretation of the data, as well as the drafting and revising of the manuscript. JS contributed to the conception and design of the work and drafting and revising of the manuscript. CA, JR, and AW contributed to the conception and design of the work and the acquisition of the data. AW, JS, JN, and CW contributed substantial drafting and revising of the manuscript. WSJ contributed to the design of work, acquisition, analysis, and interpretation of the data, design of systematic review, and drafting and revising of the manuscript. All authors have approved the final version of the manuscript.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Data S1. The rapid review search strategy.
CONSORT Statement.

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