Point of care lactate and creatinine analysis for sick obstetric patients at Queen Elizabeth Central Hospital in Blantyre, Malawi – a feasibility study

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Abstract

Background

To achieve good outcomes in critically ill obstetric patients it is necessary to identify organ dysfunction rapidly so that life-saving interventions can be appropriately commenced. However, timely access to clinical chemistry results is problematic even in referral institutions in the sub Saharan African region. Reliable point of care tests licensed for clinical use are now available for lactate and creatinine.

Aim

We aimed to assess whether implementation of point of care testing for lactate and creatinine is feasible in the obstetric unit at the Queen Elizabeth Central Hospital (QECH), Malawi, by obtaining the opinions of clinical staff on the use of these tests in practice.

Methods

During a two month evaluation period nurse-midwives, medical interns, clinical officers, registrars and consultants were given the opportunity to use StatStrip® and StatSensor® (Nova Biomedical) devices for lactate and creatinine estimation as part of their routine clinical practice in the obstetric unit. They were subsequently asked to complete a short questionnaire.

Results

37 questionnaire responses were received, 22 from nurse-midwives and the remainder from clinicians. The mean satisfaction score for the devices was 7.6/10 amongst clinicians and 8.0/10 amongst nurse-midwives. The majority of participants stated that the obstetric high dependency unit (HDU) was the most suitable location for the devices. For lactate, 31 participants strongly agreed that testing should be continued and 24 strongly agreed that it would influence patient management. For creatinine, 29 strongly agreed that testing should be continued and 28 strongly agreed that it would influence their patient management. 20 participants strongly agreed that they trust point of care devices.

Conclusion

Point of care clinical chemistry testing is feasible, practical, well received by staff and was considered by staff to have a useful role to play in the clinical care of very sick obstetric patients at this referral centre.

Keywords:
Point-of-care testing; lactic acid; creatinine; obstetrics; feasibility studies; chemistry, clinical

Introduction

In the context of obstetric practice, there are difficulties in the early recognition of severe sepsis and renal compromise in that patients are relatively young and are usually previously healthy, so the development of obvious clinical signs may occur only at a very late stage in the evolution of the condition. Thus, organ failure is often already established by the time a firm diagnosis is made. Maternal mortality is high in QECH with sepsis and pre eclampsia being amongst the most common causes of death (1).

Previous studies in low resource settings reported that point of care devices greatly enhanced the feasibility of biochemical tests (2), that they could be used quickly and easily by auxiliary health personnel (3), that they were well received by staff and that they made a positive contribution to medical care (4). Furthermore, point of care testing may enable more efficient use of scarce resources, leading to reduced length of hospital stay, fewer unnecessary hospital admissions and reduced use of blood products (5). In the local setting there are naturally tremendous challenges with regards to cost of laboratory investigations and while point of care devices are in use as part of research studies with samples tested by project staff, these have not been brought into the routine service setting. Potential difficulties associated with the introduction of point of care testing into the clinical setting include logistic problems, poor documentation of test results, lack of critical value notification system and poor quality control (6). However, these challenges may be overcome by staff training.

Lactate and creatinine testing is especially valuable for identification of critical illness amongst obstetric patients. Hyperlactataemia is common in critically ill patients and is thought to arise due to release of catecholamines in shock states (7). Lactate predicts mortality in intensive care patients (8) and its use to guide resuscitation reduces hospital mortality (9). Creatinine facilitates early detection of pregnancy-related acute kidney injury, a condition associated with devastating maternal and foetal consequences (10). However, serum lactate analysis is not currently offered in the QECH whilst creatinine analysis and feedback of results may take up to three days via the hospital laboratory.

The aim of this study was to evaluate whether implementation of point of care devices for lactate and creatinine is feasible in the Department of Obstetrics and Gynaecology at QECH. The specific objectives were as follows:

1) To explore staff opinion on whether point of care devices for lactate and creatinine are easy to use, influence patient management and whether the staff considers that there is potential for future use and sustainability.
2) To determine which cadre of staff is the most appropriate for handling point of care clinical chemistry devices and the most suitable location of the devices within the unit, including the obstetric admissions unit, labour ward and HDU.

Methods

StatStrip Xpress® lactate meters and StatSensor Xpress® creatinine meters and test strips (Nova Biomedical, Waltham, USA), licensed internationally for clinical applications, were placed in the Department of Obstetrics and Gynaecology at QECH between June and July 2015 as part of a pilot study testing the feasibility of hand-held point of care devices. Staff were briefed on the correct operation of these devices in groups or individually and user information materials were provided including normal reference ranges. Staff were encouraged to employ the devices in their routine clinical practice where they considered it appropriate for patient care. Feasibility of use was explored in different wards of the Department including the labour ward, obstetric admissions unit, obstetric HDU and the postnatal ward.

Creatinine test strips and quality control solutions were stored in the Unit refrigerator, lactate strips and solutions were stored at room temperature and quality control tests using standard solutions for lactate and creatinine were performed regularly according to the product literature.

After six weeks staff were presented with anonymous, paper-based questionnaires comprising 15 items seeking their views on point of care testing for lactate and creatinine in the Department. All members of clinical staff employed in the department of Obstetrics and Gynaecology at QECH who had used the devices or results from them were eligible for participation. Questions focussed on the overall satisfaction, perceived ease of use, any difficulties experienced and who the respondent considered should be responsible for handling these devices. Furthermore, participants were asked to rate whether testing for lactate and creatinine was useful, whether it would influence patient management, whether it should be continued, whether it would increase efficiency, the type of patients and location where it would be most useful and how much they trust results from the devices. As serum creatinine analysis is available from the hospital laboratory, participants were also asked whether they preferred point of care testing to laboratory analysis. The response options were: “strongly agree”, “somewhat agree”, “neither agree or disagree”, “somewhat disagree”, “strongly disagree” and “don’t know”. Results for overall satisfaction and perceived ease-of-use are presented as means and standard deviations (SD).

Exemption from ethics review was granted by the College of Medicine Research Ethics Committee (COMREC) under reference P.04/15/1723; approval was granted by the University Teaching and Research Ethics Committee (UTREC) at the University of St Andrews under reference MD11557.

Results

No member of staff refused to participate. A total of 37 questionnaire responses were received; 22 from nurse-midwives, eight from medical interns, three from registrars, two from consultants, one from a clinical officer and one from a final year medical student. For reporting here, staff other than nurse-midwives are referred to as clinicians. Six clinicians had used the devices 1-2 times, two 3-7 times and one more than eight times. Among nurse-midwives, five had used the devices 1-2 times, five had used them 3-7 times and three had used them more than 8 times. On a scale of 0 to 10 where 10 indicated 'extremely satisfied', the mean overall score for satisfaction with the devices was 7.6 (SD 1.4) amongst clinicians and 8.0 (SD 1.4) amongst nurse-midwives. The ease-of-use was rated as a mean 9.1 (SD 1.0) and 9.0 (SD 1.5) by clinicians and nurse-midwives respectively. Both groups most commonly stated that nurse-midwives should mainly be responsible for point of care testing, followed by "all members of staff". Three clinicians had experienced difficulties with point of care testing compared to two nurse-midwives. Difficulties mainly related to error messages; however, these were almost always due to poor technique during early use rather than intrinsic faults of the devices and were resolved and explained quickly by the investigators.

It appeared that two participants had misread the answer options "strongly disagree" and "strongly agree" in the second part of the survey, as they had rated the meters positively in the first part or commented favourably in the open space questions ("They should be enrolled in all central hospitals in Malawi"). The answers of these participants were therefore moderated to compensate for this error.

31 participants strongly agreed and two somewhat agreed that point of care testing for lactate should be continued; 22 participants strongly agreed and 13 somewhat agreed that point of care testing for lactate is useful in the Obstetrics and Gynaecology wards. Similarly, 24 participants strongly agreed and ten somewhat agreed that results from point of care lactate devices would influence the management of their patients and 30 participants strongly agreed and three somewhat agreed that lactate testing is useful in the HDU to monitor sick patients (Table 1).

29 participants strongly agreed and four somewhat agreed that creatinine testing should be continued whilst 26 participants strongly agreed and seven somewhat agreed that it is useful. 28 participants strongly agreed and six somewhat agreed that creatinine analysis would influence patient management. Creatinine can be analysed by the hospital laboratory; nevertheless, 23 participants strongly agreed and three somewhat agreed that creatinine analysis by point of care testing is preferable to its analysis by the hospital laboratory (Table 2).

26 participants strongly agreed and seven somewhat agreed that point of care testing would improve efficiency in the Obstetrics and Gynaecology wards. Most staff trusted the results from point of care meters but only 20 participants strongly agreed and nine somewhat agreed to this (Table 3).

Quality control checks were consistently within their normal ranges. Owing to power outages there were a few interruptions in refrigerator power; however, these were

of short duration and were unlikely to have adversely affected the creatinine test strips. Inadequate documentation of test and failure to recognise abnormal test results was not observed during this pilot study.

Many members of staff commented favourably on how the meters aided patient care *("I think it helps make critical decisions quickly"* – registrar) and asked for continuation of the study (*"Please continue supplying us with testing kits for continuation of testing"* – nurse-midwife; "*As long as sustainability is maintained these are very good bedside tests"* – intern).

Discussion

The findings suggest that point of care testing for both lactate and creatinine is considered helpful for clinical care and is favoured by staff in the obstetric unit. Point of care testing for lactate was considered most beneficial for use in the HDU for regular monitoring of sick patients to guide clinicians on a patient's progress or to alert them to deterioration. The availability of hand-held meters for this purpose considerably enhanced the availability and feasibility of lactate measurements, meaning that lactate could be used as a dynamic marker for risk stratification of critically ill patients in the obstetric HDU. A recent study confirmed that dynamic indices of lactate are superior predictors of mortality than static indices, since they describe not only the magnitude but also the trend of hyperlactataemia over time (11) (12). Nevertheless, static lactate indices also have an important role, for example in guiding clinical decisions as to who should be admitted to a high dependency model of care. Such decisions may have profound implications not only on patient wellbeing but also on the appropriate use of scarce resources by using available beds, staff time and investigations for those most able to benefit. Thus, point of care testing can facilitate the effective use of a limited number of HDU beds with high occupancy and accelerate the smooth "step up" care for patients who deteriorate and "step down" care for those ready to transfer to a postnatal ward (13).

Whilst it was beyond the scope of this feasibility study to formally investigate point of care testing in relation to patient outcomes or to define its cost-effectiveness, evidence from a study in emergency department patients with suspected sepsis suggest that the introduction of point of care lactate devices reduces the time to administration of intravenous fluids, Intensive Care Unit admission where needed and indeed mortality (14). Routine implementation of point of care testing in emergency departments of low and middle-income countries has been reported to be associated with improved health-related outcomes and can be cost effective (15). Given the considerable burden of sepsis in referred obstetric patients, these results are likely to be transferable to specialist obstetric units in low resource settings.

We noted that trust in the results of point of care devices was relatively low, with just over half of participants strongly agreeing that they trust the results. Studies have reported a close correlation in measurements between point of care devices and a reference standard laboratory analyser for both lactate (16) (17) and creatinine (18) (19) (20) but for staff to gain confidence in the results, an implementation strategy would need to include an initial component of validation of findings against results from an appropriate reference laboratory.

The present study was not designed to assess the influence of access to these tests to clinical decision making, outcomes and cost-effectiveness and the next stage will be to design appropriate implementation research to generate this knowledge, initially in large referral facilities such as the QECH before consideration is given to extending the approach to District level facilities.

We conclude that implementation of point of care testing in the Department of Obstetrics and Gynaecology at QECH is worthwhile and staff felt strongly that the

point of care consumables should be available for future continuation of point of care testing – *"Let it continue"* (nurse-midwife).

Abbreviations

HDU – High dependency unit

MMR – maternal mortality ratio

POC – point of care

QECH – Queen Elizabeth Central Hospital

SD – standard deviation

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Conflicts of interest

The authors declare no conflicts of interest

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	Staff group	Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree	Don't know	No response
POC testing for lactate should be continued in the Obstetrics and Gynaecology wards	Nurse-midwives	0	0	0	1 (4.5)	19 (86)	1 (5)	1 (5)
	Clinicians	1 (7)	0	1 (7)	1 (7)	12 (80)	0	0
	Total	1 (3)	0	1 (3)	2 (5)	31 (83)	1 (3)	1 (3)
POC testing for lactate is useful in the Obstetrics and Gynaecology wards	Nurse-midwives	0	0	0	8 (36)	13 (59)	1 (4.5)	0
	Clinicians	1 (7)	0	0	5 (33)	9 (60)	0	0
	Total	1 (3)	0	0	13 (35)	22 (59)	1 (3)	0
POC testing for lactate would influence the management of my patients	Nurse-midwives	0	0	0	4 (18)	16 (72)	1 (5)	1 (5)
	Clinicians	1 (7)	0	0	6 (40)	7 (46)	0	1 (7)
	Total	1 (3)	0	0	10 (27)	24 (64)	1 (3)	1 (3)
POC testing for lactate would be useful for monitoring sick patients in HDU	Nurse-midwives	0	0	0	1 (5)	17 (77)	2 (9)	2 (9)
	Clinicians	0	0	0	2 (13)	13 (87)	0	0
	Total	0	0	0	3 (8)	30 (82)	2 (5)	2 (5)

Table 1. Questionnaire results of staff members regarding their opinion on the use of lactate in the Obstetrics and Gynaecology wards at QECH. Results are displayed as number of participants (percentage). POC – point of care

	Staff group	Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree	Don't know	No response
POC testing for creatinine should be continued in the Obstetrics and Gynaecology wards	Nurse-midwives	0	0	0	3 (14)	16 (72)	0	3 (14)
	Clinicians	1 (7)	0	0	1 (7)	13 (86)	0	0
	Total	1 (3)	0	0	4 (11)	29 (78)	0	3 (8)
POC testing for creatinine is useful in the Obstetrics and Gynaecology wards	Nurse-midwives	0	0	0	6 (27)	13 (59)	0	3 (14)
	Clinicians	1 (7)	0	0	1 (7)	13 (86)	0	0
	Total	1 (3)	0	0	7 (19)	26 (70)	0	3 (8)
POC testing for creatinine would influence the management of my patients	Nurse-midwives	0	0	0	5 (23)	15 (68)	0	2 (9)
	Clinicians	1 (7)	0	0	1 (7)	13 (86)	0	0
	Total	1 (3)	0	0	6 (16)	28 (76)	0	2 (5)
POC testing for creatinine is preferable to analysis by the hospital laboratory	Nurse-midwives	1 (5)	1 (5)	0	2 (9)	14 (64)	0	4 (18)
	Clinicians	0	2 (13)	1 (7)	1 (7)	9 (60)	2 (13)	0
	Total	1 (3)	3 (8)	1 (3)	3 (8)	23 (62)	2 (5)	4 (11)

Table 2. Questionnaire results of staff members regarding their opinion on the use of creatinine in the Obstetrics and Gynaecology wards at QECH. Results are displayed as number of participants (percentage). POC – point of care

	Staff group	Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree	Don't know	No response
POC testing for would improve efficiency in the Obstetrics and Gynaecology wards	Nurse-midwives	0	0	0	4 (18)	15 (68)	0	3 (14)
	Clinicians	1 (7)	0	0	3 (20)	11 (73)	0	0
	Total	1 (3)	0	0	7 (18)	26 (73)	0	3 (8)
I trust the results of point of care devices	Nurse-midwives	0	0	2 (9)	3 (14)	13 (59)	1 (5)	3 (14)
	Clinicians	0	0	1 (7)	6 (40)	7 (47)	0	1 (7)
	Total	0	0	3 (8)	9 (24)	20 (54)	1 (3)	4 (11)

Table 3. Questionnaire results of staff members regarding their opinion the use of point of care testing in the Obstetrics and Gynaecology wards at QECH. Results are displayed as number of participants (percentage). POC – point of care