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Community Paramedic Point of Care Testing

A Comprehensive Assessment and Technology Comparison

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Final Report

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Conflicts of Interest

No research team member declares a financial or intellectual conflict of interest pertaining to this study.

The manufacturers of the devices assessed in this study were involved with initial device set-up, paramedic training, and on-going device support, but were not involved in data collection and analysis.

Contents

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Abstract

Introduction: Community Paramedic (CP) programs provide a critical bridge between the health care system and the community. Additional treatments and assessments in the community by CPs often prevents transport of the patient to an acute care facility. One of the challenges CPs face is access to timely diagnostic tests such as blood analyses. Many CP programmes transport blood to a laboratory for analysis. This process is resource intensive, presents multiple opportunities for misidentification of patients/results, prevents CPs from providing timely treatment and coordinating additional patient care initiatives while on-scene, and may increase the time the CP is not available for another patient. Point of care testing (POCT) may offer a technological solution.

Purpose: Address the Canadian Safety and Security Program (CSSP) priority of assessing the use of technology in CP programmes to inform policy and strategy by comparing CP POCT to a standard laboratory process, and contrasting two commercially available devices (Abbott i-STAT® and Alere epoc®).

Methods: There were five broad methodological approaches to this study: 1. Device validation in the CP setting; 2. Time to results; 3. CP survey; 4. Human factors assessment; and 5. Descriptive cost and device summary. Seven analytes were assessed: sodium (Na), potassium (K), chloride (Cl), creatinine (Crea), hemoglobin (Hgb), hematocrit (Hct), and glucose (Glu). All statistical tests were considered significant at the 0.05 level.

Results: A total of 108 observations assessing seven analytes on 73 patients revealed seven out of the 1,047 individual comparisons (0.7%) with discrepant critical results (i.e., a critical range was detected in POCT but not in the laboratory). These appeared to be slightly higher with i-STAT (0.9%; 95% CI -0.1%, 1.9%) compared to epoc (0.3%; 95% CI -0.3, 0.9) (p=0.323). The discrepant results occurred entirely in the Na and K analytes. In 126 out of 1,645 individual comparisons (7.7%) exceeded the acceptable comparative range between POCT and laboratory. For i-STAT there were 32 out of 523 individual comparisons (6.1%; 95% CI 4.1%, 8.2%) that exceeded this range, and for epoc there were 56 out of 523 (10.7%; 95% CI 8.1%, 13.3%) (p=0.007). The epoc had almost three times the number of out-of-range results for Cl, and twice the number for Crea compared to i-STAT. The epoc had 17 instances of out-of-acceptable comparative range results for Hct compared to zero for i-STAT. For Glu however, i-STAT had twice as many out-of-range results for values under five mmol/L and three times as many for values greater than or equal to five mmol/L.

CPs will get their results considerably quicker using POCT compared to transportation to lab (97 to 163 minutes).

CPs felt that POCT improved their ability to make timely decisions for their patients and saved transport time to laboratory services in those events where no further lab analysis is required. A POCT program, however, will not replace blood transport in all events. There was a statistically significant higher rating for the i-STAT compared to the epoc on the system usability score, and the majority of CPs preferred the i-STAT over the epoc.

The i-STAT had higher initial costs but lower operational costs; the epoc had lower initial costs but higher operational costs.

The i-STAT and epoc share many of the same characteristics such as time to results, blood volumes required, and operating temperature ranges, however there are some important differences. The epoc test cards can be stored at room temperature, while i-STAT test cartridges must be stored at two to eight °C and once removed must be used within 14 days. The i-STAT has a larger test menu than the epoc, but this is attained through multiple test cartridges, not a single card as for the epoc.

Conclusions: EMS systems that use POCT can expect that even with optimized training and rigorous quality control testing, and dependent on the analyte and POCT device, discrepant critical range values with the laboratory will occur in 0% to 1.9% of comparisons. Results outside of acceptable comparative range between the POCT and laboratory will occur in 4.1% to 13.3% of comparisons, also depending on analyte and POCT device. The epoc device had a statistically significant increased number of tests that exceeded the acceptable comparative range between POCT and lab when compared to i-STAT.

CPs felt that POCT helped to improve their ability to make timely decisions for their patients and saved transport time to laboratory services in those events where no further lab analysis is required. CPs in general preferred i-STAT over the epoc.

Both POCT systems have advantages and disadvantages that must be considered carefully prior to purchase.

Introduction

The traditional role of Emergency Medical Services (EMS) systems is to respond to emergency calls. Today's EMS and paramedic systems, however, provide a critical bridge between the hospital and the community, frequently offering specialized primary care services such as Community Paramedics (CPs). These programmes deliver complex high needs patients, such as the frail elderly, with timely access to primary and urgent healthcare in the community, especially in the continuing care setting. In collaboration with the patient's family physician or a program specific on-call physician, additional on-site assessments, diagnostics and treatments are provided in the community by specially-trained paramedics. Often this care prevents the patient from being transported to an acute care facility, which has positive implications for the patient's physical and mental health and eases the burden of overcrowding on Emergency Departments and other health care services.

One of the challenges of providing care in the community is timely access to diagnostic tests such as blood analyses, which are used to form a diagnosis, stratify by risk, and create a treatment plan. Presently many CP programmes will collect blood specimens and transport them to a lab service for analysis. This process involves the CP collecting a blood sample, transporting the sample to a blood testing site, and following-up on results, often many hours later. In some settings, such as suburban or rural, this may equate to a long transport time. This process is resource intensive, presents multiple opportunities for misidentification of patients/results, and prevents CPs from providing timely treatment and coordinating additional patient care initiatives while on-scene. It also increases the time that the CP is not available for another patient visit. An alternative process for CP programmes may be point of care testing (POCT). POCT technology has advanced considerably in the last decade, resulting in the commercial availability (at the time of this study design) of two portable devices that can provide a variety of blood tests quickly at the patient's bed side (Abbott i-STAT® and Alere epoc®).

A systematic review completed in 2013 on CP care, did not identify any peer reviewed studies that assessed the use of POCT technology in this setting.[1] A number of studies, however, have reported the use of POCT in EMS, with three studies assessing the i-STAT device in a ground EMS scenario.[2-4] One of the studies did not explicitly compare the results to laboratory values, and one study assessed the i-STAT troponin I (cTnI).[2,3] One of the studies assessed sodium, potassium, chloride, blood urea nitrogen, glucose, hematocrit and hemoglobin from i-STAT split sample tests performed in a moving ambulance, to those on the same device in the Emergency Department.[4] This study found correlation (r-values) of greater than 0.89 for all tests. No published studies could be located that used the epoc device in the EMS setting, describing either device in the setting of a community paramedic programme, assessing the usefulness of this device in the CP setting or contrasting the two portable options for POCT devices.

The purpose of this study is to address the Canadian Safety and Security Program (CSSP) priority of assessing the use of technology in CP programmes to inform policy and strategy by answering the following research questions:

1. What is the association between POCT blood results and those derived from standard laboratory processes?

2. Does POCT decrease the time to results?

3. If there is a difference in time to results, does this difference afford any advantage to patient care or operational efficiency?

4. Do CPs prefer POCT over the standard laboratory process?

5. Do CPs favour one POCT over another and why?

6. What are the costs associated with POCT testing?

7. What are the pros and cons of commercially available portable POCT devices?

Methods

Study Setting:

This study was conducted in a mature CP program that has been in existence since November, 2012, serving an urban and suburban population. The programme presently responds to approximately 6,000 patient care events per year. Patients can be generally described as medically fragile and seen in a home setting (e.g., continuing care facility, private residence, and homeless shelter). There are 23 CPs in the programme and six CP units (SUVs which have been configured to house necessary equipment and supplies) that operate out of two stations. CPs must be registered as an Emergency Medical Technologist – Paramedic with the Alberta College of Paramedics, and have at least five years of clinical experience. In addition to their formative paramedic training, CPs receive 21 days of training on assessment and treatment. The CPs have the ability to draw blood specimens and take the sample to twelve different laboratory service locations for analysis.

Study Training: CPs received one-day, or eight hours, of training for this study in the week prior to the start of the study. The curriculum included vendor delivered training on the operation of i-STAT and epoc devices, and administration and trouble-shooting strategies. In addition to the specific device training, CPs received an overview of the research study, ethics, consent procedures, additional equipment, documentation and data collection. Since drawing blood was already in the CP scope of practice and routinely being performed, no additional training in this area was provided. Each CP received an additional two-hour, quality control (QC) testing training session. While it was suggested to CPs the optimal process for using two POCT devices on-scene (Appendix A), it was left up to each individual CP on how they managed both devices as long as both devices were used as closely as possible to each other.

Device preparation and maintenance: Six i-STAT and six epoc devices were purchased and systematically tested prior to use in the study (initial device validation phase). The devices, associated test

cards/cartridges, and analytes underwent validation using split sample testing of patient blood comparatives to the laboratory reference instruments, with-in run and day to day precision testing using liquid quality control (QC) solutions and calculation verification (cal-ver) tests using liquid cal-ver solutions as per standards set by Calgary Lab Services (CLS). This occurred in a CLS laboratory and involved CLS personnel, device manufacturer representatives, and research personnel. All devices passed the validation, quality control, and calculation verification testing.

While in-service, all devices were housed in a temperature controlled and shock resistant environment; a container was constructed using a corrugated plastic box with a closed-cell extruded polystyrene foam insert with room temperature gel packs similar to containers used by Transfusion Medicine to transport blood. Test cartridges for i-STAT and test cards for epoc were also stored in the temperature controlled containers. Temperature monitors were placed on the inside and outside of the device containers to monitor the effectiveness of the container in maintaining an operating temperature of between 18°C and 30°C. All QC and cal-ver solutions and additional i-STAT test cartridges were stored in two fridges that were both temperature monitored throughout the study period. Additional epoc test cards were stored at room temperature throughout the study period. Devices underwent weekly QC testing and if applicable daily electronic simulation testing as per the manufacturers' and CLS' recommendations. For the i-STAT this included weekly testing using two levels (ampoules) of QC solutions and a daily electronic simulation test by inserting an external simulator. For the epoc this included weekly testing using four levels (ampoules) of QC solutions (see Appendix B for study procedure details).

Study design and analysis: There were five broad methodological approaches used to address the seven research questions: 1. Device validation in the CP setting; 2. Time to results; 3. CP survey; 4. Human factors assessment; and 5. Descriptive cost and device summary. All statistical tests were considered

significant at the 0.05 level. Descriptive data use mean and standard deviation for normally distributed data, or median and interquartile range otherwise.

1. Device validation in the CP setting. Patients meeting inclusion criteria were enrolled by CPs into a modified single subject design study between September 1, 2016 and November 30, 2016. Inclusion criteria consisted of patients who have capacity and are their own decision maker, age greater than or equal to 18 years, at least one study analyte ordered for testing, and that the patient understood the informed consent script. After informed consent, a routine blood draw was performed and the specimen was sent for laboratory blood testing with CLS (gold standard), but also had a portion of the drawn blood used for on-scene POCT testing (split sample). The blood tube used was a BD vacutainer PST tube with 56 units of lithium heparin. POCT testing involved the use of both i-STAT and epoc devices. The analytes sodium (Na), potassium (K), chloride (Cl), creatinine (Crea), hemoglobin (Hgb), hematocrit (Hct), and glucose (Glu) were included in the study (See Appendix B for detailed study procedures). The rationale for choosing these analytes was the high frequency of occurrence in the CP programme and availability on each of the test cartridges/cards for the two POCT devices.

Data were downloaded from the two POCT devices by one investigator. The associated electronic patient care records (ePCR) and laboratory values were sent by CPs to the same investigator using secured email. The POCT device data were linked to the applicable ePCR by using the patient's personal health number (PHN), the date of the event, the time of the event and the CP performing the test. The ePCR was linked to the applicable laboratory values using the patient's first and last name, date of birth (DOB), PHN, and date and time of event (blood draw). Data in the ePCR were verified for completeness and missing data (i.e., timestamps) shortly after the patient contact, and if applicable sent to the author of the ePCR for correction. All data were manually entered into a Microsoft Excel spreadsheet by one investigator and independently verified by a research associate. Each patient and CP was given a unique study identifier as

was each event. All identifying patient data were then removed and the data analyzed using Stata version 11 (Statacorp, College Station, Texas). POCT results were compared to the gold standard laboratory values using the methods described by Bland and Altman (2009).[5] Critical range values, defined as values for which the analyte result is considered clinically abnormal, were based on critical ranges used by CLS (Table 1). Acceptable comparative ranges, defined as the accepted deviation that a POCT can have from the gold standard of CLS analysis were based on CLS standards (Table 1). All analytes have an acceptable comparative range except Hgb, which is a calculation based on the Hct value.

Table 1: *Summary of critical range values and acceptable comparative ranges by analyte.*

Analyte	Critical Range	Laboratory to POCT Acceptable Comparative Range
Sodium (Na)	< 120 and >155 mmol/L	-4 to 4 mmol/L
Potassium (K)	<2.5 and > 6 mmol/L	-0.3 to 0.3 mmol/L
Chloride (Cl)	n/a	-5% to 5%
Creatinine (Crea)	n/a	-30 to 30 umol/L
Hematocrit (Hct)	n/a	-6% to 6 %
Hemoglobin (Hgb)	< 70 g/L	n/a
Glucose (glu)	<2.6 and > 24.9 mmol/L	< 5 mmol/L: -0.3 to 0.3 mmol/L ≥ 5 mmol/L: -10% to 10%

Note: POCT=Point of Care Testing Device

POCT results exceeding the acceptable comparative range were assessed to determine if one device contributed more out-of-range results than others. Chi-squared test and logistic regression were used with a dichotomous outcome of out-of-range-result or not out-of-range-result.

2. Time to Results. Data were provided by CLS and linked to POCT data using study event number, patient's name, DOB, PHN and the date of event. The POCT devices automatically provided a date and time stamp when results were available. The date and time on all POCT devices were synchronized on set-up and checked periodically during the data collection period. The mean of the time when results were available from the two POCT devices were compared to the earliest time that results were available from laboratory testing in Netcare (a provincial electronic health record).

3. Community Paramedic Survey. An online survey was developed to gather CP experiences, preference, and feedback regarding both POCT devices (Appendix C). The survey was pilot tested on a CP team lead and one of the investigators and refined accordingly prior to sending to all CPs involved in the study. The survey was sent by email to the CPs by one of the investigators that did not have a power relationship over the respondents. To reduce order effects of the device order in the survey responses, participants were randomly assigned the survey order for each device (either i-STAT or epoc first) using R sample command (R Core Team). Answer choices to the device preference questions were presented in random order using the Survey software platform answer randomization command (Select Survey Tool, Alberta Health Services). Data were downloaded to Microsoft Excel for descriptive analysis by members of the research team who did not have a power relationship over the participants. These investigators removed all identifying information prior to sending to the rest of the research team.

A portion of the survey involved participants completing the Systems Usability Scale (SUS) for each device.[6] The SUS is a validated reliable measuring scale of technology learnability and usability. The scores are normalized and can be compared to a benchmark of quartile ranges, acceptability ranges and adjective ratings in which 2,324 responses were gathered in 206 product studies.[7] The SUS analysis consisted of using a linear regression mixed effect model. The participants were considered as a random intercept effect taking into account their paramedic experience, experience in this specific CP program and previous exposure to the devices in a work environment.

4. Human Factors Assessment. The two Human Factors consultants on the research team (SB and LP) reviewed the device usability with both heuristic evaluation and usability testing methodologies. Heuristic evaluation is a cost-effective method of interface evaluation that uses broad categories of design principles called heuristics which were initially proposed by Neilsen (1994) and adapted for evaluation of medical devices (Zhang, 2003) to systematically evaluate device interfaces for usability problems.[8,9] The Human

Factors consultants worked through a number of tasks on the two devices, identified design issues and good design features with each of the device's respective interfaces. Solutions were also identified to mitigate the issues that were identified during the heuristic evaluation, where applicable.

Usability testing was completed by analysing video from the QC procedures with CPs. Three observation sessions were used to video record six CPs using the devices. The observations occurred at weeks nine and 10 of exposure to the devices. Participants were video recorded on a Canon Vixia HF M31 HD camcorder by researchers standing in the room where QC testing normally occurred.

Crews typically completed the QC testing on both devices at the same time by staggering starts for tests so that the waiting time for a result was used to prepare the other device's test.

Observational time to perform tasks was not calculated as the simultaneous testing of two different devices would bias results. Any device errors, including test card/cartridge errors that were encountered, issues running the tests, steps missed and feedback from the staff were incorporated into the human factors review.

5. Descriptive Cost and Device Summary. The descriptive summary included costs in Canadian dollars associated with implementing and maintaining each of the POCT devices and a summary of the characteristics of the two POCT device systems included in this study compared to the normal process of transporting blood to a lab. This descriptive information was collected and summarized by the EMS CP management investigators of this study (RK, DD, SG), throughout the course of implementing the research protocol. Device specific descriptive information was reviewed by representatives from the manufacturer for accuracy.

Ethics: All aspects of this study are approved by the University of Calgary, Conjoint Health Research Ethics Board (REB16-1000).

Results

What is the association between POCT blood results and those derived from standard laboratory processes?

Out of 1,649 patient care events during the study period, 174 patient care events had a blood draw, with 108 events enrolled in the study, from 73 participants (Figure 1). Of the 73 participants, 10 had more than one observation in the dataset. The 108 observations were from participants that collectively had a mean age of 58.7 years (SD 16.3), with 49% female.

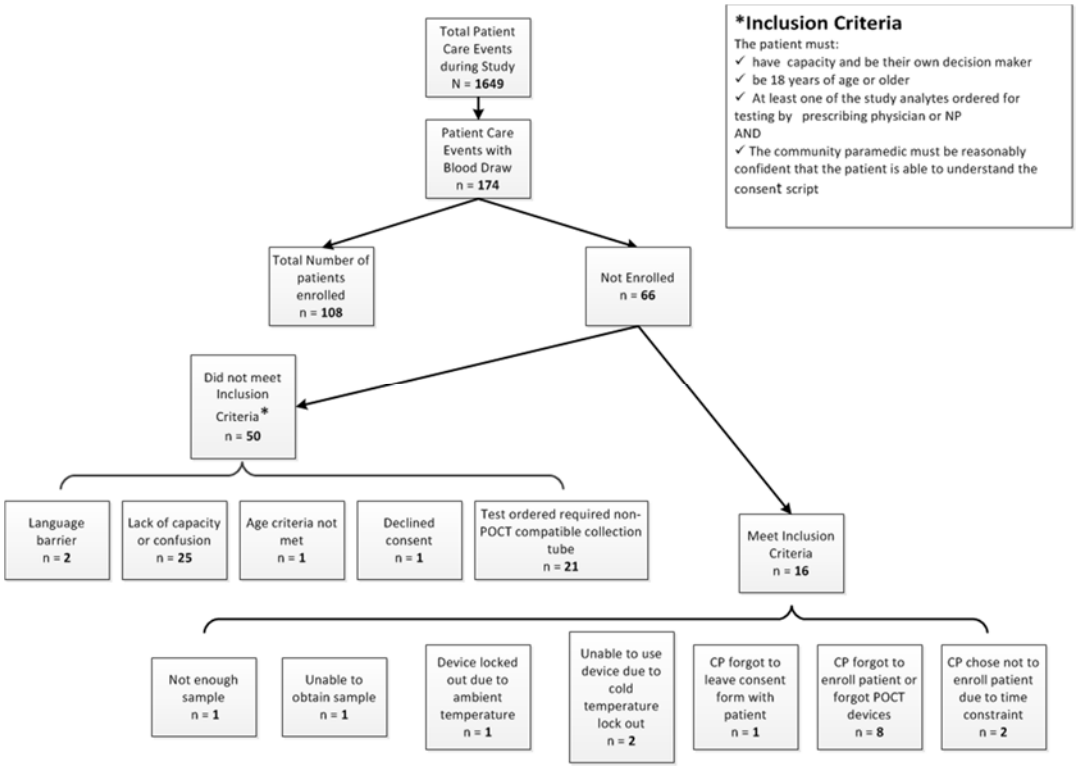

Figure 1: *Enrollment of patients for Device Validation.*

Sodium (Na): For the Na analyte, there were 98 out of 108 observations (91%) that had data from both devices and CLS (four missing i-STAT, three missing epoc, and three missing CLS). For the i-STAT, Figure 2 and Table 2 illustrates that there was one instance of the device reporting a critical value that was

not deemed critical by the gold standard and two observations that were outside of the acceptable comparative range. The epoc device similarly had one instance of the device reporting a critical value that was not deemed critical by the gold standard and two observations that were outside of the acceptable comparative range (Figure 2 and Table 2). When the epoc was compared to the i-STAT, there were two instances of one device reporting a critical value that was not deemed critical by the other device and one observation that fell outside of the acceptable comparative range (Figure 2 and Table 2).

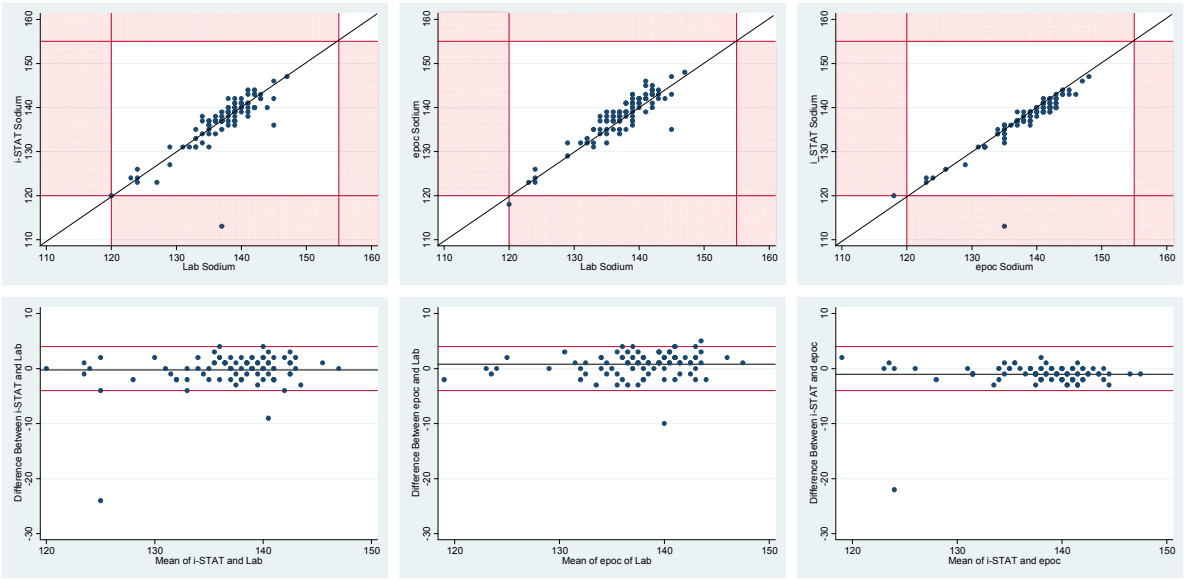

Figure 2: *Results for sodium from i-STAT and epoc compared to gold standard ('Lab' – Calgary Lab Services), and between i-STAT and epoc. All results reported in mmol/L.*
Upper graphs illustrate the critical range defined as less than 120 and greater than 155 mmol/L (red lines), with the black line denoting perfect agreement. Areas of disagreement between device and reference method are shaded in red.
Lower graphs illustrate the acceptable comparative range defined as less than -4 and greater than 4 mmol/L (red lines), with the black line denoting mean of the difference.

Potassium (K): For the K analyte, there were 97 out of 108 observations (90%) that had data from both devices and CLS (four missing i-STAT, four missing epoc, and three missing CLS). For the i-STAT, Figure 3 and Table 2 illustrates that there were two instances of the device reporting a critical value that was not deemed critical by the gold standard and 10 observations that were outside of the acceptable comparative range. The epoc device had no instances of a critical value that was not deemed critical by the gold

standard and nine observations that were outside of the acceptable comparative range (Figure 3 and Table 2). When the epoc was compared to the i-STAT, there was one instance of one device reporting a critical value that was not deemed critical by the other device and one observation that fell outside of the acceptable comparative range, and (Figure 3 and Table 2).

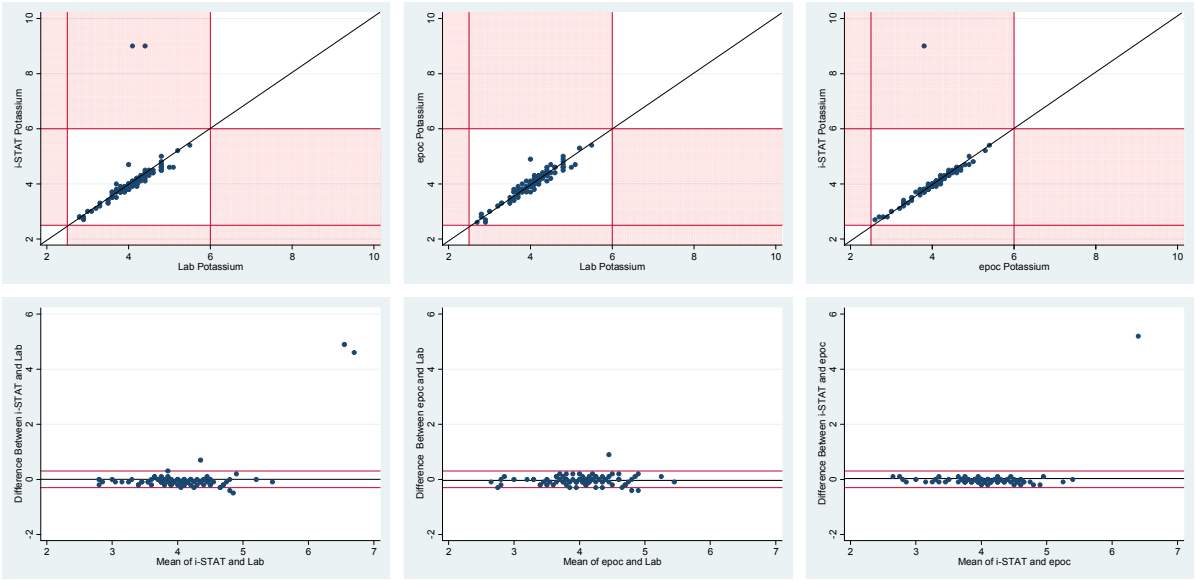

Figure 3: *Results for potassium from i-STAT and epoc compared to gold standard ('Lab' – Calgary Lab Services), and between i-STAT and epoc. All results reported in mmol/L.*
Upper graphs illustrate the critical range defined as less than 2.5 and greater than 6 mmol/L (red lines), with the black line denoting perfect agreement. Areas of disagreement between device and reference method are shaded in red.
Lower graphs illustrate acceptable comparative range defined as less than -0.3 and greater than 0.3 mmol/L (red lines), with the black line denoting mean of the difference.

Chloride (Cl): For the Cl analyte, there were 97 out of 108 observations (90%) that had data from both devices and CLS (four missing i-STAT, four missing epoc, and three missing CLS). For the i-STAT, Figure 4 and Table 2 illustrates that there were five observations that were outside of the acceptable comparative range. The epoc device had 14 observations that were outside of the acceptable comparative range (Figure 4 and Table 2). When the epoc was compared to the i-STAT, there were 10 observations that fell outside of the acceptable comparative range (Figure 4 and Table 2).

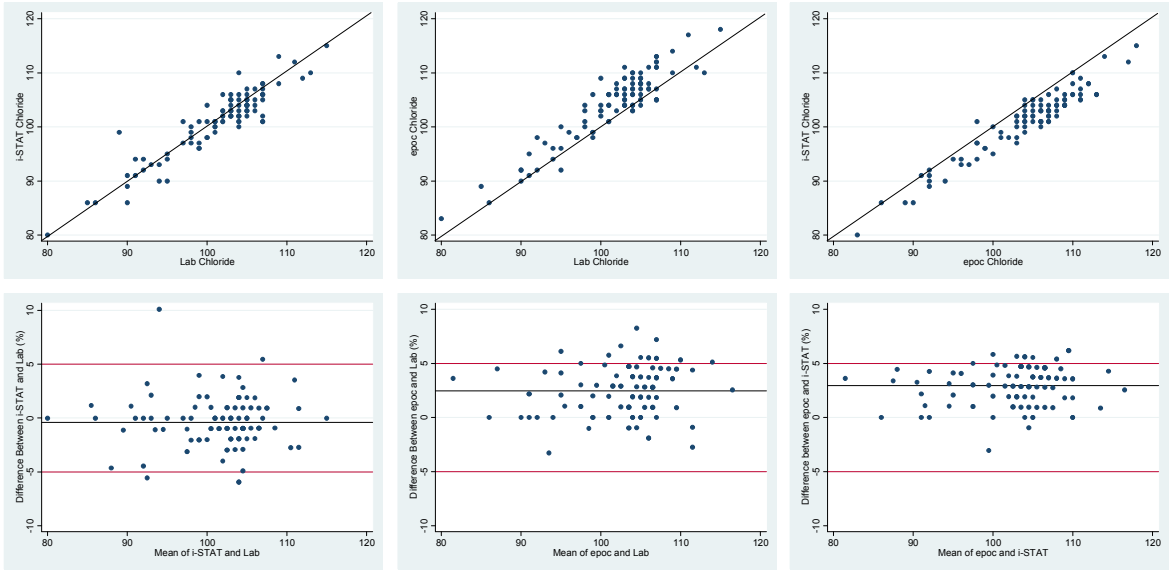

Figure 4: *Results for chloride from i-STAT and epoc compared to gold standard ('Lab' – Calgary Lab Services), and between i-STAT and epoc. All results reported in mmol/L.*

Upper graphs – there is no defined critical range; the black line denotes perfect agreement.

Lower graphs illustrate acceptable comparative range defined as less than -5% and greater than 5% of reference method (red lines), with the black line denoting mean of the difference.

Creatinine (Crea): For the Crea analyte, there were 94 out of 108 observations (87%) that had data from both devices and CLS (four missing i-STAT, six missing epoc, and four missing CLS). For the i-STAT, Figure 5 and Table 2 illustrates that there were four observations that were outside of the acceptable comparative range. The epoc device had 10 observations that were outside of the acceptable comparative range (Figure 5 and Table 2). When the epoc was compared to the i-STAT, there were seven observations that fell outside of the acceptable comparative range (Figure 5 and Table 2).

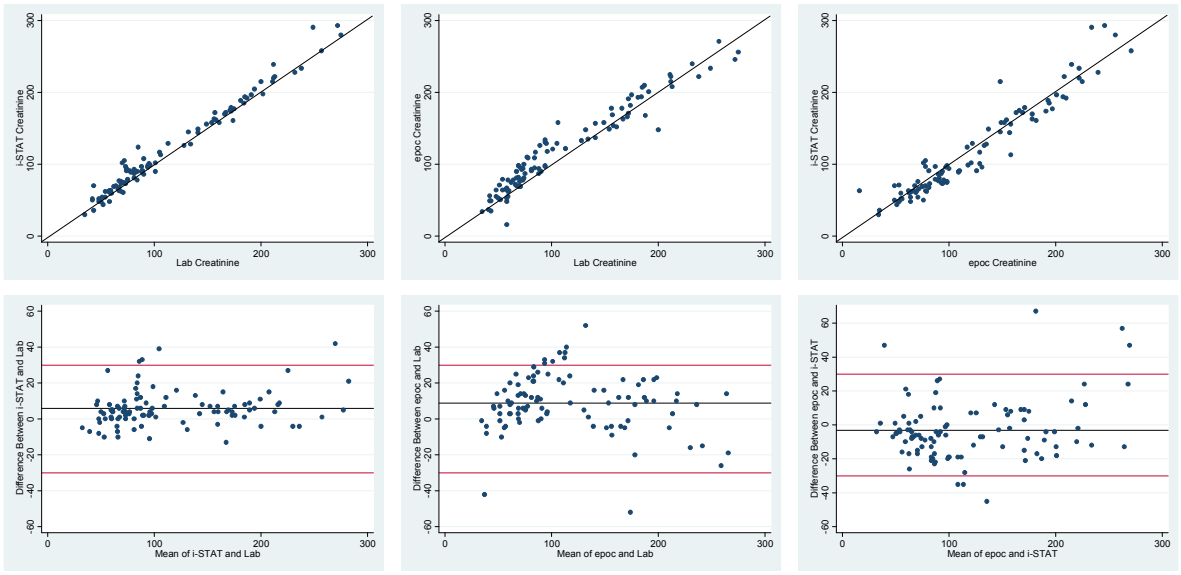

Figure 5: *Results for creatinine from i-STAT and epoc compared to gold standard ('Lab' – Calgary Lab Services), and between i-STAT and epoc. All results reported in umol/L*

Upper graphs – there is no defined critical range; the black line denotes perfect agreement.

Lower graphs illustrate the acceptable comparative range defined as less than -30 and greater than 30 umol/L of reference method (red lines), with the black line denoting mean of the difference.

Hematocrit (Hct): For the Hct analyte, there were 80 out of 108 observations (74%) that had data from both devices and CLS (four missing i-STAT, four missing epoc, and 21 missing CLS). For the i-STAT, Figure 6 and Table 2 illustrates that there were no observations that were outside of the acceptable comparative range. The epoc device had 17 observations that were outside of the acceptable comparative range (Figure 6 and Table 2). When the epoc was compared to the i-STAT, there were three observations that fell outside of the acceptable comparative range (Figure 6 and Table 2).

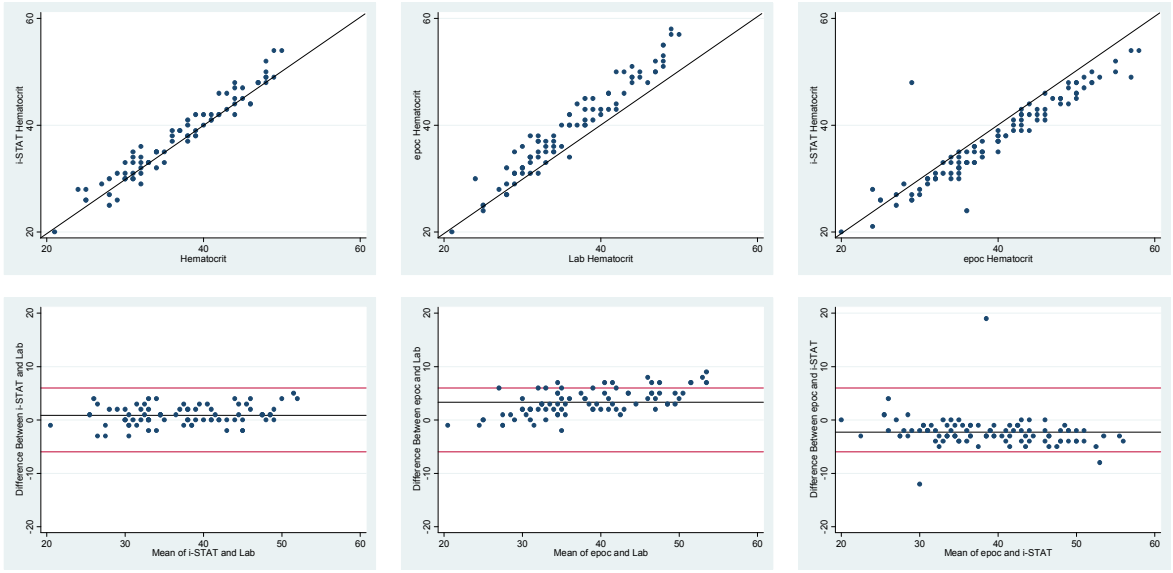

Figure 6: *Results for hematocrit from i-STAT and epoc compared to gold standard ('Lab' – Calgary Lab Services), and between i-STAT and epoc. All results reported in %.*

Upper graphs – there is no defined critical range; the black line denotes perfect agreement.

Lower graphs illustrate the acceptable comparative range defined as less than -6.0% and greater than 6.0% of reference method (red lines), with the black line denoting mean of the difference.

Hemoglobin (Hgb): For the Hgb analyte, there were 80 out of 108 observations (74%) that had data from both devices and CLS (four missing i-STAT, four missing epoc, and 21 missing CLS). Since this analyte is calculated based on Hct, there is no defined acceptable comparative range specified but we have graphed the difference for information and therefore no outliers to report. There were no disagreements between devices and the gold standard, or between devices for the critical values (Figure 7 and Table 2).

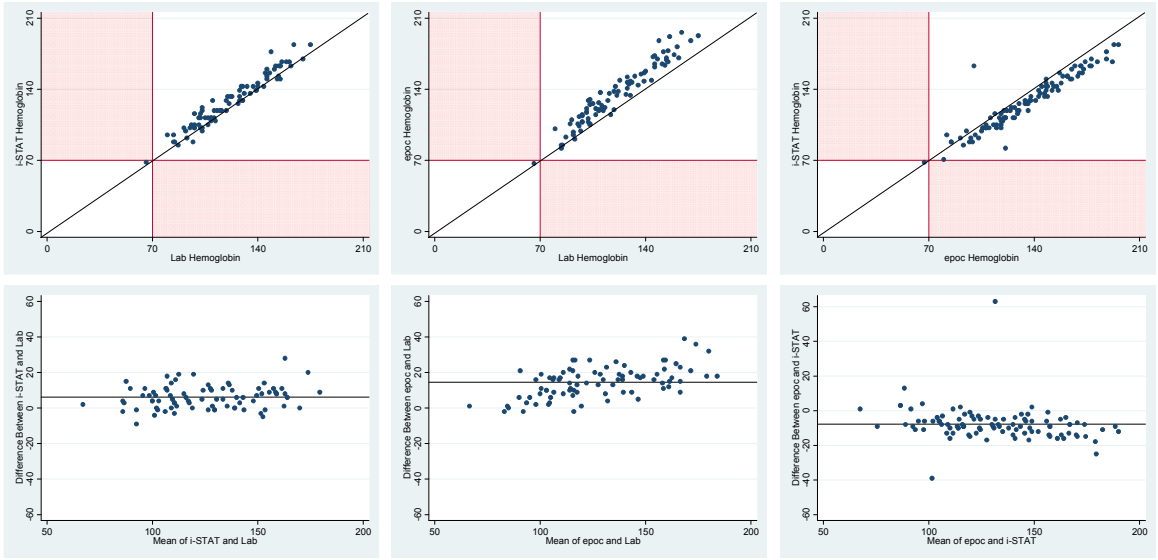

Figure 7: *Results for hemoglobin from i-STAT and epoc compared to gold standard ('Lab' – Calgary Lab Services), and between i-STAT and epoc. All results reported in g/L.*

Upper graphs illustrate the critical range defined as less than 70 g/L (red lines), with the black line denoting perfect agreement. Areas of disagreement between device and reference method are shaded in red.

Lower graphs – there is no acceptable comparative range for this analyte as it is a calculation based on hematocrit; the black line denotes mean of the difference.

Glucose (Glu): For the Glu analyte, there were 36 out of 108 observations (33%) that had data from both devices and CLS (five missing i-STAT, three missing epoc, and 70 missing CLS). For the i-STAT, Figure 8 and Table 2 illustrates there were no instances of the device reporting a critical value that was not deemed critical by the gold standard. There were five observations that were outside of the acceptable comparative range for observations less than five mmol/L, and six observations for values greater than or equal to five mmol/L. For the epoc device, there were no instances of the device reporting a critical value that was not deemed critical by the gold standard. There were two observations that were outside of the acceptable comparative range for observations less than five mmol/L and observations greater than five mmol/L respectively (Figure 8 and Table 2). When the epoc was compared to the i-STAT, there were no instances of the device reporting a critical value that was not deemed critical by the gold standard. There were three

observations that fell outside of the acceptable comparative range for observations less than five mmol/L and 13 observations for values greater than or equal to five mmol/L (Figure 8 and Table 2).

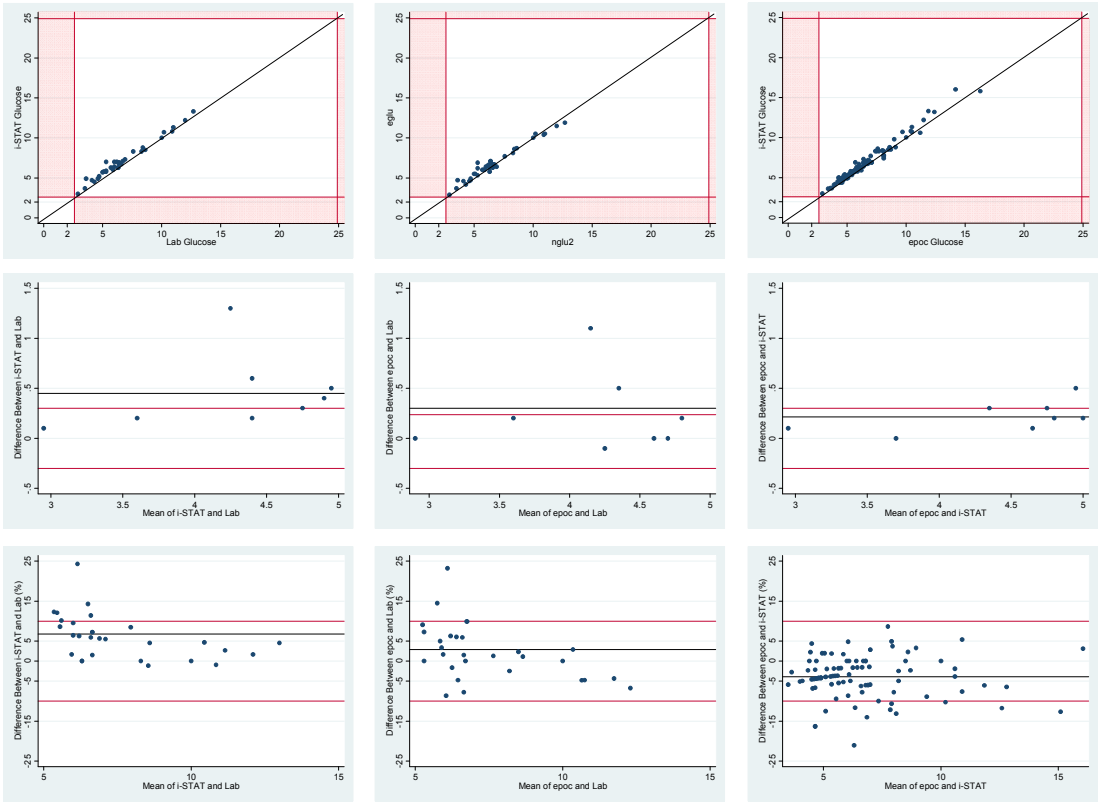

Figure 8: *Results for glucose from i-STAT and epoc compared to gold standard ('Lab' – Calgary Lab Services), and between i-STAT and epoc. All results reported in mmol/L.*

Upper graphs illustrate the critical range defined as less than 2.6 and greater than 24.9 mmol/L (red lines), with the black line denoting perfect agreement. Areas of disagreement between device and reference method are shaded in red.

Middle graphs illustrate acceptable comparative range for observations under 5 mmol/L. The acceptable comparative range is defined as less than -0.3 and greater than 0.3 mmol/L (red lines), with the black line denoting mean of the difference.

Lower graphs illustrate the acceptable comparative range for observations greater than 5 mmol/L. The acceptable comparative range is defined as less than -10% and greater than 10% (red lines), with the black line denoting mean of the difference.

Table 2: *Summary of disagreements in critical range and values outside of acceptable comparative range between laboratory and POCT by analyte and manufacturer.*

Critical Range Disagreement				
Analyte	**Lab to i-STAT**	**Lab to epoc**	**epoc to i-STAT**	**Total**
Sodium	1/101	1/102	2/101	**4/304 (1.3%)**
Potassium	2/101	0/101	1/100	**3/302 (1.0%)**
Chloride	n/a	n/a	n/a	**n/a**
Creatinine	n/a	n/a	n/a	**n/a**
Hematocrit	n/a	n/a	n/a	**n/a**
Hemoglobin	0/83	0/84	0/100	**0/267 (0.0%)**
Glucose				
<5 mmol/L	0/8	0/8	0/8	**0/24 (0.0%)**
≥ 5 mmol/L	0/29	0/29	0/92	**0/150 (0.0%)**
Total	**3/322 (0.9%)**	**1/324 (0.3%)**	**3/401 (0.7%)**	**7/1,047 (0.7%)**
		p=0.323*		
Outside of the Laboratory to POCT Acceptable Comparative Range				
Analyte	**Lab to i-STAT**	**Lab to epoc**	**epoc to i-STAT**	**Total**
Sodium	2/101	2/102	1/101	**5/304 (1.6%)**
Potassium	10/101	9/101	1/100	**20/302 (6.6%)**
Chloride	5/101	14/101	10/100	**29/302 (9.6%)**
Creatinine	4/100	10/98	7/98	**21/296 (7.1%)**
Hematocrit	0/83	17/84	3/100	**20/267 (7.5%)**
Hemoglobin	n/a	n/a	n/a	**n/a**
Glucose				
<5 mmol/L	5/8	2/8	3/8	**10/24 (41.7%)**
≥ 5 mmol/L	6/29	2/29	13/92	**21/150 (14.0%)**
Total	**32/523 (6.1%)**	**56/523 (10.7%)**	**38/599 (6.3%)**	**126/1,645 (7.7%)**
		p=0.007*		

Note: POCT=Point of Care Testing Device

*Two sample test of proportions between i-STAT compared to lab, and epoc compared to lab.

Device specific errors:

Each device was assessed against other devices by the same manufacturer. For the i-STAT devices, the proportion of out of range results by device was 0.0% to 41.7%. One i-STAT device (CP6) appeared to give more results outside of acceptable comparative ranges than others (Table 3). When i-STAT CP6 was compared to all other devices, it was found that the odds of getting a value outside of the acceptable comparative range was 3.3 times (95% CI 1.3, 8.3) that of the other devices. For the epoc devices, the

proportion of out-of-range results was 27.3% to 58.8%. There was no one epoc device that had a statistically significant difference when compared to the other epoc devices (Table 3).

Table 3: *Summary of out-of-range and in-range results for i-STAT and epoc by individual device and by manufacturer.*

Device	Out-of-range*	In-range*	Proportion Out-of-range by device
i-STAT			
CP1	0 (0.0%)	13 (100.0%)	0 (0.0%)
CP2	4 (23.5%)	13 (76.5%)	4 (14.8%)
CP3	4 (23.5%)	13 (76.5%)	4 (14.8%)
CP4	2 (20.0%)	8 (80.0%)	2 (7.4%)
CP5	2 (18.1%)	9 (81.8%)	2 (7.4%)
CP6	15 (41.7%)	21 (58.3%)	15 (55.5%)
Total Out-of-range	27/104 (26.0%)	77/104 (74.0%)	27 (100.0%)
epoc			
CP1	5 (38.5%)	8 (61.5%)	5 (10.2%)
CP2	6 (31.6%)	13 (68.4%)	6 (12.2%)
CP3	10 (58.8%)	7 (41.2%)	10 (20.4%)
CP4	6 (54.6%)	5 (45.5%)	6 (12.2%)
CP5	3 (27.3%)	8 (72.7%)	3 (6.1%)
CP6	19 (54.3%)	16 (45.7%)	19 (38.8%)
Total Out-of-range	49/106 (46.2%)	57/106 (53.8%)	49 (100.0%)

*Out-of-range refers to outside of the Laboratory to POCT acceptable Comparative Range as defined by Calgary Lab Services.

Does POCT decrease the time to results?

For the time analysis, there were data available for 106 out of 108 events (two were missing i-STAT time stamps due to an inadvertent device lock). The mean time between the mean of the two POCT device results being available, to the result being available from CLS was 129.7 minutes (SD 169.7; 95% CI 96.9,162.6). This is based on 105 observations, as one observation had a result that was three times larger than the next largest observation (3,025.15 minutes). This extreme outlying value was due to a new lab requisition being created several days later and the new date and time, not the original date and time of receiving the sample, entered.

If there is a difference in time to results, does this difference afford any advantage to patient care or operational efficiency?

From the Time Analysis phase, there were time points from leaving scene to arrive at CLS available for all 108 events. The mean time to transport a specimen to CLS was 19.7 minutes (SD 14.1; 95% CI 17.0, 22.4).

From the CP Survey phase, 19 CPs were sent a survey. While there are officially 23 CPs in the programme, three of the CPs hired during the study period did not take part in the study and one CP on parental leave also did not take part in the study. Seventeen (17) complete surveys and one partially complete survey were received (95% response rate). The respondents had a range of EMS experience from 5 to 32 years. When asked if POCT improved their ability to make timely decisions, 18 of 18 (100%) respondents strongly agreed or agreed. When asked to rate if POCT shortened their time on task, 8 of 18 respondents (44.5%) strongly agreed or agreed.

Do CPs prefer POCT over the standard laboratory process?

When asked if POCT was preferred over transporting blood to CLS, 10 of 18 respondents (55.6%) strongly agreed or agreed. Seventeen (17) of 18 respondents (94.4%) would support the implementation of a POCT process (regardless of device) in conjunction with the existing CLS process.

Do CPs favour one POCT over another and why?

Eleven (11) of 18 (61.1%) respondents chose i-STAT as the preferred device for the CP programme, with 5 (27.8%) preferring epoc, and 2 (11%) having no preference. Table 4 outlines the comments respondents provided on what they liked and did not like about the two devices.

Table 4: *Summary of comments pertaining to device preference.*

Preference	Comment
i-STAT (n=11)	• i-STAT had less errors and easier to use, clean and do QC on. • Easier to use with fewer errors and less time commitment. • Compact and easy. • Ease of use. • Easy to use, uncomplicated, gives the same results as the epoc without the frustration, annoyance & hassle! • Less complicated, easy to clean, no moving parts. • More durable, wait time is after sample introduction, easier to introduce sample and place card in reader. • Easier to use overall, simple is better for continued device confidence, likely won't require as much re-familiarization. • Felt sturdier. Easier to turn off. Quality control less time consuming. • Slightly easier to learn, handle, clean and use in different environments. • No answer entered.
epoc (n=5)	• Would not have to be regulated for temperature, no extra cooler to carry around. • More reliable. • I feel like I understand the device better for both trouble shooting and pulling up previous results. • Versatility, no refrigeration of cartridges, and versatility of testing with just one cartridge. • Ease of use, more consistent with no errors, do not have to do daily testing and do not have to refrigerate test cards.
No preference (n=2)	• No answer entered. • No answer entered.

Survey results using the SUS also match the preference data. Participants scored the i-STAT device 24.4 points higher than the epoc device ($p < 0.011$) using a linear regression mixed effect model. There was no overlap of the 95% confidence intervals using the means from that statistical model (accounting for paramedic experience), where the i-STAT mean score was 84.0 and the epoc 59.6 (Figure 9). Comparing the mean SUS scores to quartiles for usability developed by Bangor, Kortum and Miller (2008) the epoc 59.6 score is in the 1st quartile for usability; 84.0 for the i-STAT is in the 4th quartile of usability (Figure).[7]

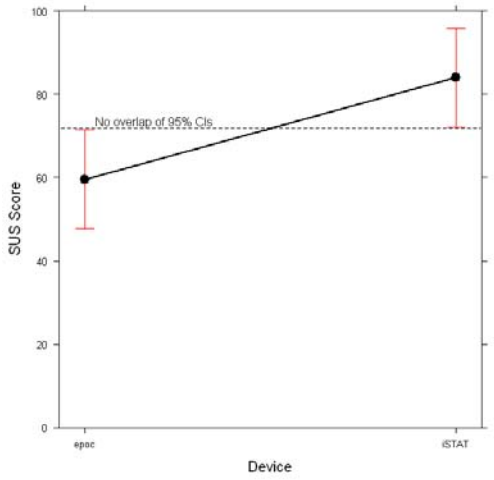

Figure 9: *Device System Usability Score (SUS) mean scores with 95% confidence intervals (calculated from a linear mixed effect model accounting for years of paramedic experience and previous use of device).*

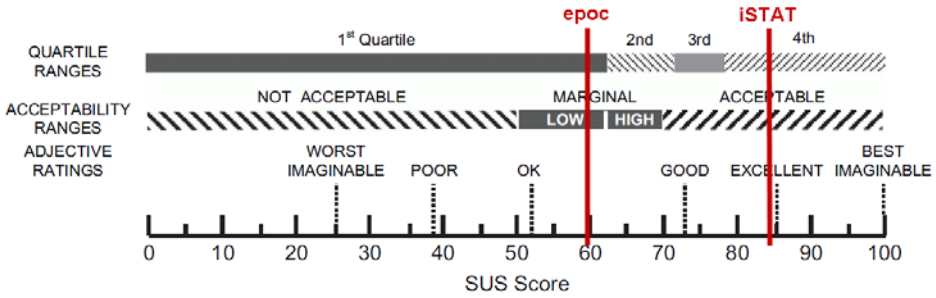

Figure 10: *Mean Systems Usability Scale (SUS) Scores for the epoc and i-STAT compared to quartile ranges, acceptability ranges and adjective ratings. Adapted from "An empirical evaluation of the System Usability Scale," by A. Bangor, P.T. Kortum, and J.T. Miller, 2008, International Journal of Human-Computer Interaction, 24(6), p. 592. Copyright 2008 by Taylor & Francis Group, LLC.*

Design differences in the two systems may have affected the perceived ease of use and thus device preference towards the i-STAT device. In general, feedback was that the i-STAT device was "simple", "easy to use", " a workhorse" type of device, whereas the epoc was described as "complicated – having more functionality than they need", "finicky", and "more difficult to use". Interestingly, over the course of the study the i-STAT device encountered more logged errors (46 of 305 tests; 15.2%) overall compared to the epoc device (53 of 469 tests; 11.9%). The i-STAT logged more errors during the quality check procedures (37 of

189 tests; 19.6%) compared to the epoc (33 of 340 tests; 9.7%); but experienced fewer errors during the blood testing in the field (9 of 116 tests; 8.0%) compared to the epoc (20 of 129 tests; 17.7%). The majority of these errors can be attributed to “human error” (under-fill or over-fill the cartridge, not introducing the sample in time, running the wrong type of test, using the incorrect solution during the QC testing, or potentially contaminating a cartridge by touching the contact points) (Figure 11).

The majority of the logged errors with the i-STAT device pertained to cartridge filling and handling errors. Feedback indicated that the users tried to under fill the i-STAT cartridge a little to avoid having the fluid (QC solution or blood) spray out the side when the cartridge door was closed. These behaviours resulted in a number of insufficient fill errors throughout the study.

Similarly with the epoc testing device the majority of errors were due to cartridge filling errors, more specifically, insufficient sample errors. Users must listen for a beep or a visual prompt on the screen to inform them to stop injecting the sample, anecdotally the paramedics stated that they would try to anticipate this beep and tended to stop prior to the beep because if they over filled the cartridge the solution or blood would squirt out the front of the machine. Further feedback suggested the audio prompt was not loud enough in some environments. When looking at the full error data for the epoc, there were a total of 32 tests that required a rerun due to insufficient samples and sample delivery issues, many of which occurred during blood testing in the field (Figure 11).

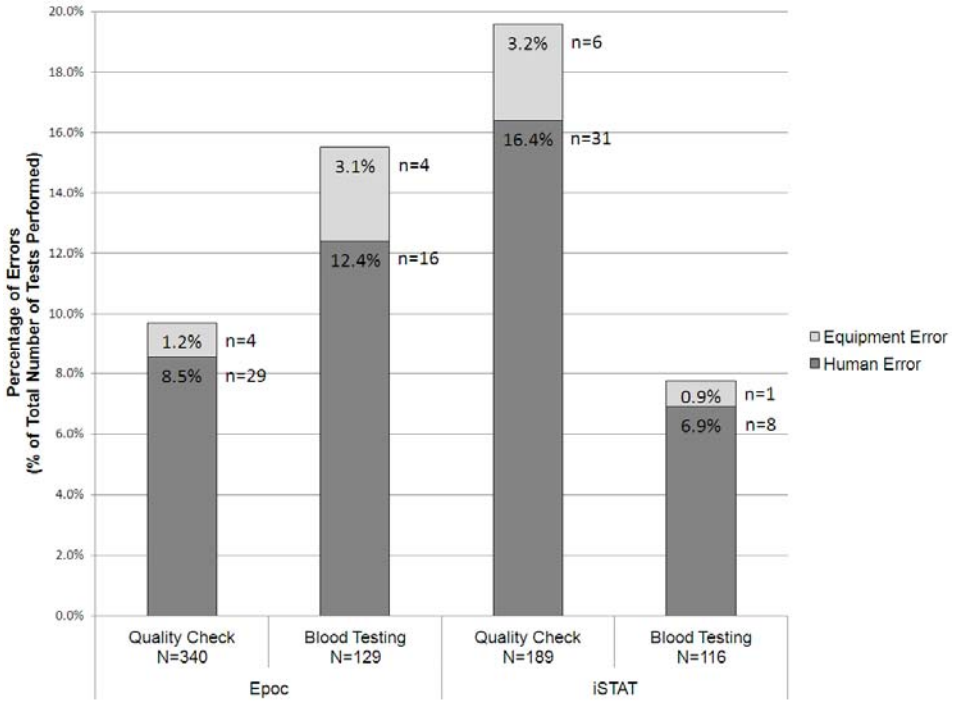

Figure 11: *Percentage of logged errors for each POCT device during Quality Check and Blood Testing.*

While both devices had their share of errors logged, it is device issues that are not logged as errors that may be contributing to the perceived difficulty of the epoc device. One of the frustrations that was observed in the analyzed QC testing sessions is the difficulty users experienced inserting the cartridge into the epoc reader. A total of 11 “unable to read barcode” alerts were recorded during the 27 (41%) observed QC tests. Some users experienced this message multiple times and anecdotal input from CP users indicated that this was a normal occurrence even with blood tests. Furthermore, the epoc device has a number of additional features and complexity. Users were observed having difficulty navigating the menus, one example was that the epoc device would default to the blood testing option and would start to configure the cartridge for that test, if they noticed this wrong option (some did not and ran QC testing as blood tests) they would have difficulty getting out of this option and into the QC testing menu.

What are the costs associated with POCT testing?

The study costs were separated into three key project phases; device purchase and set-up, training, and study data collection period.

The cost of CP and CLS personnel resources were not included in the set-up costs nor were supplies such as syringes or needles. Costs reported are based on dollar value for purchasing the item, however many items were loaned to the study or received in-kind from other areas of the organization.

Device purchase and set-up: Six ePOCs and six i-STATs were purchased for the study (one for each CP unit). The set-up costs included non-consumable items such as POCT devices, printers, chargers, downloaders, refrigerators, transport containers, and temperature monitoring devices. Consumable items included batteries, QC and verification solutions, and test cards/cartridges necessary to perform validation, precision testing and calculation verification. Tables 5 and 6 represent the total project costs per six devices.

For device validation, precision and verification testing, 145 epoc BGEM test cards and 68 i-STAT chem8+ test cartridges (these amounts include re-tests) were consumed. Twenty ampoules of level 1, level 3, level A, and level B were consumed for the epoc. Twenty ampoules of tri-control level 1 and tri-control level 3 were consumed for i-STAT. Additionally, five ampoules of hematocrit verification solution and five ampoules of calculation verification solution were consumed for epoc and ten ampoules of calculation verification solution were consumed for i-STAT.

Table 5: *Itemized costs for device purchase and set-up for the epoc.*

Description	Unit	Quantity Used	Unit Price	Total Price for Six Devices
epoc device (reader and host)	1	6	$5,600.00	$33,600.00
epoc printer	1	2	$400.00	$800.00
EUROTROL BGEM, CONTROL LEVEL 1 (10 ampoules / box)	BOX	2	$65.00	$130.00
EUROTROL BGEM, CONTROL LEVEL 3 (10 ampoules / box)	BOX	2	$65.00	$130.00
EUROTROL HCT CONTROL LEVEL A (10 ampoules / box)	BOX	2	$65.00	$130.00
EUROTROL HCT CONTROL LEVEL B (10 ampoules / box)	BOX	2	$65.00	$130.00
EUROTROL HEMATOCRIT VERIFICATION FLUIDS, 190000005 (5 ampoules of 5 unique solutions required to perform one test)	BOX	2	$150.00	$300.00
EUROTROL CALIBRATION VERIFICATION FLUID, 183000005 (5 ampoules of 5 unique solutions required to perform one test)	BOX	2	$150.00	$300.00
epoc BGEM CARD W CREATININE 50/KIT	EACH	145	$9.00	$1,305.00
			TOTAL	**$36,825.00**

Table 6: *Itemized costs for device purchase and set-up for the i-STAT.*

Description	Unit	Quantity Used	Unit Price	Total Price for Six Devices
i-STAT Device	1	6	$7,500.00	$45,000.00
Downloader	1	2	$1,288.98	$2,577.96
Electronic simulator	1	2	$700.35	$1,400.70
CARTRIDGE i-STAT CHEM 8+	EACH	68	$11.32	$769.76
CONTROL i-STAT TRILEVEL LEVEL 1 (10 ampoules / box)	BOX	2	$32.50	$65.00
CONTROL i-STAT TRILEVEL LEVEL 3 (10 ampoules / box)	BOX	2	$32.50	$65.00
Calculation Verification fluid (10 ampoules / box)	BOX	1	$65.00	$65.00
			TOTAL	**$49,943.42**

Two refrigerators were provided in-kind by EMS to maintain cold chain storage of QC solutions, cal-ver solutions, and i-STAT cartridges. Six temperature-controlled and shock resistant containers were lent to the program to house the POCT devices and test cards/cartridges while in a CP vehicle. Six temperature data loggers and a downloader to monitor the ambient and container temperatures and refrigerator temperatures were also lent to the study, and an additional eight temperature data loggers and an associated downloader were purchased (Table 7).

Table 7: *Point of Care Testing device and testing equipment support material costs.*

Description	Unit	Quantity	Unit Price	Total
Refrigerator	1	2	139.00	$278.00
Transport Container	1	6	76.46	$458.76
Temperature Data loggers	1	14	69.00	$966.00
Data logger downloaders	1	2	114.00	$228.00
			TOTAL	**$1,930.76**

Training: Each CP was provided with up to seven test cards or cartridges per device for training. All test cards and cartridges were provided in-kind to the study (expired test cards) by the epoc and i-STAT vendors. Expired QC solutions were provided by the vendor in-kind, or coloured water was used during training. Training costs are summarized in Tables 8 and 9.

Table 8: *Itemized costs for the training phase for the epoc.*

Description	Unit	Quantity	Unit Price	Total
epoc BGEM CARD W CREATININE	EACH	130	$9.00	$1,170.00
			TOTAL	$1,170.00

Table 9: *Itemized costs for the training phase for the i-STAT.*

Description	Unit	Quantity	Unit Price	Total
I-STAT CHEM 8+ CARTRIDGE	EACH	130	$11.00	$1,430.00
			TOTAL	$1,430.00

Study data collection phase: Costs in this phase include the consumables for weekly QC testing; collecting 108 patient blood samples, and re-tests (errors). Forty eight (48) ampoules of level 1, level 3, level A, and level B were consumed for weekly QC testing for the epoc. Forty eight (48) ampoules of tri-control level 1 and level 3 were consumed for weekly QC testing for the i-STAT. A total of 469 epoc test cards were used to perform weekly QC testing and obtain 108 patient blood samples (340 for weekly QC testing and 129 for blood testing). A total of 323 i-STAT cartridges were used to perform weekly QC testing and obtain 108 patient blood samples (189 for QC, 116 for patient testing, and 18 cartridges expired) (Tables 10 and 11).

Table 10: *Itemized costs for the data collection phase for the epoc.*

Description	Unit	Unit Price	Quantity Used	Total
EUROTROL BGEM, CONTROL LEVEL 1 (10 ampoules / box)	box	$65.00	5	$325.00
epoc EUROTROL BGEM, CONTROL LEVEL 3 (10 ampoules / box)	box	$65.00	5	$325.00
epoc EUROTROL HCT CONTROL LEVEL A (10 ampoules / box)	box	$65.00	5	$325.00
epoc EUROTROL HCT CONTROL LEVEL B (10 ampoules / box)	box	$65.00	5	$325.00
epoc BGEM CARD W CREATININE 50 / box	EACH	$9.00	469	$4,221.00
				$5,521.00

Table 11: *Itemized costs for the data collection phase for the i-STAT.*

Description	Unit	Unit Price	Quantity Used	Total
CARTRIDGE i-STAT CHEM 8+	EACH	$11.32	323	$3,656.36
CONTROL i-STAT TRILEVEL LEVEL 1 (10 ampoules / box)	EACH	$32.50	5	$162.50
CONTROL I-STAT TRILEVEL LEVEL 3 (10 ampoules / box)	EACH	$32.50	5	$162.50
			TOTAL	**$3,981.36**

What are the pros and cons of commercially available portable POCT devices?

The i-STAT and epoc shared numerous characteristics, but also had important differences. The characteristics of both devices and the current process in place of transporting blood to CLS for analysis are contrasted in Table 12.

Table 12: *Summary of characteristics of the Abbott i-STAT® and Alere epoc®.*

	Device operating temperature requirements	Device transport requirements	Device power requirements	Test cartridge transport requirements (in CP vehicle)	Test cartridge temperature storage requirements	Test card / cartridges
epoc	Yes (15-30°C) Device will lock out if out of temperature range	Requires protection from excessive movement / dropping If the device is misused or dropped the epoc will give an error.	Battery (rechargeable) Should recharge battery daily using AC plug in power source, to ensure device is ready for use. On a full charge the epoc is able to run 50 patient samples, the epoc system will give the user a message by the LED lights blinking to know when it is time to charge as well if it is almost depleted, the epoc will have a red banner indicating 'charge battery'	Must be protected against excessive shock (dropping, throwing, shaking) Must be protected against temperatures outside of 15-30°C during storage and transport Consider temperature monitoring device for transport container	Yes, (room temperature 15-30°C) at all times.	One test card for all analytes
i-STAT	Yes (16-30°C) Device will lock out if out of temperature range	Excessive movement / dropping well tolerated during transport.	Battery powered by two 9V lithium batteries for a minimum of 250 patient samples depending on type of test run The analyzer can also be powered by a nickel-metal-hydride rechargeable battery. Requires a charge once every three months.	Must be protected against temperatures outside 18-30°C during storage and transport Consider temperature once removed from cold storage (2-8 °C)	Yes, (cold chain 2-8°C) Or if room temperature 18-30°C, cartridge must be used within 14 days. Requires refrigeration to maintain cold chain with temperature monitoring capabilities	Large test menu, but may require multiple cartridges based on user needs
Laboratory	n/a	n/a	n/a	n/a	n/a	n/a

Table 12 (continued): *Summary of characteristics of the Abbott i-STAT® and Alere epoc®.*

	Test menu	QC fluid storage requirements	QC testing frequency*	Device validation As per CLS & AHS standards	Transport time to specimen drop off
epoc	pH, pCO2, pO2 Sodium, Potassium, Ionized Calcium, Chloride Glucose Lactate Creatinine Hematocrit Calculated parameters: Hemoglobin, cHCO3-, TCO2, BE(ecf), BE(b), cSO2, eGFR, AGap, AGapK	Cold chain (2-8°C) Requires refrigeration with temperature monitoring capabilities	• Weekly per device • Daily per device • Monthly split sample for creatinine • Weekly split sample for blood gases • Requires two test cartridges and two ampoules of QC fluid per week per device • Each new test cartridge lot# must be validated using two levels of QC fluid	Must validate all devices for all analytes prior to use, using lab-based split sample, QC fluid, and cal-ver fluid	n/a
i-STAT	Sodium, Potassium, Chloride, TCO2, Anion Gap, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, Lactate Hematocrit, Hemoglobin a pH, PCO2, PO2, TCO2a, HCO3a, Base Excess (BE)a, sO2a ACT Kaolin, ACT Celite®, PT/INR, aPTT end of 2017, ß-hCG, Cardiac Markers, CK-CK-MB BNP, cTnI, High Sene. cTnI 2018	Cold chain (2-8°C) Requires refrigeration with temperature monitoring capabilities	• Weekly per device • Daily per device • Monthly split sample for creatinine • Weekly split sample for blood gases • Requires two test cartridges and two ampoules of QC fluid per week per device • Each new test cartridge lot# must be validated using two levels of QC fluid	Must validate all devices for all analytes prior to use, using lab-based split sample, QC fluid, and cal-ver fluid	n/a
Laboratory	All analytes are available.	n/a	All QC completed by CLS	n/a	The mean time to transport a specimen to CLS was 19.7 minutes (SD 14.1; 95% CI 17.0, 22.4)

Note: CLS= Calgary Lab Services; QC=Quality control.
* As per standards set by Calgary Lab Services

Table 12 (continued): *Summary of characteristics of the Abbott i-STAT® and Alere epoc®.*

	Time to results	Start-up equipment	Training	Competency maintenance as per CLS standards
epoc	Results available on-scene 30 seconds after introduction of sample into device	Device(s) Test cards and solutions for validation (QC, calibration-verification, patient split samples) Storage and transport packaging (fridge, thermal containers) Does not include specimen collection equipment	Two hours in classroom setting for device, plus evaluation	At least three yearly
i-STAT	Results available on-scene 120 second after introduction of test cartridge into device	Device(s), Test cards and solutions for validation (QC, calibration-verification, patient split samples) Storage and transport packaging (fridge, thermal containers) Electronic simulator Does not include specimen collection equipment	Two hours in classroom setting, plus evaluation	At least three yearly
Laboratory	The mean time between the mean of the two POCT device results being available, to the result being available from CLS was 129.7 minutes (SD 169.7; 95% CI 96.9, 162.6).	Specimen transport box In accordance with Canadian Transportation of Dangerous Goods Act and Regulations (TDG) Does not include specimen collection equipment	One hour in classroom to review Laboratory specimen collection / drop off procedure	n/a

Note: QC=Quality control.
* As per standards set by Calgary Lab Services

Table 12 (continued): *Summary of characteristics of the Abbott i-STAT® and Alere epoc®.*

	Results management	Blood sample quantity required for test	Validity of results
epoc	Results not currently able to be uploaded onto provincial patient electronic healthcare record (Netcare) Results manually entered into EMS patient care record Results only viewable by CP or by physician if patient care record faxed to referring physician Additional software can be purchased to have results downloaded into a central server	Small volume of blood required <1 ml	Valid results for all analytes assessed in this study
i-STAT	Results are able to be transmitted to Netcare, however requires data management and middleware and interface to LIS (Meditech, Sunnytech, etc.). This is an expense to the user. Results manually entered into EMS patient care record Results only viewable by CP or by physician if patient care record faxed to referring physician Additional software can be purchased to have results downloaded into a central server	Small volume of blood required <1 ml	Valid results for all analytes assessed in this study
Laboratory	Once verified, results posted to the CLS database (Cerner Millennium) and then posted to Netcare. Results viewable by any healthcare provider involved in patient's care via Netcare.	Varies, but generally minimum volumes required <2 ml	Gold standard

Discussion

What is the association between POCT blood results and those derived from standard laboratory processes?

A total of 108 observations assessing seven analytes on 73 patients, and including comparisons between i-STAT and lab, epoc and lab, and i-STAT to epoc, yielded a total of 1,047 individual comparisons for assessing critical range discrepancies and 1,645 individual comparisons for assessing acceptable comparative range discrepancies. There were seven out of 1,047 individual comparisons (0.7%) where *apriori* defined discrepant critical results were reported (i.e., a critical range was detected in the device but not laboratory). These appeared to be slightly higher with i-STAT (0.9%; 95% CI -0.1%, 1.9%) compared to epoc (0.3%; 95% CI -0.3, 0.9), but these results were not statistically significant (p=0.323). The discrepant results occurred entirely in the Na and K analytes, with no discrepant results reported for either Hgb or Glu. There was a lack of agreement that exceeded *apriori* defined comparative standards between a POCT device and laboratory, or between POCT devices, in 126 out of 1,645 individual comparisons (7.7%). For the i-STAT there were 32 out of 523 individual comparisons (6.1%; 95% CI 4.1%, 8.2%) that exceeded acceptable comparative range standards, and for epoc there were 56 out of 523 (10.7%; 95% CI 8.1%, 13.3%). These results were statistically significant (p=0.007).

When the i-STAT to laboratory is compared to epoc to laboratory, there are similar levels of agreement for Na and K. However, the epoc has almost three times the number of out-of-range results for Cl, and twice the number for Crea compared to i-STAT. The epoc had 17 instances of out-of-acceptable comparative range results for Hct compared to 0 for i-STAT. For glucose however, i-STAT had twice as many out-of-range results for values under 5 mmol/L and three times as many for values greater than or equal to 5 mmol/L.

To rule out possible causes of these results, all out-of-range data for acceptable comparative ranges had a third check for data entry error performed, and no erroneous entries were found. When individual devices by manufacturer were compared, one i-STAT device accounted for over half of all out-of-range i-STAT results. This device did not have unusual incidents logged, nor was it exposed to extreme temperatures. All weekly QC testing was completed on the device. The cartridge lots were used by other i-STAT devices and so were not unique to this device. Four CPs used this device, with two of the CPs using other i-STAT devices in the study. It is unknown why this particular device would return more out-of-range results compared to the other i-STAT devices. For epoc, none of the devices had unusually large numbers of out of–range results compared to each other. Although two CPs' using one device collected 12 of the 17 out-of-range Hct results on epoc.

The reasons that the POCT could have returned out-of-range results compared to the laboratory include issues with the device, card/cartridge, or sample preparation. While it is difficult to determine retrospectively what may have been the cause, no out-of-range devices were exposed to extreme temperatures, and almost all devices passed their weekly QC. While there was the odd failure in one level of QC, there were no trends to suggest that a device was consistently returning out-of-range results. The cards/cartridges were likewise not exposed to any known extreme temperatures, and cold-chain was maintained for all i-STAT cartridges. It is possible that the preparation of the sample may have influenced the results and unknown whether the differences between devices are related to differences in the way a CP prepared the sample. Some devices had the same CPs using the same device throughout the study period.

While the number of results that exceeded the acceptable comparative range was sizeable, few instances of deviations between POCT and lab critical values were recorded. These results suggest that the incongruent findings in most instances were not large enough to affect the identification of a critical

situation. Moreover, there were no instances of a missed critical result by the POCT; in all instances the discrepancy was due to the POCT returning the critical value, not the lab.

Based on these findings, and in the jurisdiction in which this study was set, the Medical Directors feel these devices are clinically reasonable to be used in the CP setting. The results underscore the importance of proper training, initial device validation, daily and weekly QC checks, split sample testing, and handling and care of POCT devices.

This study also included a comparison between the two POCT devices. The rationale for this analysis was for systems that may have multiple prehospital agencies visiting the same patient and using devices from different manufacturers. Between the devices (epoc compared to i-STAT) there were discrepant critical results in three out of 401 individual comparisons (0.7%), and 38 out of 599 (6.3%) individual comparisons outside of comparative standards. If agencies within the same system use devices from different manufacturers, discrepant results should be anticipated.

Does POCT decrease the time to results?

If there is a difference in time to results, does this difference afford any advantage to patient care or operational efficiency?

Do CPs prefer POCT over the standard laboratory process?

CPs will get their results considerably quicker using POCT compared to transportation to lab (e.g., an estimated 97 to 163 minutes). The transport time associated with time to results is estimated to be between 17 and 22 minutes. This aligns with feedback from the CP respondents to the survey who unanimously agreed that POCT improved their ability to make timely decisions for their patients. However, only 45% of respondents felt that POCT actually shortened their time on task. This finding may be because respondents interpreted time on task as meaning time on-scene, instead of total time dedicated to an event. They may have answered this question thinking about the time on task required to enroll the patient and perform

blood testing on two devices in the context of the study. It may be that POCT increases time on-scene, even though it shortens overall time on task. Or it could be that CPs felt that they would still have to transport blood to the lab, as the POCT may not be capable of running all the tests required (e.g., white blood cells, liver panels).

For example, in the sample of 108 events there were 88 events (82%) where a white blood cell (WBC) test was also ordered. WBCs are not included in any of the test menus for the two POCT devices in this study, meaning that these events would still require transport of blood to the lab. Based on these results, it may be reasonable to assume that implementing a POCT program will not replace transporting blood for lab analysis, but rather be an 'add-on' process. Many other tests were found to have been ordered in the sample of 108 events that POCT devices are currently unable to test, however the scope of this study did not allow for further analysis of these data. Moreover, it is unknown whether the implementation of a POCT program may change the ordering habits of physicians. For example, in this sample, physicians were accustomed to ordering through the lab analytes they knew were available, and may have ordered WBC because it was convenient not because it was absolutely required. It could be that with the more limited menu of test options for POCT, physicians may order only the tests that are absolutely required (i.e., need to have) not tests that may be nice to have.

The vast majority of CPs would support the implementation of a POCT program (regardless of device) in conjunction with transporting blood to lab. However, it is important to note that just under half of CPs did not prefer POCT to transporting blood. This seemingly conflicting finding was elucidated in the comments where respondents alluded to the notion that POCT may not be sufficient to replace transporting blood to labs in all situations, but may be used in certain situations to support on-scene patient care decisions. CPs may be suggesting that having POCT may be an important option for them for certain patients, but that it may not be desirable or beneficial in all situations.

Do CPs favour one POCT over another and why?

i-STAT was the preferred device of CPs for both QC and blood testing. The preference for i-STAT was not only shown in the responses to the preference questions, the usability (SUS) questions and the QC testing observations but also in the issues observed using the POCT devices and to a lesser extent the device-logged error rates during patient testing. An issue not automatically logged in the devices' error logs was that the epoc cartridges needed to be removed and retried 11 out of 27 times (41%) before they would work in the epoc machine. Ongoing frustrations with these non-logged issues may be the reason why the users preferred the i-STAT over the epoc during the trial. The i-STAT had a lower error rate (than epoc) during blood testing and a higher error rate (than epoc) in QC testing. Field observations, unable to be conducted during this study, of blood test procedures are needed to explain why the device error rates changed between QC and blood testing. Further examination of error rates may explain some of the outliers found in the comparison of the POCT with laboratory tests.

In general, it was observed that the reasons given by people who preferred i-STAT were related to the function of the device. For example, the device was simple, it was easy to clean and use with fewer errors. But in general, the reasons for preferring epoc (except for one off comments such as ease of use, more reliable results, and easier trouble shooting), were related to the logistics of using the device. For example, the test cards do not need to be refrigerated, there is no daily electronic simulation test and one card performs all the blood tests.

What are the costs associated with POCT testing?

In the current fiscal climate, control of cost is increasingly required, yet new technology can be expensive. This study collected detailed cost data related to the three phases of the research: device purchase and set-up, training, and study data collection period.

The total cost for all three phases of the study for the epoc and i-STAT was $43,516.00 and $55,354.78 respectively. Six epoc devices were $11,838.78 (21.4%) less expensive when compared to the six i-STAT devices. Due to CLS' unfamiliarity with the epoc, an additional 20 split samples tests of patient blood comparatives to the laboratory reference instruments were performed during the validation phase. These additional tests may become unnecessary during future device validations. It is important to note, the majority of test cartridges used during initial validation occurs with the first or initial point of care device. Therefore, the validation cost associated with multiple devices would not be equivalent to a single device, as significantly less test cartridges are required for subsequent device validation. There were 18 known i-STAT cartridges that were not used within 14 days of being removed from cold chain, and with improved storage and usage procedures, these numbers could be decreased.

For the training phase of the study, epoc test cards and i-STAT test cartridges would have cost $1,170.00 and $1,430.00 respectively. Therefore, the epoc was $260.00 (18%) less expensive due to the i-STAT test cartridges costing $2.00 more each.

When excluding the initial start-up costs, the average per patient test cost was $51.12 and $36.86 for the epoc and i-STAT respectively during the data collection phase. Therefore, the i-STAT tests were $14.24 (28%) less expensive than epoc. The main reason for this difference in device costs is the i-STAT requires half the number of test cartridges and control fluids per week for QC testing. While i-STAT also requires the initial purchasing of an electronic simulator, it can be used on multiple devices and in this case included in the initial start-up costs. Schedules for QC testing were set out by CLS and AHS, in the future, the schedule for QC testing could change. The amount of QC testing each device must undergo per week versus the number of patient tests anticipated to occur should be taken into account when implementing a POCT program and device selection.

Additional cost considerations include ongoing device software management, transport container requirements, number of vehicle or device storage locations, and changes in error rates over time. Data management software for epoc was not purchased for the study; the software has initial and ongoing costs. The data management software for i-STAT is included in the device purchase. Both devices require cold chain for the QC fluids, i-STAT test cartridges require cold chain storage, and both devices must be kept at room temperature for operation. The costs of the transport containers will vary greatly depending on the setting in which they are used. In environments with large fluctuations in temperatures, more robust and expensive transport containers would be required to maintain room temperature operating ranges.

The number of vehicle or device storage locations will change the number and associated costs of purchasing supporting equipment such as printers, and i-STAT downloaders and electronic simulators. If users of the POCT devices are physically located at different sites, additional equipment may be required to support each device (electronic simulator, fridge, printer, etc.). Finally, improved training, familiarity with the device over time and allowing end users to practice on the devices should decrease error rates and thereby reducing costs.

What are the pros and cons of commercially available portable POCT devices?

As demonstrated in the table, there are many similarities and differences between i-STAT and epoc. Systems must make their decision based on existing lab services, standards in place for POCT in their jurisdiction, the needs of patient populations, and with critical input by the physicians, healthcare team and CPs that will ultimately act on the results. In particular, physicians must be well aware of the tests available on each device.

In the healthcare system where this study was conducted, multiple healthcare providers are able view the results of blood tests conducted by the laboratory. While software can be purchased to interphase the

results of POCT devices with a larger information system, these costs should be taken into consideration. Whether the devices will be housed in a central location or at multiple locations must also be taken into account as it impacts the amount of equipment required to support the devices and potentially where and how QC testing will be performed.

The i-STAT and epoc share many of the same characteristics such as time to results, blood volumes required, and operating temperature ranges, however there are some important differences. The epoc test cards can be stored at room temperature, while the i-STAT test cartridges must be stored at 2-8°C and once removed must be used within 14 days. The i-STAT has a larger test menu than the epoc, but this is attained through multiple test cartridges, not a single card as for the epoc. The i-STAT batteries can perform a greater number of tests compared to epoc.

Limitations

This study used a split sample approach where a prehospital POCT result was compared to a laboratory analysis. There are many factors that may have contributed to reported discrepancies between POCT and laboratory results such as timing, methodology, and pre-analytical issues. The timing of the blood analysis is one factor that may have influenced laboratory results as this occurred at a different time than the POCT analysis. It took between 17 and 24 minutes to transport the blood to the laboratory facility and in this time certain analytes may have altered. While this can be viewed as a limitation, it also reflects what happens in real-life, where POCT analysis is done considerably earlier than a laboratory analysis. The methodology that each POCT device used and the laboratory used is also different, which would contribute to potential differences. Finally, while all attempts were made to train and assess competence in CPs involved in this study, no observational quality assurance was performed to ensure good technique by CPs while out in the field. Differences in technique associated with mixing and storage may have affected individual samples.

While all POCT devices and EMS system time were synchronized, these times were not explicitly synchronized between EMS and CLS. It is important to note that there may have been differences between these systems that would have affected the absolute time differences reported.

Observational data on QC testing may have been influenced by the presence of research team members, and therefore may not reflect typical behaviour when a CP is not being observed.

Conclusions

EMS systems that use POCT can expect that even with optimized training and rigorous QC testing, and dependent on the analyte and POCT device, discrepant critical range values with the laboratory will occur in 0% to 1.9% of comparisons. Results outside of acceptable comparative range between the POCT and laboratory will occur in 4.1% to 13.3% of comparisons, also depending on analyte and POCT device. The epoc device had a statistically significant increased number of tests that exceed the acceptable comparative range between POCT and lab when compared to the i-STAT.

CPs felt that POCT helped to improve their ability to make timely decisions for their patients and saved transport time to laboratory services in those events where no further lab analysis is required. A POCT program, however, will not replace blood transport in all events. There was a statistically significant higher rating for the i-STAT compared to the epoc on the system usability score, and the majority of CPs chose the i-STAT over the epoc.

The i-STAT has higher initial costs but lower operational costs; the epoc has lower initial costs but higher operational costs. Both POCT systems have advantages and disadvantages that must be considered carefully prior to purchase.

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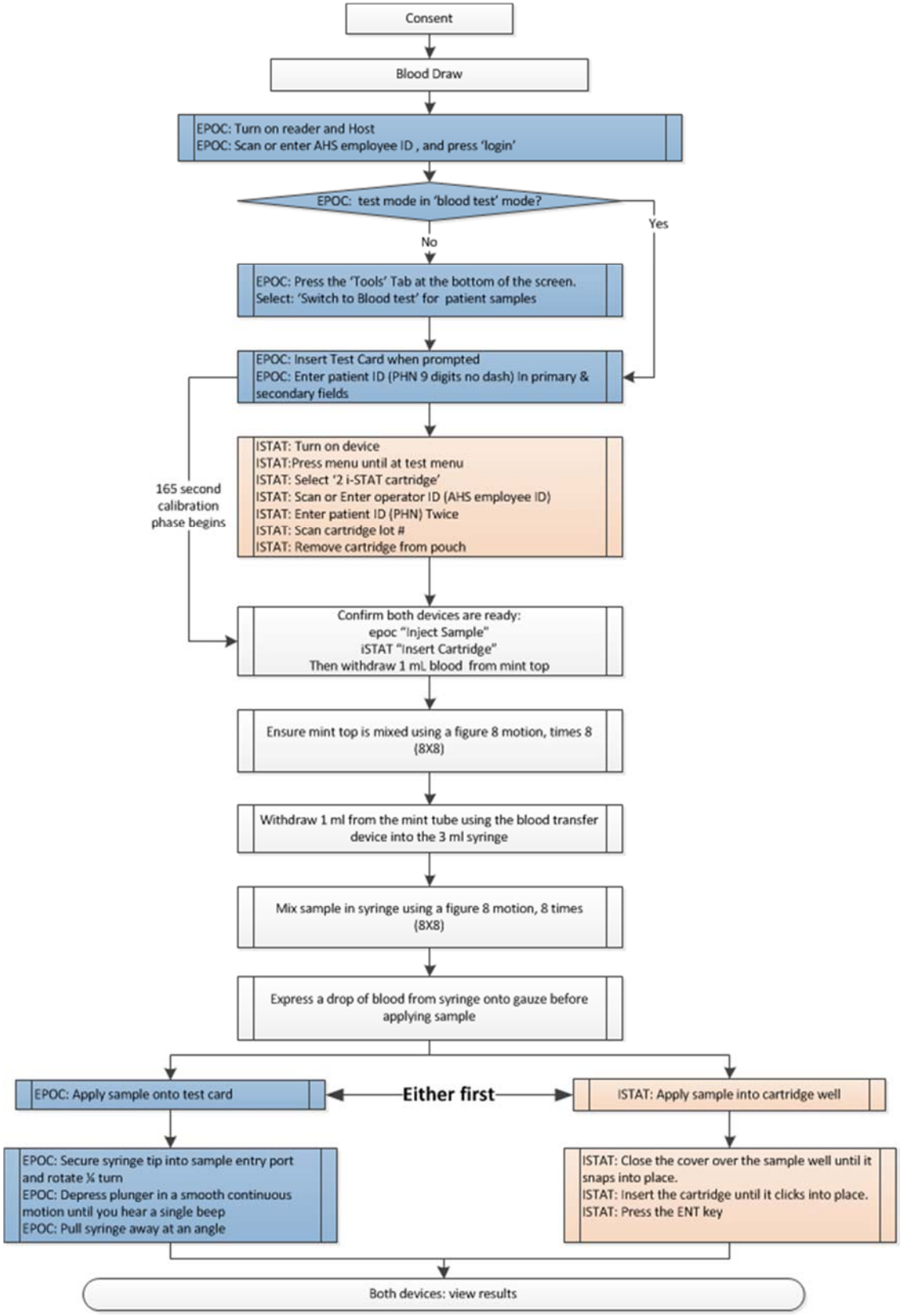
Appendix A: Community Paramedic Point of Care (CPPOC) Study Flowchart



Appendix B: Community Paramedic Point of Care (CPPOC) Study Procedures, Calgary Zone

Alberta Health Services

TITLE
COMMUNITY PARAMEDIC POINT OF CARE (CPPOC) STUDY

SCOPE Calgary Zone Community Paramedic Program	**DOCUMENT #** N/A
APPROVAL LEVEL Dr. Gerald Lazarenko, Emergency Medical Services	**INITIAL APPROVAL DATE** August 24, 2016
SPONSOR EMS	**INITIAL EFFECTIVE DATE** September 1, 2016
CATEGORY Procedure	**REVISION EFFECTIVE DATE** TBD
PARENT DOCUMENT TYPE & TITLE N/A	**NEXT REVIEW** TBD

Objectives

- To outline key components of the Community Paramedic Program's CPPOC research study for **point of care testing (POCT)** devices.

APPLICABILITY

Compliance with this procedure is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary), working with or for Emergency Medical Services (EMS). This procedure does not limit any legal rights to which you may otherwise be entitled.

1. All community paramedics (CPs) participating in the CPPOC study will receive applicable training and will maintain competency in the use of the POCT devices and study protocol.

2. The community paramedic will collect blood samples based on the referring physician or NP's request and as per program and Calgary Lab Services (CLS) collection procedures.

3. **Inclusion**

   3.1 To be considered for inclusion into the CPPOC study the referring physician or nurse practitioner (NP) must request at least one of the following tests from the patient's blood sample:

   a) Sodium (Na+)

   b) Potassium (K+)

   c) Chloride (Cl-)

   d) Glucose

   e) Creatinine (CREA)

f) NOTE: if **only** Hematocrit (HCT) or Hemoglobin (Hgb) is ordered, one of the above tests must also be ordered because the sample must be withdrawn from the mint top tube for testing with a POCT device.

3.2 In order to obtain consent from a patient, the following criteria must be met:

a) Patient must have capacity and be their own decision maker;

b) Patient must be 18 years of age or older; and

c) The community paramedic must be reasonably confident that the patient is able to understand the consent script.

3.3 Prior to testing a patient's blood sample in a POCT device, the community paramedic must:

a) Read the *Study Consent Script* to the patient;

b) offer the patient an opportunity to review the *University of Calgary (UofC) Study Information & Consent Form*; and

c) Complete the *Study Consent Script*. NOTE: this must be completed for each event even if the patient has previously consented to the study.

3.4 The patient must sign, or if unable to physically sign provide their verbal consent and the community paramedic will sign on their behalf two copies of the *UofC Study Information & Consent Form.*

3.5 A signed *UofC Study Information & Consent Form* must be retained by the community paramedic and placed into the study folder at either Hopewell or Southgate at the end of each day and a signed copy left with the patient.

3.6 If consent is not given, the patient blood sample must not be tested in a POCT device and the reason for no consent be documented on the *Study Consent Script*. NOTE: Collect the patient's specimen as per standard CP & CLS procedures.

4. Equipment

4.1 POCT devices and the associated cartridges must only be transported and stored in the approved carrying case.

4.2 Each carrying case has been assigned to a specific data logger that monitors and records the interior temperature of the case to ensure the temperature remains 18-30°C.

4.3 All equipment **must** remain together as assigned i.e. i-STAT #1 in carrying case #1 with data logger #1

4.4 The community paramedics shall refer to the CPPOC study algorithm (refer to appendix A) and follow the *CPPOC Study epoc® and i-STAT® Device procedures* when testing blood samples using a POCT device.

4.5 If an issue with a POCT device, cartridges, carrying case or data logger is encountered, community paramedics can refer to the quick troubleshooting guides. If you are unable to resolve, do not continue with the study and contact Dana or Stacy.

5. Documentation

5.1 The community paramedic must use the patient's PHN (9 digits, no dash) as the patient ID for each POCT device in the primary and secondary fields. NOTE: If patient does not have a PHN, the community paramedic will enter their DOB as an ID using the format 0yyyyMMdd e.g. for June 8, 1950 = 019500608 and December 25, 1950 019501225

5.2 The community paramedic must use their AHS employee ID for the operator ID on each device.

5.3 The blood collection shall be documented in electronic patient care record (ePCR) using the 'blood draw' treatment button and the results from the CLS lab followed up on Netcare as per current CP practice. NOTE: The results from the POCT devices **must not be recorded** in the ePCR , the exception to this is if a critical result or out of range result is obtained – see section 6.1 for information.

5.4 The associated ePCR must be RightFaxed to the Quality Assurance Strategist, dana.dalgarno@ahs.ca. (Note: regardless if the device fails or there is an error on the results, the ePCR must be faxed).

5.5 Once received, the community paramedic or designate must RightFaxed the Netcare CLS results to the Quality Assurance Strategist, dana.dalgarno@ahs.ca as soon as possible.

5.6 The community paramedic must accurately document times using the applicable timestamps, as per *CPPOC Study Timestamp document*. (appendix B)

a) *'Blood Draw' treatment* = time of blood draw.

b) *'Depart Scene / Hospital'* = Time patient's home left - enroute to CLS laboratory

c) *'Arrive Destination'* = Time specimen is dropped off specimen at CLS laboratory counter

5.7 All applicable study document forms must be placed in each device's binder at Hopewell (HW) or Southgate (SGT) at the end of the community paramedic's shift.

a) Signed *Study Consent Script*

b) if applicable, signed *UofC Study Information & Consent Form*

c) *Daily iStat electronic simulation log*

d) *Weekly QC solution test log*

e) *POCT Issues log*

6. Results Management

6.1 POCT device results **must not be disclosed** to the patient or the referring physician or NP, except in the following:

a) When an out of range value(s) that was not ordered on the original requisition or a critical value(s) is obtained on both POCT devices, the community paramedic must immediately notify and consult with the referring physician to determine a treatment plan and document the consultation on ePCR. NOTE: If unable to contact referring physician, contact MCN physician

b) When an out of range value(s) that was not ordered on the original requisition or a critical value(s) is only obtained on **one** POCT device, the community paramedic shall:

- Repeat the patient sample on the same POCT device and if a critical or out of range value is obtained, immediately notify and consult with the referring physician to determine a treatment plan and document in ePCR. NOTE: do not withdraw any additional blood from the mint top tub to perform a retest.
- If a critical or out of range value is not obtained, no further action is required.

c) If there is not enough of the patient sample for the community paramedic to repeat another test on the POCT device the community paramedic shall consult with the referring physician, notify them of the results from both POCT devices and the patient presentation to determine a treatment plan, suggest the test is added to the CLS requisition and document in ePCR. NOTE: If unable to contact referring physician, contact MCN physician

7. Quality Control (QC)

7.1 A **daily** morning QC temperature check must be performed by a community paramedic on each fridge (HW & SG) housing the POCT equipment and the findings recorded on the '*CPPOC Study Temperature Check*' form (refer to Appendix D).

a) If a temperature failure is noted, the community paramedic shall immediately notify the Quality Assurance Strategist, Dana or the Staff Development Officer Stacy.

b) The patient coordinator (PC) is responsible for confirming the daily fridge check is completed at Hopewell and Southgate. (there is a daily event in the PC schedule on eScheduler reflecting this).

7.2 The community paramedic must perform a **daily** electronic simulation QC test on their i-STAT® device as per the *CPPOC Study i-STAT® Device procedure* and the result recorded on the *i-STAT daily electronic simulator test form*.

a) If the test fails, the community paramedic shall immediately notify Dana or Stacy.

7.3 The data logger in the carrying case must be visually checked **throughout** a shift and if the alarm icon (indicating temperature greater than 30C) is displayed do not use cartridges and immediately notify Dana or Stacy.

7.4 Each Thursday, the community paramedic must perform a **weekly** QC solution test as per the *CPPOC Study epoc® and i-STAT® Device procedures* and record the results on *the CPPOC Study QC solution testing form*.

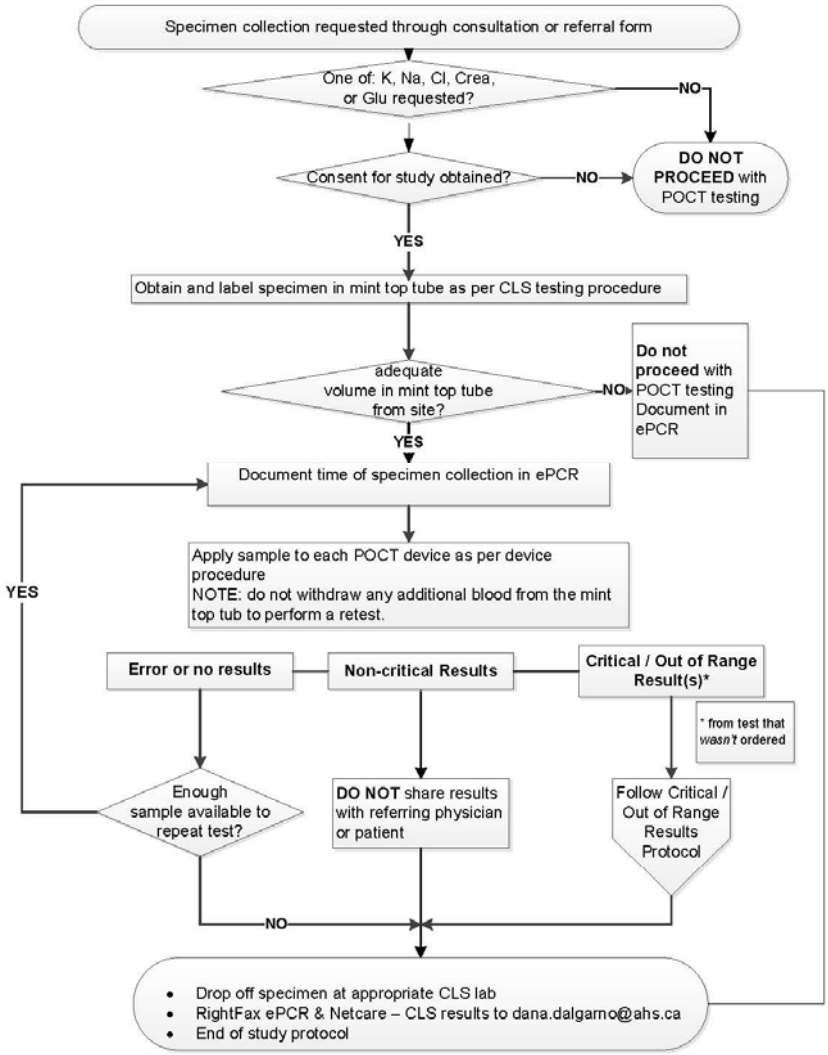
a) If a test fails, the community paramedic shall immediately notify Dana or Stacy.

7.5 Other POCT issues such as cartridge failure, expiry, batteries, etc. must be documented on the *POCT issues log*.

REFERENCES

- CPPOC Study i-STAT® & epoc® QC solution test log
- CPPOC Device Issues log
- EMS epoc® powerpoint
- EMS i-STAT® powerpoint
- DRDC Research Proposal
- CPPOC Study epoc® Procedure
- CPPOC Study i-STAT® Procedure
- UofC Consent Form
- Study Consent Script

APPENDIX "A"

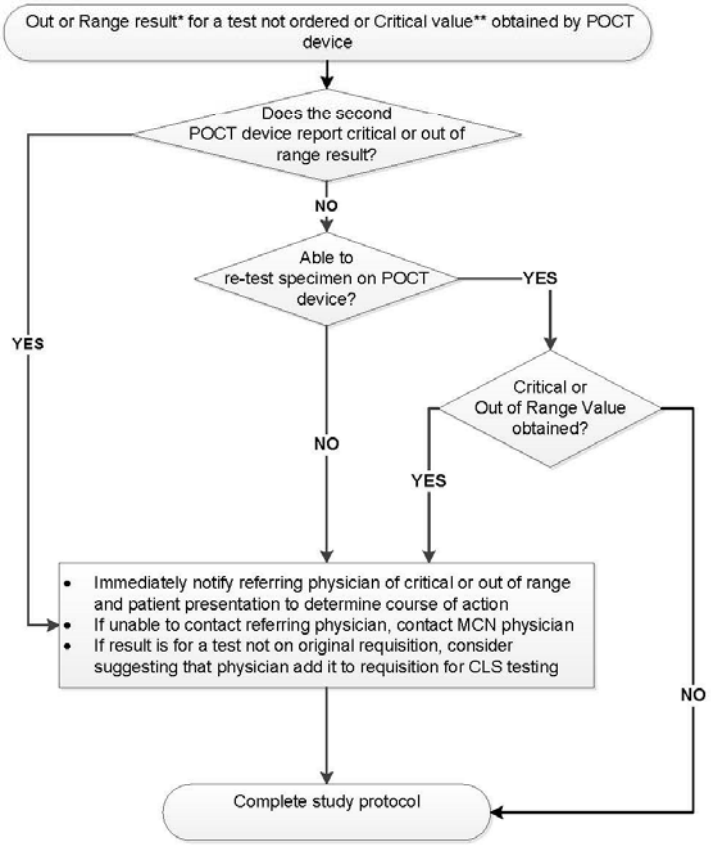

Specimen collection requested through consultation or referral form
One of: K, Na, Cl, Crea, or Glu requested?
NO
Consent for study obtained?
NO
DO NOT PROCEED with POCT testing
YES
Obtain and label specimen in mint top tube as per CLS testing procedure
adequate volume in mint top tube from site?
NO
Do not proceed with POCT testing Document in ePCR
YES
Document time of specimen collection in ePCR
Apply sample to each POCT device as per device procedure
NOTE: do not withdraw any additional blood from the mint top tub to perform a retest.
YES
Error or no results
Non-critical Results
Critical / Out of Range Result(s)*
* from test that wasn't ordered
Enough sample available to repeat test?
DO NOT share results with referring physician or patient
Follow Critical / Out of Range Results Protocol
NO
Drop off specimen at appropriate CLS lab
RightFax ePCR & Netcare – CLS results to dana.dalgarno@ahs.ca
End of study protocol

APPENDIX "B"

POCT Study Timestamps

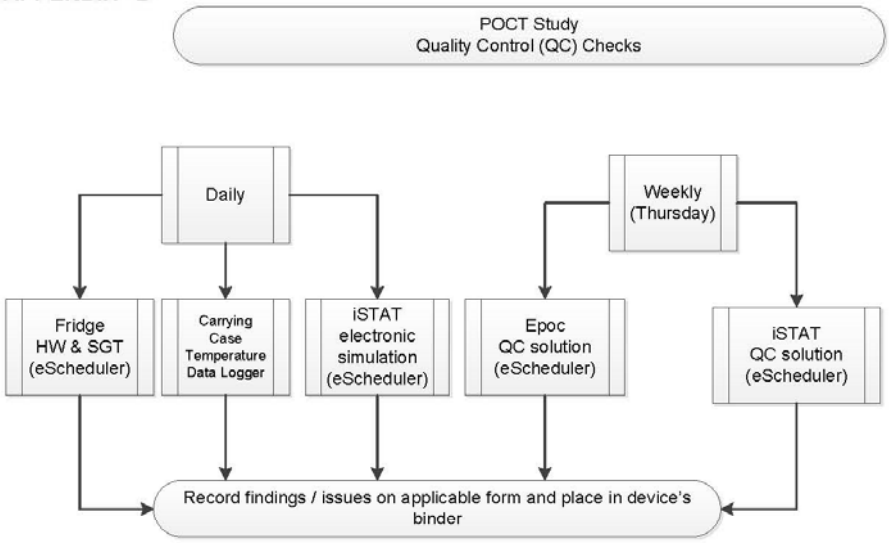
A. Use '*Blood Draw*' treatment button to document time of blood draw.
B. Use *'Depart Scene / Hosptial'* time stamp to document time you leave patient's home.
C. Use *'Arrive Destination'* time stamp to document time you drop off specimen at CLS laboratory counter.

APPENDIX "C"



TEST	*CRITICAL VALUES
Potassium (K+)	All: less than **2.5 mmol/L** 4 months - 150 years: greater than **6.0 mmol/L**
Sodium (Na+)	Less than **120 mmol/L** or greater than **155 mmol/L**
Glucose (Glu)	Less than **2.6mmol/L** or greater than **24.9 mmol/L**
Hemoglobin	Equal to or less than **60 g/L**
*for **out of range values**, refer to CLS website or Netcare	

APPENDIX "D"


POCT Study
Quality Control (QC) Checks
Daily
Weekly
(Thursday)
Fridge
HW & SGT
(eScheduler)
Carrying
Case
Temperature
Data Logger
iSTAT
electronic
simulation
(eScheduler)
Epoc
QC solution
(eScheduler)
iSTAT
QC solution
(eScheduler)
Record findings / issues on applicable form and place in device's
binder

Appendix C: Community Paramedic Point of Care (CPPOC) Study Survey

CPPOC Study - Survey for Community Paramedics - iSTAT first

Consent

TITLE The validity and reliability of point of care testing devices in the community paramedic setting

SPONSOR Department of National Defense, Defense Research and Development Canada, Canadian Safety and Security Program.

INVESTIGATORS
Investigators: AHS EMS: Ian Blanchard, Dana Dalgarno, Stacy Goulder, Ryan Kozicky, Gerald Lazarenko, Keith Spackman; AHS Human Factors: Jason Laberge, Susan Biesbroek, Lenore Page; Calgary Lab Services: Karen Leaman, Lyle Redman, Suzanne Snozyk; University of Calgary: Christopher Doig, Eddy Lang, Tyler Williamson.

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BACKGROUND

As you are aware, the Calgary Zone Community Paramedic program has been participating in a study assessing the validity and reliability of point of care testing (POCT) devices. In addition to assessing how valid and reliable these devices are compared to the normal practice of transporting blood to Calgary Lab Services, we would like to get your perspective on POCT, and the POCT devices used in this study.

WHAT IS THE PURPOSE OF THE SURVEY?

The purpose of this survey is to explore your thoughts as a Community Paramedic on whether POCT testing affords any advantage to patient care or operational efficiency compared to normal practice, if you prefer POCT over normal practice, and if you favour one POCT device over another and why.

WHAT WOULD I HAVE TO DO?

We are asking that you complete this 43 question survey. We estimate that this survey will take less than 60 minutes to complete.

WHAT ARE THE RISKS?

There are minimal risks associated with your participation in this survey. While AHS EMS managers and medical directors are on the research team, your responses will not be linked in any way with your identity. Members of the research team will not be able to determine who participates and who does not.

WILL I BENEFIT IF I TAKE PART?

Yes, you will benefit in that your opinion will be incorporated into the decision making around POCT testing for the Community Paramedic program. Your opinion is important to making the right decision for patient care and Community Paramedics, please provide as much information as you can so that we can understand your perspective.

DO I HAVE TO PARTICIPATE?

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CPPOC Study - Survey for Community Paramedics - iSTAT first

Introduction & Participant Demographics

During the survey you will be asked questions about yourself, specific to each POCT device as well as general questions about your device preference and POCT in the context of the Community Paramedic Program. Once you start the survey, please complete the entire survey.

1. How many years (in total) have you been registered as a paramedic in Alberta?*

2. How many years or months (in total) have you worked in the community paramedic program (please qualify response with months or years)?*

3. Do you have any other post-secondary training (certificates, diplomas or degrees) aside from your paramedic training?*
   - ○ Yes
   - ○ No

CPPOC Study - Survey for Community Paramedics - iSTAT first

iSTAT - Background and Usability

The following questions are about your experiences using the iSTAT device. We'll ask questions in four (4) sections. The first being the iSTAT's overall usability, then performing quality checks, the daily simulator test and finally performing blood testing with patients.

4. Have you had **previous experience** using the **iSTAT** system prior to this study?*
   - YES
   - NO

5. The following 10 questions are derived from the "systems usability scale", a validated scale that allows for comparison across different systems and provides a global view of usability assessment.

   Please record your immediate responses to the following 10 usability questions, if you feel you cannot respond to a particular item you should mark the center point of the scale.*

	Strongly Disagree				Strongly Agree
I think that I would like to use the iSTAT frequently					
I found the iSTAT unnecessarily complex					
I thought the iSTAT was easy to use					
I think that I would need the support of a technical person to be able to use the iSTAT					
I found the various functions in the iSTAT were well integrated					
I thought there was too much inconsistency with the iSTAT					
I would imagine that most people would learn to use the iSTAT very quickly					
I found the iSTAT very cumbersome to use					
I felt very confident using the iSTAT					
I needed to learn a lot of things before I could get going using the iSTAT					

CPPOC Study - Survey for Community Paramedics - iSTAT first

iSTAT Weekly Quality Checks

6. Approximately how many **weekly iSTAT** Quality Checks (QC) have you performed during this study? (One quality check includes the tests from both solution ampoules)*

- ○ I never performed a weekly quality check
- ○ I performed ___ weekly quality checks

CPPOC Study - Survey for Community Paramedics - iSTAT first

iSTAT Weekly Quality Checks

7. For the **weekly iSTAT** Quality Checks (QC), how easy was it to:*

	Very Difficult	Difficult	Neutral	Easy	Very Easy
Find space to ensure iSTAT device is level during testing	○	○	○	○	○
Turn the iSTAT on	○	○	○	○	○
Keep the iSTAT steady when entering information using the keypad	○	○	○	○	○
Get the iSTAT ready to run a QC sample	○	○	○	○	○
Read the iSTAT screen instructions	○	○	○	○	○
Scan the appropriate barcodes with the iSTAT scanner	○	○	○	○	○
Fill the iSTAT sample well to the appropriate level	○	○	○	○	○
Insert the cartridge into the iSTAT	○	○	○	○	○
Know when the iSTAT test is complete	○	○	○	○	○
Interpret the iSTAT testing results displayed	○	○	○	○	○
Determine if the QC iSTAT results are out of range	○	○	○	○	○
Record the iSTAT results	○	○	○	○	○
Turn the iSTAT off	○	○	○	○	○
Clean the iSTAT following use	○	○	○	○	○

8. Did you encounter any issues while doing the **weekly iSTAT** Quality Checks?*
   - ○ YES
   - ○ NO

9. Did you find the **temperature requirements** for the Quality Check solutions and cartridges for the **iSTAT** confusing?*
   - ○ YES
   - ○ NO

CPPOC Study - Survey for Community Paramedics - iSTAT first

iSTAT - Daily Electronic Simulator Checks

10. Approximately how many **daily (electronic simulator) iSTAT** Quality Checks (QC) have you performed during this study?*

- ○ I never performed a daily electronic check
- ○ I performed ___ daily electronic checks

CPPOC Study - Survey for Community Paramedics - iSTAT first

iSTAT Daily Electronic Simulator Checks

11. For the **daily (electronic simulator) iSTAT** Quality Checks (QC) , how easy was it to:*

	Very Difficult	Difficult	Neutral	Easy	Very Easy
Find space to ensure iSTAT device is level during testing	○	○	○	○	○
Turn the iSTAT on	○	○	○	○	○
Keep the iSTAT steady when entering information using the keypad	○	○	○	○	○
Get the iSTAT ready to run the simulator check	○	○	○	○	○
Read the iSTAT screen instructions	○	○	○	○	○
Scan the simulator barcode with the iSTAT scanner	○	○	○	○	○
Insert the simulator into the iSTAT	○	○	○	○	○
Know when the iSTAT test is complete	○	○	○	○	○
Interpret the iSTAT test result displayed	○	○	○	○	○
Determine if the simulator check has passed	○	○	○	○	○
Record the iSTAT results	○	○	○	○	○
Turn the iSTAT off	○	○	○	○	○
Clean the iSTAT following use	○	○	○	○	○

CPPOC Study - Survey for Community Paramedics - iSTAT first

iSTAT - Blood Testing with Patients

12. Approximately how many **blood tests** did you *attempt* to run on the **ISTAT** during this study?*
    - ○ I never attempted or performed a blood test(s)
    - ○ I performed ___ blood test(s)

CPPOC Study - Survey for Community Paramedics - iSTAT first

iSTAT Blood Testing with Patients

13. Were you part of a two person team when using the **ISTAT** to test patients' blood samples?*
    - Always
    - Often
    - Sometimes
    - Rarely
    - Never

14. For **testing patients' blood samples** using the **iSTAT,** how easy was it to:*

	Very Difficult	Difficult	Neutral	Easy	Very Easy
Find space to ensure iSTAT device is level during testing					
Turn the iSTAT on					
Keep the iSTAT steady when entering information using the keypad					
Get the iSTAT ready to run a blood sample					
Read the iSTAT screen instructions					
Enter the patient's ID					
Fill the iSTAT sample well to the appropriate level					
Insert the cartridge into the iSTAT					
Know when the iSTAT test is complete					
Interpret the iSTAT test result displayed					
Determine if the patient's iSTAT results are out of range					
Turn the iSTAT off					
Clean the iSTAT following use					

15. Have you encountered any issues while **testing blood** with the **ISTAT**?*
    - YES
    - NO

16. In which **setting** did you use the **iSTAT**?*
    - Continuing Care Facility (LTC, SL, Lodge, PCH)
    - Private Home
    - Shelter
    - Vehicle
    - Other

17. Did the patient settings (e.g. continuing care facility, home, vehicle, shelter) in which you used the **ISTAT** influence any of your answers about how easy it was to test patient's blood samples?*
    - YES
    - NO

CPPOC Study - Survey for Community Paramedics - iSTAT first

iSTAT - Likes and Dislikes

18. What did you **like** about the **iSTAT** device?*

19. What did you **NOT like** about the **iSTAT** device?*

CPPOC Study - Survey for Community Paramedics - iSTAT first

epoc - Background and Usability

The following questions are about your experiences using the epoc device. We'll ask questions in three (3) sections. The first being the epoc's overall usability, then performing quality checks and finally performing blood testing with patients.

20. Have you had **previous experience** using the **epoc** system prior to this study?*
    - ○ YES
    - ○ NO

21. The following 10 questions are derived from the "systems usability scale", a validated scale that allows for comparison across different systems and provides a global view of usability assessment.

    Please record your immediate responses to the following 10 usability questions, if you feel you cannot respond to a particular item you should mark the center point of the scale.*

	Strongly Disagree				Strongly Agree
I think that I would like to use the epoc frequently	○	○	○	○	○
I found the epoc unnecessarily complex	○	○	○	○	○
I thought the epoc was easy to use	○	○	○	○	○
I think that I would need the support of a technical person to be able to use the epoc	○	○	○	○	○
I found the various functions in the epoc were well integrated	○	○	○	○	○
I thought there was too much inconsistency with the epoc	○	○	○	○	○
I would imagine that most people would learn to use the epoc very quickly	○	○	○	○	○
I found the epoc very cumbersome to use	○	○	○	○	○
I felt very confident using the epoc	○	○	○	○	○
I needed to learn a lot of things before I could get going using the epoc	○	○	○	○	○

CPPOC Study - Survey for Community Paramedics - iSTAT first

epoc Weekly Quality Checks

22. Approximately how many **weekly epoc** Quality Checks (QC) have you performed during this study? (One quality check includes the tests from both solution ampoules)*

- ○ I never performed a weekly quality check
- ○ I performed ___ weekly quality checks

CPPOC Study - Survey for Community Paramedics - iSTAT first

epoc Weekly Quality Checks

23. For the **weekly epoc** Quality Checks (QC), how easy was it to:*

	Very Difficult	Difficult	Neutral	Easy	Very Easy
Find space to ensure epoc device is level during testing	○	○	○	○	○
Turn epoc host (top part) on	○	○	○	○	○
Turn epoc reader (bottom part) on	○	○	○	○	○
Keep the epoc steady when entering information using the keypad or stylus pen	○	○	○	○	○
Get the epoc ready to run a QC sample	○	○	○	○	○
Read the epoc screen instructions	○	○	○	○	○
Scan the appropriate barcodes with the epoc scanner	○	○	○	○	○
Insert the test card into the epoc	○	○	○	○	○
Fill the epoc sample well to the appropriate level	○	○	○	○	○
Know when the epoc test is complete	○	○	○	○	○
Interpret the epoc testing results displayed	○	○	○	○	○
Determine if the QC epoc results are out of range	○	○	○	○	○
Record the epoc results	○	○	○	○	○
Turn epoc host (top part) off	○	○	○	○	○
Turn epoc reader (bottom part) off	○	○	○	○	○
Clean the epoc following use	○	○	○	○	○

24. Did you encounter any issues while doing the **weekly** Quality Check with the **epoc**?*
- ○ YES
- ○ NO

25. Did you find the **temperature requirements** for the Quality Check solutions and test cards for the **epoc** confusing?*
- ○ YES
- ○ NO

CPPOC Study - Survey for Community Paramedics - iSTAT first

epoc - Blood Testing with Patients

26. Approximately how many **blood tests** did you *attempt* to run on the **epoc** during this study?*

- ○ I never attempted or performed a blood test(s)
- ○ I performed ___ blood test(s)

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epoc - Blood Testing with Patients

27. Were you part of a two person team when using the **epoc** to test patients' blood samples?*
    - Always
    - Often
    - Sometimes
    - Rarely
    - Never

28. For the **testing patients' blood samples** using the **epoc,** how easy was it to:*

	Very Difficult	Difficult	Neutral	Easy	Very Easy
Find space to ensure epoc device is level during testing					
Turn epoc host (top part) on					
Turn epoc reader (bottom part) on					
Keep the epoc steady when entering information using the keypad / stylus pen					
Get the epoc ready to run a blood sample					
Read the epoc screen instructions					
Enter the patient's ID					
Insert the test card into the epoc					
Fill the epoc sample well to the appropriate level					
Know when the epoc test is complete					
Interpret the epoc test result displayed					
Determine if the patient's epoc results are out of range					
Turn the epoc host (top part) off					
Turn the epoc reader (bottom part) off					
Clean the epoc following use					

29. Have you encountered any issues while **testing blood** with the **epoc**?*
    - YES
    - NO

30. In which **setting** did you use the **epoc**?*
    - Continuing Care Facility (LTC, SL, Lodge, PCH)
    - Private Home
    - Shelter
    - Vehicle
    - Other

31. Did the patient's setting (e.g. continuing care facility, home, vehicle, shelter) in which you used the **epoc** influence any of your answers about how easy it was to test patient's blood samples?*
    - YES
    - NO

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epoc - Likes and Dislikes

32. What did you **like** about the **epoc** device?*

33. What did you **NOT like** about the **epoc** device?*

CPPOC Study - Survey for Community Paramedics - iSTAT first

General Device Preference

The following questions are about your experiences using both devices.

34. Thinking about what you liked and disliked about both devices, do you prefer one device over the other for performing a **QUALITY CHECK** procedure?*
    - NO - I have no preference
    - YES - I prefer iSTAT
    - YES - I prefer epoc

35. Thinking about what you liked and disliked about both devices, do you prefer one device over the other for performing a **BLOOD TEST** procedure?*
    - NO - I have no preference
    - YES - I prefer iSTAT
    - YES - I prefer epoc

36. Looking back at your experience with both devices, did it seem like you encountered **more errors** with one of the devices?*
    - YES - it seemed like there were more errors when I used epoc
    - YES - it seemed like there were more errors when I used iSTAT
    - NO - they seemed about the same

37. Thinking about what you liked and disliked about both devices, if you had a choice on which device the Calgary CP program should use, what would it be?*
    - iSTAT
    - No preference
    - Other (please specify)
    - epoc
    - Neither (I don't want a POCT device)

CPPOC Study - Survey for Community Paramedics - iSTAT first

POCT - Operational Impact

The following questions are about the operational impact of point of care testing (POCT)

38. Thinking about point of care testing of blood specimen using **any** type of POCT device, please answer:*

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
POCT will shorten my time on task	○	○	○	○	○
I would prefer POCT over transporting blood to CLS	○	○	○	○	○
POCT will improve my ability to make timely patient care decisions	○	○	○	○	○
Community Paramedic POCT results need to be accessible by other health care providers	○	○	○	○	○

39. If you had a choice for the CP program, would you support the implementation of a POCT process (regardless of device) in conjunction with our existing CLS process?*

○ YES
○ NO

40. Please indicate the test you think would be useful for a POCT device in the community paramedic setting in the list below.*

	USEFUL	NOT USEFUL	NOT SURE
Sodium (Na)	○	○	○
Potassium (K)	○	○	○
Chloride (Cl)	○	○	○
TCO2	○	○	○
Anion Gap	○	○	○
Ionized Calcium (iCa)	○	○	○
Glucose (Glu)	○	○	○
Urea Nitrogren (BUN)/Urea	○	○	○
Creatinine (Crea)	○	○	○
Lactate	○	○	○
Hematocrit (Hct)	○	○	○
Hemoglobin* (Hgb)	○	○	○
pH	○	○	○
PCO2	○	○	○
PO2	○	○	○
TCO2	○	○	○
HCO3	○	○	○
Base Excess (BE)	○	○	○
sO2	○	○	○

ACT Kaolin	○	○	○
ACT Celite	○	○	○
PT/INR	○	○	○
β-hCG	○	○	○
cTnI	○	○	○
CK-MB	○	○	○
BNP	○	○	○
eGFR	○	○	○
AGap	○	○	○
AGapK	○	○	○

41. Are there other tests **not listed above** you think would be useful for a POCT device in the community paramedic setting? *

42. Please provide any further comments you have:

CPPOC Study - Survey for Community Paramedics - epoc first

Consent

TITLE The validity and reliability of point of care testing devices in the community paramedic setting

SPONSOR Department of National Defense, Defense Research and Development Canada, Canadian Safety and Security Program.

INVESTIGATORS
Investigators: AHS EMS: Ian Blanchard, Dana Dalgarno, Stacy Goulder, Ryan Kozicky, Gerald Lazarenko, Keith Spackman; AHS Human Factors: Jason Laberge, Susan Biesbroek, Lenore Page; Calgary Lab Services: Karen Leaman, Lyle Redman, Suzanne Snozyk; University of Calgary: Christopher Doig, Eddy Lang, Tyler Williamson.

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Or

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CPPOC Study - Survey for Community Paramedics - epoc first

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2. How many years or months (in total) have you worked in the community paramedic program (please qualify response with months or years)?*

3. Do you have any other post-secondary training (certificates, diplomas or degrees) aside from your paramedic training?*
   - ○ Yes
   - ○ No

CPPOC Study - Survey for Community Paramedics - epoc first

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CPPOC Study - Survey for Community Paramedics - epoc first

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   - ○ I performed ___ weekly quality checks

CPPOC Study - Survey for Community Paramedics - epoc first

epoc Weekly Quality Checks

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	Very Difficult	Difficult	Neutral	Easy	Very Easy
Find space to ensure epoc device is level during testing	○	○	○	○	○
Turn epoc host (top part) on	○	○	○	○	○
Turn epoc reader (bottom part) on	○	○	○	○	○
Keep the epoc steady when entering information using the keypad or stylus pen	○	○	○	○	○
Get the epoc ready to run a QC sample	○	○	○	○	○
Read the epoc screen instructions	○	○	○	○	○
Scan the appropriate barcodes with the epoc scanner	○	○	○	○	○
Insert the test card into the epoc	○	○	○	○	○
Fill the epoc sample well to the appropriate level	○	○	○	○	○
Know when the epoc test is complete	○	○	○	○	○
Interpret the epoc testing results displayed	○	○	○	○	○
Determine if the QC epoc results are out of range	○	○	○	○	○
Record the epoc results	○	○	○	○	○
Turn epoc host (top part) off	○	○	○	○	○
Turn epoc reader (bottom part) off	○	○	○	○	○
Clean the epoc following use	○	○	○	○	○

8. Did you encounter any issues while doing the **weekly** Quality Check with the **epoc**?*
   - ○ YES
   - ○ NO

9. Did you find the **temperature requirements** for the Quality Check solutions and test cards for the **epoc** confusing?*
   - ○ YES
   - ○ NO

CPPOC Study - Survey for Community Paramedics - epoc first

epoc - Blood Testing with Patients

10. Approximately how many **blood tests** did you *attempt* to run on the **epoc** during this study?*
    - ○ I never attempted or performed a blood test(s)
    - ○ I performed ___ blood test(s)

CPPOC Study - Survey for Community Paramedics - epoc first

epoc - Blood Testing with Patients

11. Were you part of a two person team when using the **epoc** to test patients' blood samples?*
    - Always
    - Often
    - Sometimes
    - Rarely
    - Never

12. For the **testing patients' blood samples** using the **epoc,** how easy was it to:*

	Very Difficult	Difficult	Neutral	Easy	Very Easy
Find space to ensure epoc device is level during testing					
Turn epoc host (top part) on					
Turn epoc reader (bottom part) on					
Keep the epoc steady when entering information using the keypad / stylus pen					
Get the epoc ready to run a blood sample					
Read the epoc screen instructions					
Enter the patient's ID					
Insert the test card into the epoc					
Fill the epoc sample well to the appropriate level					
Know when the epoc test is complete					
Interpret the epoc test result displayed					
Determine if the patient's epoc results are out of range					
Turn the epoc host (top part) off					
Turn the epoc reader (bottom part) off					
Clean the epoc following use					

13. Have you encountered any issues while **testing blood** with the **epoc**?*
    - YES
    - NO

14. In which **setting** did you use the **epoc**?*
    - Continuing Care Facility (LTC, SL, Lodge, PCH)
    - Private Home
    - Shelter
    - Vehicle
    - Other

15. Did the patient's setting (e.g. continuing care facility, home, vehicle, shelter) in which you used the **epoc** influence any of your answers about how easy it was to test patient's blood samples?*
    - YES
    - NO

CPPOC Study - Survey for Community Paramedics - epoc first

epoc - Likes and Dislikes

16. What did you **like** about the **epoc** device?*

17. What did you **NOT like** about the **epoc** device?*

CPPOC Study - Survey for Community Paramedics - epoc first

iSTAT - Background and Usability

The following questions are about your experiences using the iSTAT device. We'll ask questions in four (4) sections. The first being the iSTAT's overall usability, then performing quality checks, the daily simulator test and finally performing blood testing with patients.

18. Have you had **previous experience** using the **iSTAT** system prior to this study?*
    - YES
    - NO

19. The following 10 questions are derived from the "systems usability scale", a validated scale that allows for comparison across different systems and provides a global view of usability assessment.

    Please record your immediate responses to the following 10 usability questions, if you feel you cannot respond to a particular item you should mark the center point of the scale.*

	Strongly Disagree				Strongly Agree
I think that I would like to use the iSTAT frequently					
I found the iSTAT unnecessarily complex					
I thought the iSTAT was easy to use					
I think that I would need the support of a technical person to be able to use the iSTAT					
I found the various functions in the iSTAT were well integrated					
I thought there was too much inconsistency with the iSTAT					
I would imagine that most people would learn to use the iSTAT very quickly					
I found the iSTAT very cumbersome to use					
I felt very confident using the iSTAT					
I needed to learn a lot of things before I could get going using the iSTAT					

CPPOC Study - Survey for Community Paramedics - epoc first

iSTAT Weekly Quality Checks

20. Approximately how many **weekly iSTAT** Quality Checks (QC) have you performed during this study? (One quality check includes the tests from both solution ampoules)*

- ○ I never performed a weekly quality check
- ○ I performed ___ weekly quality checks

CPPOC Study - Survey for Community Paramedics - epoc first

iSTAT Weekly Quality Checks

21. For the **weekly ISTAT** Quality Checks (QC), how easy was it to:*

	Very Difficult	Difficult	Neutral	Easy	Very Easy
Find space to ensure iSTAT device is level during testing	○	○	○	○	○
Turn the iSTAT on	○	○	○	○	○
Keep the iSTAT steady when entering information using the keypad	○	○	○	○	○
Get the iSTAT ready to run a QC sample	○	○	○	○	○
Read the iSTAT screen instructions	○	○	○	○	○
Scan the appropriate barcodes with the iSTAT scanner	○	○	○	○	○
Fill the iSTAT sample well to the appropriate level	○	○	○	○	○
Insert the cartridge into the iSTAT	○	○	○	○	○
Know when the iSTAT test is complete	○	○	○	○	○
Interpret the iSTAT testing results displayed	○	○	○	○	○
Determine if the QC iSTAT results are out of range	○	○	○	○	○
Record the iSTAT results	○	○	○	○	○
Turn the iSTAT off	○	○	○	○	○
Clean the iSTAT following use	○	○	○	○	○

22. Did you encounter any issues while doing the **weekly ISTAT** Quality Checks?*

- ○ YES
- ○ NO

23. Did you find the **temperature requirements** for the Quality Check solutions and cartridges for the **ISTAT** confusing?*

- ○ YES
- ○ NO

CPPOC Study - Survey for Community Paramedics - epoc first

iSTAT - Daily Electronic Simulator Checks

24. Approximately how many **daily (electronic simulator) iSTAT** Quality Checks (QC) have you performed during this study?*

- ○ I never performed a daily electronic check
- ○ I performed ___ daily electronic checks

CPPOC Study - Survey for Community Paramedics - epoc first

iSTAT Daily Electronic Simulator Checks

25. For the **daily (electronic simulator) iSTAT** Quality Checks (QC) , how easy was it to:*

	Very Difficult	Difficult	Neutral	Easy	Very Easy
Find space to ensure iSTAT device is level during testing	○	○	○	○	○
Turn the iSTAT on	○	○	○	○	○
Keep the iSTAT steady when entering information using the keypad	○	○	○	○	○
Get the iSTAT ready to run the simulator check	○	○	○	○	○
Read the iSTAT screen instructions	○	○	○	○	○
Scan the simulator barcode with the iSTAT scanner	○	○	○	○	○
Insert the simulator into the iSTAT	○	○	○	○	○
Know when the iSTAT test is complete	○	○	○	○	○
Interpret the iSTAT test result displayed	○	○	○	○	○
Determine if the simulator check has passed	○	○	○	○	○
Record the iSTAT results	○	○	○	○	○
Turn the iSTAT off	○	○	○	○	○
Clean the iSTAT following use	○	○	○	○	○

CPPOC Study - Survey for Community Paramedics - epoc first

ISTAT - Blood Testing with Patients

26. Approximately how many **blood tests** did you *attempt* to run on the **iSTAT** during this study?*

- ○ I never attempted or performed a blood test(s)
- ○ I performed ___ blood test(s)

CPPOC Study - Survey for Community Paramedics - epoc first

iSTAT Blood Testing with Patients

27. Were you part of a two person team when using the **iSTAT** to test patients' blood samples?*
    - Always
    - Often
    - Sometimes
    - Rarely
    - Never

28. For **testing patients' blood samples** using the **iSTAT,** how easy was it to:*

	Very Difficult	Difficult	Neutral	Easy	Very Easy
Find space to ensure iSTAT device is level during testing					
Turn the iSTAT on					
Keep the iSTAT steady when entering information using the keypad					
Get the iSTAT ready to run a blood sample					
Read the iSTAT screen instructions					
Enter the patient's ID					
Fill the iSTAT sample well to the appropriate level					
Insert the cartridge into the iSTAT					
Know when the iSTAT test is complete					
Interpret the iSTAT test result displayed					
Determine if the patient's iSTAT results are out of range					
Turn the iSTAT off					
Clean the iSTAT following use					

29. Have you encountered any issues while **testing blood** with the **iSTAT**?*
    - YES
    - NO

30. In which **setting** did you use the **iSTAT**?*
    - Continuing Care Facility (LTC, SL, Lodge, PCH)
    - Private Home
    - Shelter
    - Vehicle
    - Other

31. Did the patient settings (e.g. continuing care facility, home, vehicle, shelter) in which you used the **iSTAT** influence any of your answers about how easy it was to test patient's blood samples?*
    - YES
    - NO

CPPOC Study - Survey for Community Paramedics - epoc first

iSTAT - Likes and Dislikes

32. What did you **like** about the **iSTAT** device?*

33. What did you **NOT like** about the **iSTAT** device?*

CPPOC Study - Survey for Community Paramedics - epoc first

General Device Preference

The following questions are about your experiences using both devices.

34. Thinking about what you liked and disliked about both devices, do you prefer one device over the other for performing a **QUALITY CHECK** procedure?*
    - ○ YES - I prefer epoc
    - ○ YES - I prefer iSTAT
    - ○ NO - I have no preference

35. Thinking about what you liked and disliked about both devices, do you prefer one device over the other for performing a **BLOOD TEST** procedure?*
    - ○ YES - I prefer epoc
    - ○ YES - I prefer iSTAT
    - ○ NO - I have no preference

36. Looking back at your experience with both devices, did it seem like you encountered **more errors** with one of the devices?*
    - ○ NO - they seemed about the same
    - ○ YES - it seemed like there were more errors when I used iSTAT
    - ○ YES - it seemed like there were more errors when I used epoc

37. Thinking about what you liked and disliked about both devices, if you had a choice on which device the Calgary CP program should use, what would it be?*
    - ○ epoc
    - ○ Other (please specify)
    - ○ No preference
    - ○ Neither (I don't want a POCT device)
    - ○ iSTAT

CPPOC Study - Survey for Community Paramedics - epoc first

POCT - Operational Impact

The following questions are about the operational impact of point of care testing (POCT)

38. Thinking about point of care testing of blood specimen using **any** type of POCT device, please answer:*

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
POCT will shorten my time on task	○	○	○	○	○
I would prefer POCT over transporting blood to CLS	○	○	○	○	○
POCT will improve my ability to make timely patient care decisions	○	○	○	○	○
Community Paramedic POCT results need to be accessible by other health care providers	○	○	○	○	○

39. If you had a choice for the CP program, would you support the implementation of a POCT process (regardless of device) in conjunction with our existing CLS process?*

○ YES
○ NO

40. Please indicate the test you think would be useful for a POCT device in the community paramedic setting in the list below.*

	USEFUL	NOT USEFUL	NOT SURE
Sodium (Na)	○	○	○
Potassium (K)	○	○	○
Chloride (Cl)	○	○	○
TCO2	○	○	○
Anion Gap	○	○	○
Ionized Calcium (iCa)	○	○	○
Glucose (Glu)	○	○	○
Urea Nitrogren (BUN)/Urea	○	○	○
Creatinine (Crea)	○	○	○
Lactate	○	○	○
Hematocrit (Hct)	○	○	○
Hemoglobin* (Hgb)	○	○	○
pH	○	○	○
PCO2	○	○	○
PO2	○	○	○
TCO2	○	○	○
HCO3	○	○	○
Base Excess (BE)	○	○	○
sO2	○	○	○

ACT Kaolin	○	○	○
ACT Celite	○	○	○
PT/INR	○	○	○
β-hCG	○	○	○
cTnI	○	○	○
CK-MB	○	○	○
BNP	○	○	○
eGFR	○	○	○
AGap	○	○	○
AGapK	○	○	○

41. Are there other tests **not listed above** you think would be useful for a POCT device in the community paramedic setting? *

42. Please provide any further comments you have:

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Introduction: Community Paramedic (CP) programs provide a critical bridge between the health care system and the community. Additional treatments and assessments in the community by CPs often prevents transport of the patient to an acute care facility. One of the challenges CPs face is access to timely diagnostic tests such as blood analyses. Many CP programmes transport blood to a laboratory for analysis. This process is resource intensive, presents multiple opportunities for misidentification of patients/results, prevents CPs from providing timely treatment and coordinating additional patient care initiatives while on-scene, and may increase the time the CP is not available for another patient. Point of care testing (POCT) may offer a technological solution.

Purpose: Address the Canadian Safety and Security Program (CSSP) priority of assessing the use of technology in CP programmes to inform policy and strategy by comparing CP POCT to a standard laboratory process, and contrasting two commercially available devices (Abbott i-STAT® and Alere epoc®).

Methods: There were five broad methodological approaches to this study: 1. Device validation in the CP setting; 2. Time to results; 3. CP survey; 4. Human factors assessment; and 5. Descriptive cost and device summary. Seven analytes were assessed: sodium (Na), potassium (K), chloride (Cl), creatinine (Crea), hemoglobin (Hgb), hematocrit (Hct), and glucose (Glu). All statistical tests were considered significant at the 0.05 level.

Results: A total of 108 observations assessing seven analytes on 73 patients revealed seven out of the 1,047 individual comparisons (0.7%) with discrepant critical results (i.e., a critical range was detected in POCT but not in the laboratory). These appeared to be slightly higher with i-STAT (0.9%; 95% CI -0.1%, 1.9%) compared to epoc (0.3%; 95% CI -0.3, 0.9) (p=0.323). The discrepant results occurred entirely in the Na and K analytes. In 126 out of 1,645 individual comparisons (7.7%) exceeded the acceptable comparative range between POCT and laboratory. For i-STAT there were 32 out of 523 individual comparisons (6.1%; 95% CI 4.1%, 8.2%) that exceeded this range, and for epoc there were 56 out of 523 (10.7%; 95% CI 8.1%, 13.3%) (p=0.007). The epoc had almost three times the number of out-of-range results for Cl, and twice the number for Crea compared to i-STAT. The epoc had 17 instances of out-ofacceptable comparative range results for Hct compared to zero for i-STAT. For Glu however, i-STAT had twice as many out-of-range results for values under five mmol/L and three times as many for values greater than or equal to five mmol/L.

CPs will get their results considerably quicker using POCT compared to transportation to lab (97 to 163 minutes).

CPs felt that POCT improved their ability to make timely decisions for their patients and saved transport time to laboratory services in those events where no further lab analysis is required. A POCT program, however, will not replace blood transport in all events. There was a statistically significant higher rating for the i-STAT compared to the epoc on the system usability score, and the majority of CPs preferred the i-STAT over the epoc.

The i-STAT had higher initial costs but lower operational costs; the epoc had lower initial costs but higher operational costs.

The i-STAT and epoc share many of the same characteristics such as time to results, blood volumes required, and operating temperature ranges, however there are some important differences. The epoc test cards can be stored at room temperature, while i-STAT test cartridges must be stored at two to eight °C and once removed must be used within 14 days. The i-STAT has a larger test menu than the epoc, but this is attained through multiple test cartridges, not a single card as for the epoc.

Conclusions: EMS systems that use POCT can expect that even with optimized training and rigorous quality control testing, and dependent on the analyte and POCT device, discrepant critical range values with the laboratory will occur in 0% to 1.9% of comparisons. Results outside of acceptable comparative range between the POCT and laboratory will occur in 4.1% to 13.3% of comparisons, also depending on analyte and POCT device. The epoc device had a statistically significant increased number of tests that exceeded the acceptable comparative range between POCT and lab when compared to i-STAT.

CPs felt that POCT helped to improve their ability to make timely decisions for their patients and saved transport time to laboratory services in those events where no further lab analysis is required. CPs in general preferred i-STAT over the epoc.

Both POCT systems have advantages and disadvantages that must be considered carefully prior to purchase.