

ABSTRACTS



Promoting a Culture of Quality and Consistency in Critical and Point of Care Testing

24th International Symposium

October 4-6, 2012

Prague, Czech Republic

Sponsored by the AACC Critical and Point-of-Care Testing Division

In cooperation with the Czech Society of Clinical Biochemistry (CSKB) and the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), and under the auspices of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).

WELCOME

On behalf of the AACC Critical and Point-of-Care Testing Division and our collaborating organizations, the Czech Society of Clinical Biochemistry (CSKB), the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), I would like to welcome you to Prague and this 24th International Symposium.

This symposium asks the questions, “Is point-of-care testing (POCT) reliable enough to facilitate early clinical decision making? Is it appropriate as an aid to optimize patient management in a hospital or primary care setting?” The answers to these questions depend on the quality and interpretation of the analytical results produced by POCT. Yet, little information is available on the quality error rate of POCT and how this may influence patient decision making.

One area in which these questions are particularly poignant is tight glycemic control which is the topic of a debate during the initial session of the meeting. The meeting will also address these questions from the perspective of point-of-care testing in different settings and will consider the testing benefits provided by POCT alongside the impact of quality errors on patient care. The meeting will also consider the challenge of POCT applications outside of the hospital to include military applications, sports medicine, and transplantation patient self management in a home setting. It will introduce new POCT technologies such as those using iPhones and tablets for clinical assessment of critically ill patients and look at applications of infrared technology.

I want to thank our partners from industry who are helping to support this meeting and who are working with us to improve the quality of point-of-care testing. I also want to thank our speakers and attendees who add to our knowledge of how best to use point-of-care tests in patient care.

Thank you for joining us in Prague this week. I hope you enjoy the conference.

Jeffrey A. DuBois, PhD, FACB
Chair, CPOCT International Symposium Planning Committee

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PROGRAM OVERVIEW

This 2 ½ day conference includes posters and presentations by clinicians and scientist who are leaders in the field of critical and point of care testing. The following scientific areas are being covered during the meeting.

- Why are there differences in reported benefits and outcomes with tight glycemic protocols in critical care patients? A debate.
- Sources and prevention of errors in point-of-care testing
- Point-of-care testing beyond the hospital
- Developing effective strategies to achieve quality point-of-care testing results
- New technologies in point-of-care testing

This intermediate level conference will prepare attendees to:

- Provide explanations for differences in tight glycemic protocol outcomes.
- Implement effective strategies for meeting quality standards in point-of-care testing.
- Evaluate the use of point-of-care testing outside of the hospital for identifying or managing patients with chronic diseases
- Assess the use of point-of-care testing for patient management in a hospital or primary care setting
- Educate colleagues about new and emerging technologies in critical and point of care testing.

PROGRAM SCHEDULE

October 3, 2012

6:00pm Wine and cheese reception

October 4, 2012

8:30am **WELCOME REMARKS**

Dr. Jeffrey DuBois, Conference Chair
Prof Dr. Tomas Zima, DSc, Vice-Chair
Dr. Ian Watson, EFLM President

8:45am

Keynote Address

Current and Emerging Quality Perspectives in POCT

Maurice O’Kane, MD, Altnagelvin Hospital, Londonderry, UK

SESSION 1: Why are there differences in reported benefits and outcomes with tight glycemic protocols in critical care patients? A debate.

9:30am

Moderator: Martha Lyon, PhD, Royal University Hospital, Saskatchewan, CN

9:40am

Greet Van den Berghe, MD, PhD, University of Leuven, Belgium
Anthony Furnary, MD, Starr-Wood Cardiac Group of Portland, OR, USA
James Krinsley, MD, Stamford Hospital, Stamford, CT, USA

10:10am

Break

11:55am

Panel Discussion/Q&A

12:30pm

Lunch

SESSION 2: Sources and Prevention of Errors in Point of Care Testing

2:00pm

Moderator: Robbert Slingerland, Isala Klinieken, The Netherlands

2:10pm

Change Management and Point-of-Care Testing
Marion Fokkert, Isala Klinieken, Zwolle, The Netherlands

2:40pm

Meeting POC Expectations of the Clinician
Sverre Sandberg, MD, PhD, Haukeland University Hospital, Bergen, Norway

3:10pm

Break

3:40pm

Biological Variation and Point-of-Care Testing
Rob Jansen, PhD, Equas SKML, Nijmegen, The Netherlands

4:10pm

Causes and Frequencies of Failed Electronic Transmission of Point-of-Care Test Results.
Linda Sandhaus, MD, University Hospitals of Cleveland, OH, USA

4:25pm

Panel Discussion/Q&A

5:00pm

Poster viewing and Reception

6:00pm

Adjourn

October 5, 2012

8:00 am

Vendor Presentations

Moderator: Anne Skurup, Radiometer, Bronshoj, Denmark
HemoCue
Abbott Diabetes Care
Nova Biomedical

SESSION 3: Point-of-Care Testing Beyond the Hospital

9:00am

Moderator: Ian Watson, PhD, University Hospital Aintree, Liverpool, UK

9:10am

POC Diagnostics in the Military

Major Tracey Smith-Straney, University Hospital Aintree, Liverpool, UK

9:40am

Self Management of Renal and Pancreas Transplant Patients

Paul Van der Boog, MD, Consulting Nephrologist, Leiden University Medical Center, The Netherlands

10:10am

Break

10:40am

POC Athletic Testing: A New Approach to Evaluating Sports Performance

Ioan Stoian, MD, PhD, National Institute of Sports Medicine, Bucharest, Romania

11:10am

Towards Sustainable Point-of-Care Testing in Remote Australia

Brooke Spaeth, Flinders University, Bedford Park, South Australia

11:25am

Comparative Effectiveness of the VerifyNow P2Y12 Test and Light Transmittance Aggregometry for Assessment

Merel Kuhbauch, BASc, Accumetrics, San Diego, CA

11:40am

Panel Discussion/Q & A

12:15pm

Lunch

SESSION 4: Developing Effective Strategies to Achieve Quality POCT Results

1:30pm

Moderator: Linda Sandhaus, MD, University Hospitals of Cleveland, OH, USA

1:40pm

Errors in POCT: When Improbable Situations Become Possible

James Nichols, PhD, Vanderbilt University School of Medicine, Nashville, TN, USA

2:10pm

Efficient Implementation of Quality Standards for POCT Can Improve Patient Outcomes

Kenneth Blick, PhD, University of Oklahoma, Oklahoma City, OK, USA

2:40pm

Break

3:10pm

Achieving Quality POCT in a Regional Emergency Care System

Per Simonsson, MD, PhD, University and Regional Laboratories Region Skåne, Malmö, Sweden

- 3:40pm Rapid Test Quantum Blue® Faecal Calprotectin as Predictor of Relapse in Patients Under Maintenance Treatment with Infliximab®
Manuel Otero Santiago, University of Santiago Clinical Hospital, Santiago de Compostela, Spain.
- 3:55pm Bacterial Contamination of Glucose Test Strips: Does the Packaging Matter?
Jean-Winoc Decousser, PharmD, PhD, University Hospital Antoine-Béclère, Clamart, France
- 4:10pm Panel Discussion/Q&A
- 4:40pm Adjourn
- 6:30pm CPOCT Awards Dinner

October 6, 2012

- 8:00am **Vendor Presentations**
Moderator: Brad Karon, MD, PhD, Mayo Clinic, Rochester, MN, USA
Siemens Healthcare Diagnostics
Alere
Radiometer
- SESSION 5: New Technologies in Point-of-Care Testing**
- 9:00am **Moderator: Larry Crolla, PhD, Northwest Community Hospital, Arlington Heights, IL, USA**
- 9:10am** New iPhone and iPad Acid-base Interpretation Apps in Clinical Assessment of Critically ill Patients: Is that a Problem or a Step into the Future?
Jesper Wandrup, PhD, Radiometer, Bronshoj, Denmark
- 9:40am Utilizing IR Detection Technologies in POCT Devices
Susan Selgren, PhD, Siemens Healthcare Diagnostics, Norwood, MA, USA
- 10:10am Break
- 10:40am Advances in Infectious Disease Molecular Diagnostics at the Point-of-Care Site
Ian George, PhD, Enigma Diagnostics, Salisbury, UK
- 11:10am Improving Clinical Outcomes by Split Central Venous Sampling of Parathyroid Hormone
Vida Montgomery, Keck Medical Center of USC, Los Angeles, CA
- 11:25pm A Novel Technology for 5-Part Differentiation of Leukocytes Point-of-Care.
Stellan Lindberg, PhD, HemoCue AB, Ängelholm, Sweden
- 11:40am Panel Discussion/Q&A
- 12:00pm Adjourn

SPEAKER ABSTRACTS

Abstracts are listed in the order of presentation by session.

Note: These abstracts have been reproduced without editorial alteration from the materials supplied by the authors. Grammar, spelling, style, syntax and usage are those of the author.

Point of Care Testing – Current and Emerging Quality Perspectives

Dr Maurice O’Kane

Clinical Chemistry Laboratory, Altnagelvin Hospital, Londonderry, N. Ireland, United Kingdom

Point of Care Testing [POCT] represents one of the fastest growth areas in the clinical diagnostic arena. POCT is used in a wide range of settings [secondary care, primary care, pharmacies, patient self monitoring] and for a range of purposes [diagnosis, screening and disease monitoring]. Each application poses particular challenges for both the analytical measuring system and the operator. A major advantage of POCT is the rapid availability of a test results which has the potential to expedite clinical decision making and might therefore contribute to better patient management and improved outcomes. The seminal report from the Institute of Medicine in 1999 [‘To err is human: building a safer healthcare system’] highlighted the issue of patient safety and estimated that 98 000 deaths per year in the US might be attributable to medical error. Although the contribution of errors in diagnostic testing to iatrogenic morbidity and mortality is unclear, it is likely to be significant given the central role of test results in clinical decision making. The use of POCT as opposed to central laboratory testing may reduce some types of error, particularly in the pre-analytical phase e.g. sample identification, but may be more vulnerable to other types of error e.g. failure of the clinical operator to follow the standard operating procedure. An understanding of the relative risks and benefits would help inform decision making regarding the introduction and use of POCT.

It is difficult to evaluate the quality error rates associated with POCT and there is limited information available on this. Evidence suggests that the overall frequency of errors is variable and may be higher than that found in central laboratory testing. Furthermore the types of error differ: in POCT these may centre around the analytical phase [in contrast to central laboratory testing, where the majority of errors occur in the pre-analytical phase]. The fact that many such errors are due to failure of the clinical operator to follow standard procedures, highlights the importance of training and robust governance structures in the management of POCT. Improved instrument and process engineering e.g. automated internal quality control, may help reduce certain types of error.

Clinical management is complex and POCT forms only one element of this. The introduction of POCT may require the modification of patient care pathways if the full clinical benefit is to be attained. An increasingly important quality perspective will be to demonstrate the impact of POCT on patient outcomes.

Change Management and Point-of-Care Testing

Marion Fokkert, Isala Clinics, Zwolle, the Netherlands

Point-Of-Care (POCT) management of diabetes status has become more important with the sharp increase of the number of glucose measurements in hospitals. In order to fulfill the turn-around-time needed for appropriate glucose management lab measurements are no longer sufficient. This is because of the complexity of the lab-organisation and the glucose requests which are often unpredictable in time. Currently, many new POC-assays enter our market. All assays have their own challenges regarding accurate measurement or interpretation of results.

In the past, the general idea was the POC instruments were easy to handle and for that reason didn't need much effort in order to introduce in the hospital and to maintain their performance. Firms just sold their instruments. Nowadays it is appreciated that a successful implementation of POC testing depends on several factors besides the devices and technical installation themselves.

The POC coordinator plays an important role in this process. He or she is the spider in the web of the POC system. Change Management is a structured approach to get the nurses (instructions and motivation) and management POC-oriented and to keep their focus on non-treatment items. For example pre-analytical factors but also the awareness of POC investments which should be outcome measured.

This lecture will address the following items: the experiences over 10 years in the Isala Clinics, the skills needed to effectively implement change management in your organisation and challenges from daily POC-business.

Meeting Point-of-Care Expectations of the Clinician

Sverre Sandberg, Laboratory of Clinical Biochemistry, Haukeland University Hospital, Bergen and NOKLUS, University of Bergen. Sverre.sandberg@isf.uib.no

What expectations do clinicians have to point of care instruments? It is probably very simple. In the public sector it is about timeliness. In the private sector it is about timeliness and money. In both situations, the clinicians definitely will expect the laboratory result to be “true” – what they read in the display, they trust.

The result must be present in the right time so that actions regarding the patient can be implemented as soon as possible. In a hospital this means that the result e.g. must be present during a surgical intervention e.g. PTH measurements. It is only rational to implement a POCT after timeliness, quality and costs compared to centralised laboratory testing has been evaluated. With few exceptions, analysing constituents with a POC instruments in itself will be more costly compared to centralised laboratory analysing. Taking into account patient outcome and length of stay in the hospital, this may change. In general, whether or not a POC instrument should be used should be the responsibility of the Laboratory after consultations and discussions with the clinicians. What constituents that should be analysed with POC instruments will vary from hospital to hospital depending on the local environment. In the office laboratory, the expectations from the physicians are that the result should, in general, be available during consultation. If it not, clinicians can usually wait 1-2 days for the result from the central laboratory. Reimbursement is a powerful tool to decide which analytes should be analysed by POC instruments. The laboratory profession should therefore be active when it comes to negotiations about which tests to reimburse.

Clinicians will usually not understand theoretical questions about “what analytical quality is necessary”. To get information about what quality they expect from the POC instrument, the questions therefore have to be phrased in a different way. For example, in a monitoring situation, questions about what changes in the concentration of a constituents (critical difference – CD) they will react on, will indirectly give information about the analytical quality that is expected. The CD can theoretically be calculated from the formula below where bias represent the systematic difference in the measurement procedure between the two measurements, z represent the probability that the clinicians’ need before taking action. The CV_{ws} is the within-subject biological variation and CV_a is the analytical imprecision. When the CD is given by the clinicians), the CV_a can be calculated by rearranging the formula.

$$CD = bias + z \times \sqrt{2} \times \sqrt{CV_{ws}^2 + CV_a^2}$$

Results from questionnaires dealing with CD circulated to between 4 000 – 10 000 clinicians in different European and non-European countries will be presented. The case histories mimicked common clinical scenarios in general practice and investigated the interpretation of HbA1c, Hb, INR and urinary albumin (micro-albuminuria).

References

1. Skeie S et al. Postanalytical external quality assessment of blood glucose and hemoglobin A1c: an international survey. *Clin Chem.* 2005;51:1145-1153.
2. Aakre KM et al. Postanalytical External Quality Assessment of Urine Albumin in Primary Health Care: An International Survey. *Clin Chem.* 2008;54:1630
3. Kristoffersen AH et al. Interpretation and management of INR results: A case history based survey in 13 countries. *Thromb Res.* 2012, in press

Biological Variation and Point-of-Care Testing

Rob Jansen and Robbert Slingerland

Point-of-care glucose meters are used increasingly in semi- and non-professional context. The quality of glucose measurements depends on the quality of the equipment, the quality of use, and the pre-analytical conditions.

Physicians and other health care providers are used to the quality of glucose measurements of central laboratories. Results from these laboratories comply with requirements based on the biological variation concept. Actions like insulin dosage are performed based on the intrinsic assumption of such quality. Therefore measurements performed on POCT meters and glucose meters for home use should comply with the minimal requirements of this concept.

A good measurement starts with a good measuring system. The Dutch national external quality assessment scheme organization (SKML) issues the SKML Quality Mark for POCT and self-tests. In The Netherlands the national society for Clinical Chemistry and Laboratory Medicine (NVKC) issued a Guideline on the use of glucose POCT meters and meters for home-use. The guideline focusses on three aspects:

- SKML quality marked meters
- Education of users of the meters under direct or indirect (train the trainer) supervision of an accredited laboratory
- Control of meters in use by (POCT) or under supervision (home use meters) of an accredited laboratory

The system defined in the guideline is presently introduced. It guarantees the embedding of glucose measuring outside of the hospital laboratory within the quality systems of these and according to ISO 15189 and ISO 22870.

The SKML Quality Mark comprises the following criteria for blood glucose equipment: 1) Fulfillment of compliance with ISO 15197 and/or TNO guideline criterion; 2) Fulfillment of the total allowable error (TEa) criterion; 3) Fulfillment of the total allowable interfering substances bias criterion; and 4) Fulfillment of the haematocrit criterion. The SKML-Quality Mark system was tested on 14 meters. The TEa criterion was violated by two meters. The main reason for the violation was bias. With respect to interfering substances, bias of the same magnitude and sign as the bias without additive was seen for all meters for acetaminophen, indicating no additional interference. For ascorbic acid, an additional bias was seen for several meters. However, significant bias was demonstrated for two meters.

A national education program will be developed by a multidisciplinary commission that should be used by specialists in laboratory medicine in the regions for education of POCT and home meter users. In addition e-learning modules will be developed for continuing education.

POCT meters are tested according to the guideline by accredited laboratories in a traceability chain. The laboratory calibrates its comparison method using a SKML Glucose Trueness Verificator and assesses the performance of the POCT meters. Home use meters mostly are checked in decentralized situations against calibrated POCT meters.

Causes and Frequencies of Failed Electronic Transmission of Point-of-Care Test Results

Linda Sandhaus MD, Lois Schultz MT(ASCP), Karen Meyerson MT(ASCP), Ruth Natali MT(ASCP), Christine Schmotzer MD

Documentation of patient laboratory test results, including point-of-care test (POCT) results in the electronic medical record (EMR) is a high priority for health care organizations. At University Hospitals Case Medical Center, Telcor middleware is used to connect moderate-complexity POCT analyzers to SoftLab, the laboratory information system (LIS), which is interfaced to Eclipsys, the electronic medical record (EMR). These devices include ITC Signature Elites (22 in 7 locations), Radiometer ABL80 blood gas analyzers (5 in 2 locations), IL GEM4000 blood gas analyzers (11 in 6 locations), and Siemens Stratus (2 in one location). Test results that do not transmit to the LIS are displayed in a Telcor “exception” file. POCT coordinators monitor the Telcor exceptions daily and attempt to resolve them to enable transmission of the results. Resolution often involves contacting the device operator to provide correct patient information. The number of unresolved Telcor exceptions is a quality indicator in our POCT quality assurance plan. Data spanning an 18 month time period are tabulated below.

Month	Total Tests	Total Exceptions (%)	Unresolved Exceptions (%)
August 2010	3704	199 (5.4)	100 (2.7)
September 2010	3340	183 (5.5)	64 (1.9)
October 2010	3887	422 (10.8)	280 (7.2)
February 2011	4056	216 (5.3)	203 (5.0)
May 2011	3168	91 (2.9)	81 (2.6)
July 2011	3548	129 (3.6)	107 (3.0)
November 2011	2885	59 (2.0)	43 (1.5)
January 2012	3646	204 (5.6)	186 (5.1)
Mean	3529	188 (5.1)	133 (3.6)

Telcor exceptions are classified as system errors or operator errors. System errors are errors that are outside of the operator’s control, such as LIS down-time or incomplete patient data in the admission/discharge/transfer system. Examples of operator errors include entering an incorrect medical record number or failure to download the device within the 3 day time window. A detailed analysis of 60 consecutive days indicated 39% system errors and 61% operator errors. The most frequent error was

operator failure to download the Signature Elites. There were two spikes in system errors that were caused by an interruption in wireless connectivity and an LIS down-time.

In our experience, about 5% of POCT results do not initially transmit to the EMR; about 30% of these “exceptions” can be resolved. Electronic transmission of POCT results to an EMR has many points of vulnerability due to the numbers of people, device types, and interfaces that are involved.

Point of Care Testing in the Battlefield

Major Tracey Smith-Straney, University Hospital Aintree, Liverpool, UK

Operation Herrick is the codename under which all British operations in the war in Afghanistan have been conducted since 2002. It consists of the British contribution to the NATO-led International Security Assistance Force (ISAF) and support to the US led Operation Enduring Freedom (OEF). Since 2003, Herrick has increased in size and breadth to match ISAF's growing geographical intervention in Afghanistan. The 20th Armoured Brigade led the formation of British troops in Helmand Province for Operation HERRICK 15 from October 2011-March 2012.

Medical

The role of the Defense Medical Service (DMS) is to contribute to the conservation of fighting strength and morale of military personnel. The DMS is responsible for advising commanders on the maintenance of health and prevention of disease in peace and in addition, the collection, medical classification, evacuation and treatment of the sick and wounded in war. The Field Hospital is located as a forward based facility in Camp Bastion in Helmand Territory Southern Afghanistan; it has been hard standing since 2008. During this time units posted there have included regular army field hospitals and Territorial Army (TA) or reservist field hospitals (UK) as well as large elements of the American and Danish medical services. This field hospital has cared for and continues to care for sick and wounded of tri service personal, members of the Afghan National army and police force, International troops and injured civilians who may have sustained injuries as a result of Taliban suicide bombings or military air strikes.

This presentation gives an overview of my role as an army reservist posted for a 2nd tour of Afghanistan during Herrick 15a, working in the newly commissioned Pathology Laboratory. Over this period we saw well over 1000 casualties, from minor injuries to massive trauma. My directive was to ensure that all UK practiced laboratory standards were maintained as far as practical, establish and take part in the relevant hospital committees to make informed decisions on the needs of the hospital with regard to all aspects of the pathology service. The presentation will emphasize how crucial the use of point of care testing devices aide the massive transfusion protocol of the busiest trauma hospital in the world.

Home-monitoring of renal function in renal transplant patients using the Statsensor POC device

P.J.M. van der Boog¹, C.L. van Lint¹, S. van Dijk¹, A.J.M. Rövekamp³, C.M. Cobbaert², F. Romijn², A.J. Rabelink¹

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The number of people with chronic conditions continues to rise, while the number of healthcare professionals caring for those patients is expected to decrease. Self-management offers a way to control volume and costs of chronic care. Involving patients into the management of their disease results in better clinical control and greater autonomy of the patient. It improves adherence with medical standards and reduces healthcare utilization.

There is currently no validated Disease Management Systems (DMS) aimed at self-management. A DMS that offers all options necessary for self-management should fulfil a lot of requirements concerning content, technique, organization and finance. In addition, implementation of self management places demands at patients and care providers. Their attitudes, behaviours and skills are crucial for the results of self-management. The changes from a directing role to a more supporting role for the healthcare professional may create fear of losing control over therapy and uncertainty about job boundaries. Willingness to adopt this new role is absolutely necessary. Incorporation of new medical devices is necessary to enlarge the possibilities of self management. This is a complex process which has to be performed with great carefulness.

In the current care process, renal transplant patients usually visit the out-patient clinic about 20 times during the first year after their transplantation. During this period the serum creatinine concentration is an important parameter to assess the presence of rejection. “The Nova StatSensor™ Creatinine Point-of-Care Monitoring System” gives the opportunity to monitor renal transplant patients at home and allocate a part of the control to patients themselves.

To determine its applicability in the home care setting the POC-system was first tested for its analytical performance, followed by performance testing in an outpatient clinic setting.

Reference Change Values (RCV) are advocated as an appropriate tool for monitoring changes. For the used POC-system, there was a 2.5 increase in RCV as compared to the central laboratory method. Therefore, for clinical use it is not acceptable to replace the central laboratory method by the POC-system. However, home monitoring of renal function after renal transplantation concerns a specific setting: First, for detection of rejection especially serial intra-individual changes are important (and less absolute values). Second, enhancement of the number of measurements enhances the reliability. Therefore, in the feasibility study we asked patients to measure their creatinine level more frequently compared to the standard care (once a day compared to once a week).

Patients entered their measurements into the web-based DMS. A virtual coach generated feedback on these measurements to the patient. The healthcare professional was able to see patients' measurements entered into their Personal Health Record.

Patients highly valued the self-monitoring and the automatic feedback. The execution of the measurements was simple and it gave them insight in the current renal function. An increase and

decrease of renal function could be detected. However, for both patients and healthcare professionals, the deviation of the absolute value and the higher analytical variation of the self measurement values compared to the central lab values, caused some doubt regarding the interpretation of the measurements. This illustrates the need for meter improvement and a quality mark.

Expecting desirable analytical performance of the POC- meter in the future, we believe we can reduce the number of outpatient clinic visits in renal transplant patients in a safe way by implementing this system for monitoring their creatinine concentration at home. In a current study this will be analyzed.

Point-of-care athlete testing, a new approach of sport performance evaluation

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National Institute of Sports Medicine, Bucharest, Romania Point-of-care testing is defined as testing performance at or near the sites of training or competitions, in the precise conditions likely to be really experienced. In sport science, usually such tests are not as reliable as laboratory tests, but often have greater validity because of their greater specificity. This is invariably difficult to achieve as there are numerous factors experienced in competition which are near to impossible to replicate in training or testing environment. A combination of regular field based testing (because of the practical, easy and immediate nature of the testing) together with occasional laboratory testing (because of accuracy, reliability and quality) is a good option for most sports.

From many parameters used to monitor trainings we chose acid-base status, for the relevance in reflecting in or post-exercise homeostatic changes. In sport performance, excessive efforts to maintain internal homeostasis in normal limits may have limiting even negative effects on performance capacities. It is possible to appreciate sport energetic requirements (energetic pathways contribution and efficiency in sustaining exercise), functional status in basal / rest conditions and exercise, exercise metabolic costs, post-exercise recovery evolution, using calculated functional indexes. Using an ABL microlab (Radiometer, Copenhagen) the following acid-base status parameters are determined: hemoglobin (Hb), acidity / basicity (pH), partial pressure of carbon dioxide in blood (pCO₂), partial pressure of oxygen in blood (pO₂), oxygen saturation (sO₂), bicarbonate (HCO₃), actual base excess (ABE), standard base excess (SBE), standard bicarbonate (SBC), alveolar-arterial oxygen tension difference (AaDpO₂). Blood lactate values are also determined. Based on specific acid-base disturbances, we can appreciate performance capacity, reveal the metabolic costs, and also recovery drive.

The possibility (or ability) of point-of-care testing to be done in various conditions has demonstrated a significant potential to change the way of monitoring training and recovery. However, the lab cannot exactly reproduce the external environmental factors: run and bike – road conditions, weather, hills, wind resistance; rowing, canoeing –water conditions, current, weather, wind, boat friction / water resistance, that athletes experience in training and playing or training locations (even altitude campus). Based on these results, valuable coaching decisions could be taken. It is essential that the coach identifies a reliable, experienced support team of professionals that can manage the details of competition based testing leaving the coach free to coach. In trainings, competition or during rest periods, point-of-care testing can provide the coach and athlete information about areas of weakness or limitation, about developing and improving performance. These kinds of tests respect sport specificity and environmental factors, experience and training status, age and sex. Based on the testing results, it is possible to create the athlete's profile, for training to performance.

Towards Sustainable Point-of-Care Testing in Remote Australia

Authors: Brooke Spaeth, Mark Shephard, Beryl Mazzachi, John Loudon, Janet Rigby, Vinod Daniel, Malcolm Auld, Steven Schatz and Amanda Lingwood

Introduction

The Northern Territory (NT) in Australia is one of the most remote regions in one of the most geographically isolated countries of the world, with many of its communities being located hundreds or even thousands of kilometres from the nearest central laboratory service. Pathology samples may take from several days to several weeks to reach laboratories, with similar times reported for results to be returned to health services. There are also many significant health issues which affect the Territory's large Indigenous population in particular, including very high rates of chronic and acute diseases and the high incidence of preventable hospitalisations.

For the past 5 years, the Northern Territory Department of Health has partnered with the Community Point-of-Care Services unit at Flinders University to deliver quality-assured point-of-care testing (POCT) on the i-STAT device (Abbott Point of Care, Australia) for the provision of selected pathology services in 31 remote health centres in the Territory. The i-STAT provides a practical option for the provision of pathology services in remote NT communities, as tests are conducted on-site on a small blood sample, results for tests such as electrolytes, urea, creatinine, troponin I, blood gases and lactate, INR and haemoglobin are available in 10 minutes or less, and clinical management can be initiated 'on the spot'.

Materials and Methods

Remote area nurses and Aboriginal Health Workers were trained and received competency certification as qualified POCT operators through a program of primary workshops, mobile on-site training and access to on-line training resources and videos. A quality management program was implemented to routinely monitor the analytical quality of the i-STAT in field use, while telephone and newsletter support services as well as feedback reports for health centre managers were established. A research plan analysed the operational effectiveness, analytical quality, clinical effectiveness and satisfaction levels with the POCT service.

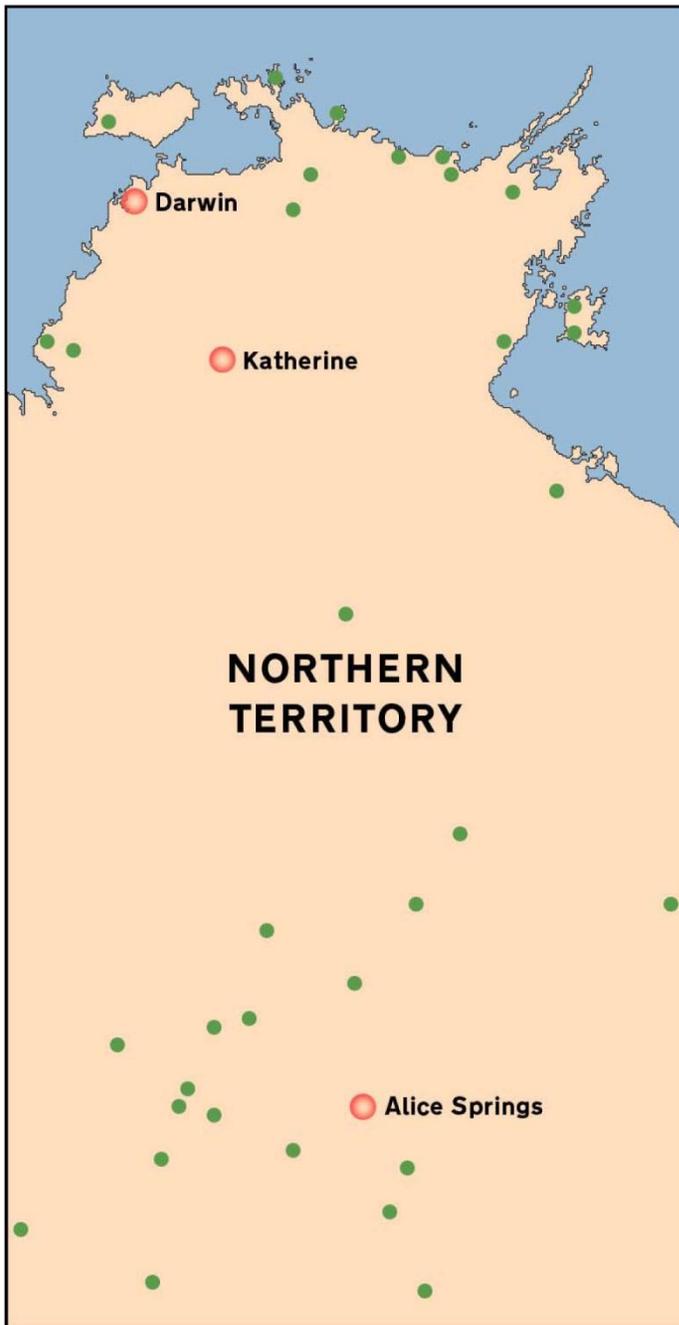
Results

Over 350 health professional staff have been trained as qualified POCT operators. More than 6200 i-STAT tests have been performed across the first three years of program operation. Patient testing on the i-STAT was highest for the INR (representing just over 40% of total testing). Analytical quality for POCT consistently met profession based analytical goals and/or state of the art laboratory performance for most tests, with the percentage of acceptable quality control results for all tests on the i-STAT averaging over 95%. Clinical case studies sourced from the i-STAT central data station (which electronically captured de-identified patient and quality data from all remote services) confirmed the clinical effectiveness of POCT for acute and chronic conditions. Community satisfaction with POCT was validated using qualitative surveys of device operators. Greater than 80% of respondents believed POCT was more convenient than the laboratory and assisted in the stabilisation of acutely ill patients.

Discussion

The Northern Territory POCT Program has proven operationally effective, analytically sound, clinically and culturally effective, and well-received by health professional staff. The main challenges for the program's sustainability continue to be maintaining standards of training and analytical quality in the face of high staff turnover.

Figure 1. General location of remote health centres participating in the NT POCT Program.



Errors in POCT: When Improbable Situations Become Possible

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Point-of-care testing (POCT) is laboratory testing conducted close to the site of patient care. In a core laboratory, the majority of samples are analyzed in one location, on a few, high-volume workstations, by highly-skilled and experienced technologists. POCT, on-the-other hand, involves dozens of sites, with hundreds of devices, and thousands of clinically-focused operators. The number of people, devices and amount of testing involved in the process is a setup for error. This presentation will focus on common and uncommon sources of POCT error and ways that manufacturers and consumers can work together to better detect and prevent errors that could lead to incorrect test results. The CLSI EP23-A guideline, Laboratory Quality Control Plans Based on Risk Management will be presented as a framework for understanding risk with POCT devices and how we can better control risk in our POCT programs.

Effective Implementation of a Quality Focused POC Testing Program Improves Critical Care/Patient Care Outcomes at the Oklahoma University Medical Center

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Professor

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The development of a high quality Point-of-Care and Core Laboratory testing program for a large medical center requires 1) a focus on the quality control program and goals of a real-time laboratory service for critical care/emergency care patients and 2) the shared commitment of administration, laboratory professionals, physicians, nurses, respiratory therapists, information technology/system experts, and vendor partners. Point-of-Care testing is clearly an essential aspect of any real-time testing program because frequently traditional core laboratory testing cannot meet the required clinical turnaround time (TAT) and/or specimen requirements. Indeed, in our Neonatal Intensive Care Unit (NICU) for example, over 30 percent of our newborns weigh less than 1.3 kg, with 10 percent in the micropremie category weighing less than 1.0 kg. Since these infants require frequent monitoring of critical care analytes, we utilize 1) POC testing using less than 100 ul of whole blood with critical care test result TAT in approximately 2.5 minutes, 2) a one step lean testing protocol involving the newborn's primary nurse care provider, 3) electronic physician test orders with electronic transmission of results to critical care physicians reviewing data on mobile cell phones and tablets, 4) bar code scanning of patients' ID bracelets and nurse super users badges, and 5) close coordination of testing with laboratory POC Testing Coordinators and the Laboratory Director. Actual TAT studies revealed a mean TAT of 2.65 minutes with a standard deviation of +/- 0.16 minutes; the observed TAT CV% was 5.85. A recent peer review of our overall POC testing program and patient care outcomes revealed a high level of support from Nurse Super Users and physicians in the NICU and other POC test areas throughout the OUMC hospitals and clinics. Our central Core Laboratory oversight of quality standards provides support of 1) the overall POC testing program, 2) testing devices and all reagents including liquid quality control material, 3) coordination with POC testing vendor partners, 4) training and recertification of nurses, RT, and laboratory testing personnel, 5) regulatory requirements including coordination of proficiency testing, 6) monitoring of quality control data, 7) information technology requirements and electronic interfaces, 8) troubleshooting and support of program, and 9) planning and coordination of new systems and applications for POC testing. While many projects are underway, the POC testing program at OUMC has been a major success in terms of critical care/patient care effectiveness since the early beginnings in 1985 when the first POC testing device was deployed by the central laboratory.

Implementing a region program for POCT service to emergency departments

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In a regional top-management decision, our laboratory was given the mission to control and quality assure all POCT activities in a region with 1.1 million inhabitants and 10 hospitals. I will present the results of the project to optimise, coordinate, manage and quality assure the POCT services to ten hospitals with different clinical demands related to workloads and medical complexity.

Based on previous work, new region-wide recommendations, procurements, IT-connectivity, services, training, accreditation (ISO 15189) and QA are been implemented at the emergency departments of the ten hospitals with different missions, services and opening hours. Agreements defining collaboration, services, instruments, IT and the fees for the POCT service have been signed.

Analysing venous samples on blood gas analysers has been introduced at the major emergency departments and this routine makes it possible to obtain basic metabolic parameters (NA, K, Ca, Cl, Glucose, Lactate, Creatinine) within a few minutes. The use of this expanded panel of tests is appreciated by the staff and has dramatically increased the total number of tests performed on POCT blood gas analysers. Venous blood analyses has reduced turn-around times and the costs for routine clinical chemistry parameters, and as a consequence reduced reimbursement to the laboratories. Transferability of test results thus becomes an issue to address. Bias between whole blood POCT and plasma central lab results must be followed and minimised. By split sample methods we have shown clinically acceptable transferability between results obtained in our labs and on POCT instrument at emergency departments.

A number of quality issues still have to be solved. One problem is POCT instruments lack a method to detect haemolysis, which is a major problem in particular at emergency units. A clinical awareness is important so that erroneous results may be correctly interpreted.

IT-systems have to be improved as present QA systems are developed with the needs of a single hospital in focus. A QA system capable of supervising a regional system spanning ten hospitals is essential for efficient quality management.

Take-home-message: A coordinated region POCT system for emergency care departments needs a regulated, multi-level relationship between the POCT coordinator, core labs, clinical departments, IT providers and industry.

Rapid test Quantum Blue[®] faecal calprotectin as predictor of relapse in patients under maintenance treatment with Infliximab[®]

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Background: In inflammatory bowel disease (IBD), predicting relapse by measuring non-invasive biomarkers could allow early treatment adaptation. Few data exists about the usefulness of close monitoring of calprotectin to predict relapse. The aim of the study was to evaluate the predictive value of rapid test for faecal calprotectin levels for flares in patients with IBD under maintenance treatment with Infliximab[®].

Methods: A prospective study was designed. Inclusion criteria were IBD patients (Crohn's disease (CD) and ulcerative colitis (UC)) in clinical remission under a stable 5mg/kg Infliximab[®] therapy. Rapid test for fresh faecal calprotectin in a lateral flow immunoassay was measured the day of the infusion, received in gastroenterology office. Clinical examination was performed two months later infusion. Relapse was defined as a as a Harvey-Bradshaw score >4 in CD patients and as a Mayo score >2 in UC patients. U-Mann Whitney test, Chi square test, Odds Ratio, ROC analysis and Logistic regression were performed in IBM[®] SPSS 20.

Results: 43 patients were recruited (mean age 46 years \pm 11.9), 23 (53.5%) were female, 62.8% had CD and 37.2% UC. After two months, 35 (81.4%) patients remained in clinical remission and 8 presented a relapse.

In patients in remission median calprotectin levels were 115.6 mg/kg of faeces. Patients who flared had significantly higher calprotectin levels at the moment of flare (median calprotectin levels of 278.9 mg/kg). (U-MW p<0.001)

Further ROC analysis (flare vs remission) suggested that a calprotectin level of 110.5 mg/kg indicated as the best cut-off point showed high sensitivity (100%) and high specificity (74.3%) to model flare. Area under the curve was 0.875 with good accuracy (p=0.001 SE: 0.053 CI 95%: 0.772-0.978). For a value of calprotectin over 110.5 mg/Kg an OR= 1.889 (p<0.001; CI 95%:1.207-2.957) was obtained. Logistic regression analysis showed a 0.6% increase risk per unit of calprotectin (p=0.047) in a model adjusted for age and sex.

Conclusions: In IBD patients under infliximab maintenance therapy calprotectin levels highly correlate with prediction of a relapse. Remission is associated with low levels. More studies and an increased number of patients should confirm the utility or usefulness of calprotectin rapid test to modulate therapy in consultant office.

Bacterial contamination of glucose test strips: does the packaging matter?

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Introduction:

The role of fomites in bacterial transmission is still debated and need further investigations. We previously reported the putative role of the glucose test strips (GTS) as a reservoir for bacteria and a way to cross contamination between patients if the recipient was shared (Vanhaeren *et al.*, Am J Infect Control 2011). Nevertheless this study concerned only one type of packaging and its role was not evaluated.

Purpose of the study:

We aim to explore the bacterial contamination of GTS available in three different packaging, i.e., two multi-uses vials (A and B) and one unitarian packaging (C).

Material and Methods:

GTS from three different brand names were collected from three different teaching hospitals from the Assistance Publique – Hôpitaux de Paris (AP-HP) network.

In different wards, opened vials or boxes of GTS containing less than a half of the initial number of strips were collected and centralized in the same laboratory (Department of Bacteriology and Infection Control, CHU Antoine Béclère, Clamart, FRANCE). Each strip was placing in 1 ml of 0.9% NaCl and vortexed during 30s. One hundred microliters of the suspension was cultured on Colombia colistin nalidixic acid and Drigaski. Viable bacteria were counted after 24 h and 48 h of culture at 37°C. Bacterial contamination was reported as a number of bacteria per strip. The inside of the box containing unitarian strips (C) was swabbed, the swab released in 1 ml of 0.9% NaCl and 100 µl inoculated as previously reported. Once empty, 1ml of 0.9% NaCl was added to the inside of vials of the multi-uses packaging (A, B); cultures were performed as previously reported.

Results: The percentage of strips yielded a positive bacterial culture were 2.5% (C, 5/196) for the unitarian packaging, 5.2% for the first multi-uses vial (A, 5/97) and 11.6% for the second multi-uses vial (B 17/146). No bacteria was isolated from the packaging of the unitarian strips (0/2) but viable bacteria were obtained from the vial of the two multi-uses packaging (2/8 and 3/9 positive vials, respectively).

The median number and ranges of bacterial counts for positive GTS were 10 per positive strip / [0-10] for the unitarian packaging (C), 56 per positive strip / [10-230] for the first multi-uses vial (A) and 135 per positive strip [10 - 900] for the second multi-uses vial (B).

Discussion / Conclusion

Indeed packaging of GTS matters in their bacterial contamination during use. Hidden sources of bacteria could lead to cross contamination between patients if the GTS recipient was shared. Strict hand hygiene and/or unitarian packaging constitute simple measures to control GTS bacterial contamination.

New iPhone and iPad Acid-base Data Interpretation Apps in Clinical Assessment of Critically Ill Patients: Is that a Problem or a Step into the Future?

Jesper H Wandrup, Dr med, Cand Scient, MD Specialist of Chemical Pathology, Radiometer Medical Aps

Wireless mobile technologies smartphones and other mobile communications devices have been proclaimed great promises for new ways of managing diseases and lowering health care costs. One third of physicians surveyed by PriceWaterHouse Coopers' HRI (Health Research Institute, UK (1)) said they make decisions based on incomplete information. They believe the greatest benefit of mobile devices will be to help them make decisions faster as they access more accurate data and support in real-time.

In the past one study of 34 physicians (including residents and staff physicians) found that accuracy rates for unaided ABG (Arterial Blood Gases) data interpretation given traditional laboratory data in numerical format were, on average, 39%, with a range of 0% to 80% (2). Vergara (3) found that ABG data interpretation was more accurate when physicians used an algorithm-based software application, compared with using a paper-based algorithm tool or subjectively interpreting data without decision support (88% vs. 64% vs. 43%, $P<0001$). Since those original publications recent reports (4,5) seem to indicate that doctors and nurses in intensive care still are struggling with interpreting the blood gas analysis accurately.

Evidence is building that tablets (iPads) are a hit with some intensive care physicians and nurses. However, healthcare IT leaders are expressing concerns about governance, risk and security. That means every clinical laboratory and anatomic pathology group in the United States will need a strategy on how to allow physicians and intensive care nurses to use their iPads to order medical laboratory tests and view and interpret results as soon as available Point of Care.

Through draft guidance release on July 21, 2011 the FDA (6) defined a small subset of mobile medical Apps ("Applications (computer programs)" that may impact on the performance or functionality of currently regulated medical devices and as such, will require FDA oversight.

In current presentation of this new POC mobile health care hype I will discuss possible benefits and possible regulatory constraints of some medical Apps available on the Apps-market intended to help intensive care doctors and nurses to interpret acid-base results in the critical care setting.

1. PriceWaterHouseCoopers. Health Research Institute. Healthcare unwired. New business models delivering care anywhere. September 2010.
2. Hingston DM, et al. A computerized Interpretation of arterial pH and blood gas data: Do physicians need it? *Respir Care* 1982;27:809-15
3. Vergara F. Evaluating the accuracy of an time spent in analysis of acid-base reports by three methods: Is a computer-aided method best? *Proc AMIA Symp.* 1998:1092
4. Austin K et al. Accuracy of interpretation of arterial blood gases by emergency doctors. *Emergency Medicine Australasia* 2010;22:159-165
5. Doig AK et al. Graphical Arterial Blood Gas Visualization Tool Supports Rapid and Accurate Data Interpretation. *Comput Inform Nurs.* 2011;29:204-11
6. Draft Guidance for Industry and Food and Drug Administration Staff. Mobile Medical Applications. Document issued on: July 21, 2011

Utilizing IR detection technologies in POC devices

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The use of IR sensors and indicators has entered the POC arena. For example, urinalysis strips now use IR dyes to improve performance by indicating product storage. This technology domain holds great future promise to enable clinicians and manufacturers to encode information into a reagent disposable. A survey of advances in 2D bar coding and read write technology will demonstrate a range of potential future advances in quality control and product safety. Additionally the use of IR signals and sensors to enable detection of markers directly will be reviewed.

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Molecular testing at the point of care

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The use of molecular diagnostics will start to decentralize away from the central reference laboratory as a new generation of sample to result systems reach the market. These simple-to-use systems will be capable of processing a range of clinical samples and support a growing menu multiplexed infectious disease and personalized medicine assays. The delivery of timely and cost effective molecular diagnostic information by these systems will help to support clinical decisions and therapy choice.

IMPROVING CLINICAL OUTCOMES BY SPLIT CENTRAL VENOUS SAMPLING OF PARATHYROID HORMONE

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Keck Medical Center of University of Southern California is a private, non-profit, 400-bed research and teaching facility located in Los Angeles and staffed by the faculty of USC's Keck School of Medicine. In recent years, many of our endocrine surgeons have requested the rapid intra-operative parathyroid testing as a necessary adjunct to the gold standard of four-gland exploration as a way to exclude multi-glandular disease. The parathyroidectomies performed at our hospitals are assisted and monitored by Intra-Operative Intact Parathyroid Hormone (IO I-PTH) testing. The current IO I-PTH methodology is an immunochemiluminescence assay (ICMA) manufactured by Future Diagnostics that uses a two-antibody sandwich technique for measuring the intact chain (1-84 amino acid) parathyroid hormone molecule. For the past eight years, we have averaged about forty to forty-five parathyroidectomies per year. We have noticed a remarkable decrease in cases of unexplained persistent hypercalcemia after parathyroidectomies.

The availability of the IO I-PTH has been especially crucial with cases of unrecognized ectopic or multiple adenomas, unrecognized supernumerary glands, insufficient excision of hyperplastic tissue, and occasional difficulty encountered in histological differentiation between hyperplastic and adenomatous glands. Yves Chapis in France (1990) and George Irvin in Miami, Florida (1991) independently reported the use of IO I-PTH monitoring as an adjunct to parathyroidectomy in patients that had positive pre-operative localization with Technetium-99m-Sestamibi scintigraphy or high resolution ultra-sonography. The surgical technique requires a pre-incision peripheral IO I-PTH level followed by a post-gland removal level obtained ten minutes after the pathologic parathyroid tissue has been removed. The criteria used to predict post-operative normocalcemia in single gland disease is a drop of fifty percent in the pre-incision hormone level at five or ten minutes after gland excision. These criteria are predictive of a cure in 95% of patients. Weber et al have shown that in patients with four gland hyper-plasia, a 90% drop in IO I-PTH from baseline may be required to confirm excision of Hyper-functioning Parathyroid tissue.

With the advent of the Internet, many patients are doing their research prior to their initial specialist visit. Patients are increasingly requesting minimally invasive surgeries (MIS), limiting the popularity of the four-gland exploration. Using the MIS technique, the patient heals faster and the majority of surgeries are performed as outpatient, saving resources for the hospital. For performance of MIS parathyroid surgery, it is essential that the patient have pre-operative localization of the abnormal parathyroid tissue (solitary adenoma) which then directs a targeted operative approach leaving normal parathyroid tissue undisturbed. Our present study describes the technique of using split venous IO I-PTH samples obtained from the right and left internal jugular veins in patients undergoing parathyroidectomy that have failed to localize an abnormal gland pre-operatively with a Sestamibi scan or high definition ultrasonography. One hundred sixty-six patients underwent neck exploration for hyperparathyroidism at the Keck Hospital of USC between July 2005 and December 2009. Of these patients, a cohort of 66 individuals had IO I-PTH levels drawn from the right and left jugular veins. These 66 consecutive patients represented a change in protocol designed to minimize the extent of surgery and to determine the value of the split central venous PTH levels in verifying the side of the adenoma. Ten of the 66 patients had secondary hyperparathyroidism and were excluded from the study. The peripheral vein sample obtained after induction of general anesthesia served as the baseline pre-operative PTH level. The two internal jugular vein samples were compared looking for a gradient between the right and left sides. Thirty-three patients had positive pre-operative localization of the abnormal parathyroid tissue by Technetium-99m-Sestamibi scintigraphy and confirming high resolution neck ultrasonography. The split sample IO I-PTH gradient was used to confirm the side indicated by pre-operative localization studies. Twenty-three patients failed to localize abnormal parathyroid tissue pre-operatively by conventional imaging. In this latter group, the split internal jugular vein samples were compared looking for a gradient in the absolute PTH value which then directed the initial side of surgical exploration. If an abnormal gland was identified, it was removed and the IO I-PTH was determined ten minutes later from a peripheral vein. Failure of the IO I-PTH to drop greater than 50% from the baseline value resulted in a bilateral four gland exploration. Our studies show that the greater the absolute value of the gradient between the left and right IJ samples, the more likely the gradient was to predict the side of the tumor. Furthermore, it is evident that a gradient greater than 200 correctly predicted tumor side with 100% accuracy. For values between 20 and 200, the gradient correctly predicted tumor side in 15 of 17 (88%) patients. In summary, identifying the correct side of

parathyroid gland pathology allows the surgeon to perform a more focused and less invasive operation without compromising results and minimizing the morbidity of bilateral surgery.

A Novel Technology for 5-Part Differentiation of Leukocytes Point-of-Care

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Introduction and technology: A new hematology system has recently been introduced by HemoCue®. The novel system uses state-of-the-art image analysis techniques to count the white blood cells and perform a 5-part differentiation. A microcuvette serves as a pipette, sample container and reaction chamber. A blood sample of approximately 10 µL is drawn into a cavity by capillary action. The blood dissolves the dry chemistry in the microcuvette, the red cells (erythrocytes) are hemolyzed and the nuclei of the white blood cells are stained. No dilution is required. When the microcuvette is inserted into the analyzer the measurement starts automatically. A fix volume used in the test is defined by the length of the cavity in the microcuvette and the size of the image (no. of pixels). A camera moved by a high precision motor to achieve an exact and repeatable movement is used to capture images of the stained white blood cells. As the camera moves throughout the cavity of the microcuvette, it takes more than 30 images of each cell. Image analysis technique is used to decide when a cell is in focus, and all focused cells are merged into one final image. By vision technology the cells are then classified into neutrophils, lymphocytes, monocytes, eosinophils, basophils, pathological white blood cells (blasts and immature granulocytes) and others.

The analyzer will flag all samples containing pathological white blood cells. An advanced inbuilt QC-system will check for correct filling of the microcuvette, dirt, improper light, unsharpness, reagent stability etc. The system is factory calibrated and needs no further calibration by the user.

HemoCue® has in the development of the algorithms used state-of-the-art vision technology. More than 30 different features (size, shape, texture, granules etc) have been identified for each cell type and translated into a mathematical algorithm that has been implemented in the analyzer.

Results: The HemoCue® WBC DIFF has shown to give reliable results comparable to laboratory cell counters. Performance including studies from two hospitals and three outdoors doctor's offices will be presented in the poster.

	ADVIA® 2120 (Växjö Central Hospital)	Beckman Coulter® LH750 (Malmö University Hospital)	Sysmex® XS-1000i (Three doctors offices)
Total leukocytes	$y = 0,93*x - 0,17$ $r = 0,993$ $n = 119$	$y = 0,98*x - 0,23$ $r = 0,996$ $n = 116$	$y = 0,97*x - 0,18$ $r = 0,997$ $n = 114$
Neutrophils	$y = 0,87*x + 0,02$ $r = 0,994$ $n = 101$	$y = 0,94*x + 0,02$ $r = 0,994$ $n = 84$	$y = 0,98*x + 0,05$ $r = 0,989$ $n = 92$
Lymphocytes	$y = 0,96*x + 0,18$ $r = 0,94$ $n = 101$	$y = 0,99*x + 0,10$ $r = 0,96$ $n = 84$	$y = 1,01*x - 0,01$ $r = 0,98$ $n = 92$
Monocytes	$y = 1,2*x - 0,16$ $r = 0,69$ $n = 101$	$y = 0,63*x + 0,01$ $r = 0,58$ $n = 84$	$y = 0,51*x + 0,01$ $r = 0,76$ $n = 92$
Eosinophils	$y = 0,92*x + 0,02$ $r = 0,76$ $n = 101$	$y = 1,13*x + 0,00$ $r = 0,86$ $n = 84$	$y = 1,11*x - 0,02$ $r = 0,91$ $n = 92$

Table 1. Data from comparison against three different cell counters

Conclusion: The novel POCT HemoCue® WBC DIFF technology is built on state-of-the-art vision technology. The results from the system are accurate and precise and correlate well to laboratory cell counters.

A white blood cell count including a 5-part diff at the point of care will increase the availability of already well established and frequently used lab parameters. Rapid and easy access will be a valuable tool for physicians in making direct and more well informed decisions in several clinical conditions.

POSTER ABSTRACTS

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Glucose meter performance criteria for moderate levels of glycemic control estimated by error simulation modeling

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Objective: We previously used two different error simulation models to estimate performance criteria necessary for safe and effective tight glycemic control, based on the observed distribution of glucose values from critically ill patients on a tight glycemic control protocol (glucose target 80-110 mg/dL) at one institution¹. In this study we use these same simulation models to investigate the impact of a more moderate glycemic target (110-150 mg/dL) on required glucose meter performance criteria.

Methods: In April 2010 the protocol used in the St. Marys Hospital (Rochester, MN) ICU was changed from a traditional tight glycemic control protocol to a more moderate glycemic target (110-150 mg/dL). To understand the impact of a more moderate glycemic target and protocol on required performance criteria for glucose meters; we retrospectively collected all point of care glucose measurements performed in three ICU areas (medical, cardiovascular surgery, vascular surgery) over a three month period (October-December 2010). We also determined the number and percentage of individual patients with one or more glucose values < 40 mg/dL (severe hypoglycemia) and 40-60 mg/dL (moderate hypoglycemia). Two error simulation models were used to assess the effects of glucose meter bias and imprecision on insulin dosing errors as defined in the moderate glycemic control protocol. One model varies bias and imprecision between $\pm 20\%$ and creates 20,000 simulated glucose values for selected original glucose values from the distribution of values in the ICU population. The other model assumes a Gaussian distribution of errors and creates 1000 simulated glucose values from each original glucose value; and can separately determine the rates of negative (too little insulin given) and positive (too much insulin given) dosing errors¹. Results are expressed as percent of insulin dosing decisions with one, ≥ 2 , or ≥ 3 category insulin dosing errors assuming that total allowable error (TEa = percent bias + 1.65 x imprecision in percent CV) is either 10%, 15% or 20%.

Results: Among 25,948 ICU glucose values, the median (interquartile range) glucose value was 134 (118-154) mg/dL. 4/1503 (0.26%) of patients experienced one or more episodes of severe hypoglycemia, while 33/1503 (2.2%) of patients had moderate hypoglycemia. Both models predict that one category insulin dosing errors occur frequently (30-90% of dosing decisions) at 10-20% TEa. Two category insulin dosing errors occur with only 0.2% of dosing decisions when 10% TEa is assumed, with 2-5% frequency when 15% TEa is modeled, and with 6-20% frequency when 20% TEa is allowed. Only the 20% TEa condition allows any frequency of three or more category insulin dosing errors. In contrast with simulation models for tight glycemic control¹, positive (too much insulin given) three category dosing errors are very infrequent (< 0.2%) at 10%, 15%, and 20% TEa.

Conclusions: Glucose meters that operate within a 15% total allowable error tolerance are unlikely to produce large (3 or more category) insulin dosing errors. Limiting glucose meter

TEa to 10% or 15% should also reduce the number of two category insulin dosing errors. Given the distribution of glucose values and insulin dosing categories in the moderate glycemic control protocol, no large (≥ 3 category) positive (too much insulin given) insulin dosing errors are predicted even at 20% TEa. This may in part explain the low incidence of severe and moderate hypoglycemia observed among ICU patients on the protocol.

References: 1. Karon BS, Boyd JC, Klee GG. Clin Chem 2010;56:1091-7.

The roll of glucose monitoring and regulation by POCT in hospitalized patients with diabetes mellitus: a pilot study

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Introduction

A major complication in patients with diabetes mellitus during clinical stay is acute disturbances in glucose concentration. Fast intervention is important to prevent further clinical complications. The aim of this study was to decrease the number of hypoglycemias (glucose <4 mmol/L) and hyperglycemias (glucose >15 mmol/L) during clinical stay.

Materials and methods:

During a seven months period, adult patients with diabetes mellitus type I or II staying on chirurgic department were included. Directly after admission to the hospital, monitoring and adjustment of glucose concentration of these patients on daily basis was arranged based on initial diabetic status according to the advise of internist in conjunction with diabetes nurse. Glucose was measured four times a day by HemoCue201DM glucose POCT device, which is a part of our POCT devices network of the hospital. The number of complications was compared before and after the introduction of this way of monitoring and correcting the glucose concentration instantly.

Results

In the period before this type of regulation of glucose concentration, 3310 glucose measurements were performed. 517(15.6%) complications were recorded, 44(1,3%) hypoglycemias and 473 (14.3%) hyperglycemias. After this procedure was introduced, 2087 glucose measurements were performed. Only 93(4,5%) complications were recorded, 31(1.4%) hypoglycemias and 62(3.3%) hyperglycemias. A significant decrease ($p < 0.001$) in hyperglycemias was observed.

Conclusion

Introduction of monitoring and instant correction of glucose concentration in hospitalized patients with diabetes contributed to a significant decrease in hyperglycemias whereas the number of hypoglycemias remained unchanged. The decentralised measurement of glucose contributes to a safer diabetic care for admitted patient.

Relationship of glucose concentration in capillary whole blood and venous plasma during 75gOGTT

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We studied the difference in glucose concentrations between fingertip(capillary)whole blood and venous plasma during 75g oral glucose tolerance test(75gOGTT) voluntary subjects.

POCT devices were used StatStrip(nova biomedical, MA, USA) and Glutest-mint(Sanwa Kagaku Kenkyusho, Nagoya , Japan). Hexokinase method(HK) was used Autosera S GLU(Sekisui Medical , Tokyo, Japan) and Hitachi P7700 Automatic Analyzer(Hitachi High-Technologies, Tokyo, Japan). IRI was measured by fluorescent enzyme immunoassay(FEIA) by AIA-200ST(Tosoh, Tokyo, Japan).

The results were shown in Table 1. The peak of post-loaded IRI levels in venous serum was 30 min. The difference of mean values between venous whole blood and venous plasma was 8.7-13.7 mg/dL for StatStrip and 0.1-6.5 mg/dL for Glutest-mint.

The peak of post-loaded glucose levels were 30-60 min for venous plasma, 30-60 min for fingertip whole blood in StatStrip, 30-90 min for fingerstrip in Glutest-mint, 30-60 min for venous whole blood in both StatStrip and Glutest-mint.

The post-loaded glucose levels in capillary whole blood were higher than those in venous plasma. And post-loaded glucose levels were shown inter-individual differences.

Table 1 Results of 75gOGTT

75gOGTT				Time						
analyte	Sample		Method	Unit	0 min	30 min	60 min	90 min	120 min	180 min
Glucose	Venous	Plasma	HK method	mg/dL	103.6 +/- 12.3*	168.8 +/- 31.2	170.3 +/- 61.2	155.6 +/- 69.3	145.9 +/- 53.1	89.5 +/- 45.0
		Whole blood	POCT(StatStrip)	mg/dL	114.1 +/- 12.5	179.4 +/- 32.4	184.0 +/- 64.4	167.2 +/- 71.7	157.8 +/- 57.6	98.2 +/- 46.4
			POCT(Glutest-mint)	mg/dL	103.7 +/- 12.2	175.3 +/- 34.6	174.1 +/- 59.8	161.2 +/- 73.8	150.0 +/- 53.5	92.7 +/- 48.4
	Fingertip	Whole blood	POCT(StatStrip)	mg/dL	114.9 +/- 10.6	190.3 +/- 25.7	182.3 +/- 61.2	170.2 +/- 60.4	152.3 +/- 49.2	97.1 +/- 46.3
			POCT(Glutest-mint)	mg/dL	101.7 +/- 11.3	169 +/- 30.2	167.7 +/- 56.4	161.6 +/- 69.4	152.1 +/- 56.2	89.1 +/- 44.2
	IRI	Venous	Serum	FEIA method	uU/mL	7.3 +/- 4.4*	53.1 +/- 33.8	46.9 +/- 22.9	39.8 +/- 21.6	43.4 +/- 18.5

* mean +/- SD, n=9

An Evaluation of a Rapid HIV Test on Neonate Blood as a Potential Surrogate Sample for Mothers of Unknown HIV Status. Charles T. Beavers, Chris Alexander, Kenneth E. Blick*. Department of Pathology, U. of Oklahoma Health Sciences Center, Oklahoma City, OK, 73110.

Although HIV testing in pregnant women is recommended by the CDC guidelines, current POC tests are only FDA approved for the testing of individuals over age 16. Since there is a 48 hour window of opportunity post-partum to identify HIV exposed neonates and prophylactically administer anti-retroviral therapy, it becomes critical to know the HIV status of the mother. Unfortunately, as we have found in our institution, occasionally the mother is either unavailable or refuses to consent to a HIV test. In this situation, rapid testing of the neonate provides a crucial opportunity to assess perinatal exposure and thus trigger treatment with anti-retroviral therapy in time to greatly reduce perinatal HIV transmission to the neonate. Accordingly, the focus of this study is to correlate the neonate's HIV serological results with those from the mother in order to 1) establish that the neonate's results adequately reflect the HIV status of the mother and 2) that our rapid point-of-care (POC) HIV testing device (OraQuick Advance HIV-1/2 test) correlates with our more established Siemens Centaur method and the methods being used at Mayo Laboratories.

The study population consisted of 90 children, 50 under four days old and 14 from age fourteen days to eleven years old. When neonates are compared to mothers for HIV serologies, we observed the following: OraQuick= 13 negative/13 negative; 2 positive/2 positive; Centaur=7 negative/7 negative; 4 positive/4 positive. When the OraQuick results are compared to the Centaur, we observed the following: 51 negative/51 negative and 4 positive/4 positive. On comparison of OraQuick results with Mayo, we observed the following: 35 negative/35 negative and 3 positive/3 positive. The latter three positive results were confirmed by Western Blot. On one Ora Quick neonate positive, the result was confirmed by the mother's positive results on Ora Quick, Centaur and Mayo, the latter also confirmed by Western Blot. Summarizing, our rapid HIV test results to date compare favorably between neonates and mothers regardless of the method employed.

Implementation of an Expanded Point-of-Care Testing (POCT) Site Inspection Checklist in a Large Academic Medical Center: Implications for the Management of a POCT Program

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Abstract

Introduction: Management of point-of-care testing (POCT) continues to present challenges. Improvements in device design and the use of POCT data management systems have improved the ability of hospitals to manage POCT programs. The use of site inspections by POCT coordinators has been a mainstay for maintaining regulatory compliance in POCT although this process is labor intensive.

Methods: We implemented an expanded POCT site inspection checklist modeled after the requirements of the Joint Commission. The checklist included categories not specifically related to POCT such as the environment of care and safety.

Results: The average number of deficiencies per site in 2011 was 2.37 (range 0-10). Only 18% of site inspections produced no citations. In contrast in 2010 the average number of deficiencies per site was 3.17 and only 8.7% of sites had no citations. The most frequently cited deficiencies (24.2%) related to safety followed by maintenance of proper procedures and documentation of competency assessment.

Conclusions: Despite improvements in many POCT devices and data management systems, regular site inspections are still required to identify regulatory deficiencies and improve testing quality. The use of an expanded site inspection checklist will identify many areas for improvement that are not specifically related to POCT alone.

Integrated POCT glucose testing in Europe: from cradle to adulthood, ten years of experience in the Antwerp University Hospital.

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In June 2000, a Belgian National Directive made hospital central laboratories responsible for all clinical biological testing performed within the hospital walls, thereby including point-of-care tests (POCT). These recommendations also limit the use of POCT to those cases where the advantage for the patient is clearly demonstrated. Important additional recommendations are that implementation of decentralized testing should be the result of an agreement between the clinical biologists and the clinicians, and that competence and obligations of the clinical biologists for POCT are equal to those required in the central laboratory. This includes the pre-analytical, analytical and post-analytical phases, the choice of instruments and reagents, quality assurance rules and training and follow-up of personnel performing POCT. A study of decentralized testing in our hospital in 2000 showed that POCT for glucose was the least compliant with these directives (many different brands of instruments, no quality measures, no traceability, no uniform handling of patient results etc), and thus the most urgent test to be reorganized. There is also enough scientific and clinical evidence to justify POCT for glucose in well-defined patient populations. This conclusion was presented to the hospital direction and green light was given to look for a unique standardized glucose POCT system for the entire hospital, integrable with the lab information system (LIS). A core working group explored the market in 2001 and two systems were selected for evaluation. Analytical quality was evaluated by the lab and user friendliness was evaluated by means of a user survey in 3 hospital wards (high, median and low POCT glucose consumers). Following the final selection of the Roche Accu-Check Inform I system linked to the Datacare middleware in 2002, an expanded working group prepared and guided the hospital wide implementation of this system in 2003 (with exception of the ICU, where POCT glucose is performed on blood gas instruments). Key issues were the realization of patient identification by means of a bar-coded bracelet, user identification by means of a bar-coded batch, internal quality control procedures, and user training. Defining responsibilities, logistics, communication and 24 hour support by the lab were additional priorities. Glucose POCT quality control with liquid reagents is performed daily by the nurses and a POCT-cell, consisting of three 0.33 FTE lab technicians, ensures the daily follow-up of POCT testing and POCT quality control results. The number of instruments increased and changed from 36 Accu-Check Inform I devices in 2003 to 75 Accu-Check Inform II devices in 2012. Meanwhile, the 'closed' Datacare middleware was also replaced by the 'open' cobas IT middleware, and wireless communication was installed in 2011. Since 2006, an external quality assessment program for POCT glucose is offered by the Belgian Scientific Institute for Public Health. Results of this 3-monthly program have clearly demonstrated the importance of external quality control for POCT, as some poorly performing instruments virtually

disappeared from the market, while good performers showed a significant increase of their market share. Conclusion: implementing one integrated POCT glucose system in the hospital ensures constant, good quality results, that are traceable from the moment they are generated by the POCT instrument till they are available in the electronic patient data file.

Using EQA (PT) for quality improvement (Comparison of the results from POCT systems and clinical laboratories in EQA programmes)

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SEKK is a provider of external quality assessment (EQA) accredited to ISO 17043 and offering EQA programmes in the Czech and Slovak territories for nearly 20 years. In recent years, a massive increase has been noticed in the number of POCT devices meant for on-the-spot testing in general practitioners' surgeries, ambulances, and in clinical units (e.g. outside of the laboratory). The steep growth in the number of POCT users participating in our EQA system during the past 10 years is shown in Figure 1.

The key question is: Do the results obtained using POCT devices measure up to the quality of those obtained in laboratories?

To answer this question, the following examples of CRP determination with POCT devices, glucose determination by glucometers (GLC), and prothrombin test (INR) have been used.

Basic principles

Commercial samples are used in the above mentioned EQA programmes, two for each participant (A and B samples). The results must be sent to the EQA provider within 10 days. The assigned values (AV) are set by statistical methods as the robust means (according to ISO 13528:2005). For each test a criterion is defined in the form of the maximum tolerable relative deviation of the participant's result from the assigned value (referred to as D_{\max}). The participant can be considered as successful if both of the results are found to be within the interval $\pm D_{\max}$ % around AV.

CRP determination

The EQA programme for the CRP measurement by POCT devices was offered for the first time in 2004 (300 participants). At present, more than 1700 participants are engaged in the programme. Although users of four various POCT systems participate in this programme, only two of them are represented significantly (QuikRead a NycoCard).

The concentration of samples ranges from 10 to 95 mg/l.

All results are evaluated in the aggregate (the results are not divided into groups); $D_{\max} = 24$ %.

Total successfulness of the CRP determination over a long period of time ranges between 80 and 90 %.

Total reproducibility (measured using CV) is within 10 - 13 %. However, the reproducibility of the results is significantly dependant on the measuring system used and on the concentration of CRP in the sample, which is a phenomenon hardly ever observed in the laboratory. In the laboratory, CV ranges around 6 %.

Glucose determination (GLC)

The EQA programme aimed for glucose measurement was started in 1996. At present, two cycles are carried out each year. The number of participants is above 200. A wide range of glucometer brands is represented (Abbott, Bayer, LifeScan, Nova, Roche, etc.). Glucose concentration in individual samples ranges between 3 and 13 mmol/l. Reference method values set down by RfB, Bonn, Germany, are available for the samples. The results are evaluated in groups set up by the type of glucometer ($D_{\max} = 10$ %). Total successfulness of glucose determination over a long period is between 60 and 90 % depending on the glucometer type used. Total reproducibility lies within a CV interval of 7 to 15 %.

Prothrombin test (INR)

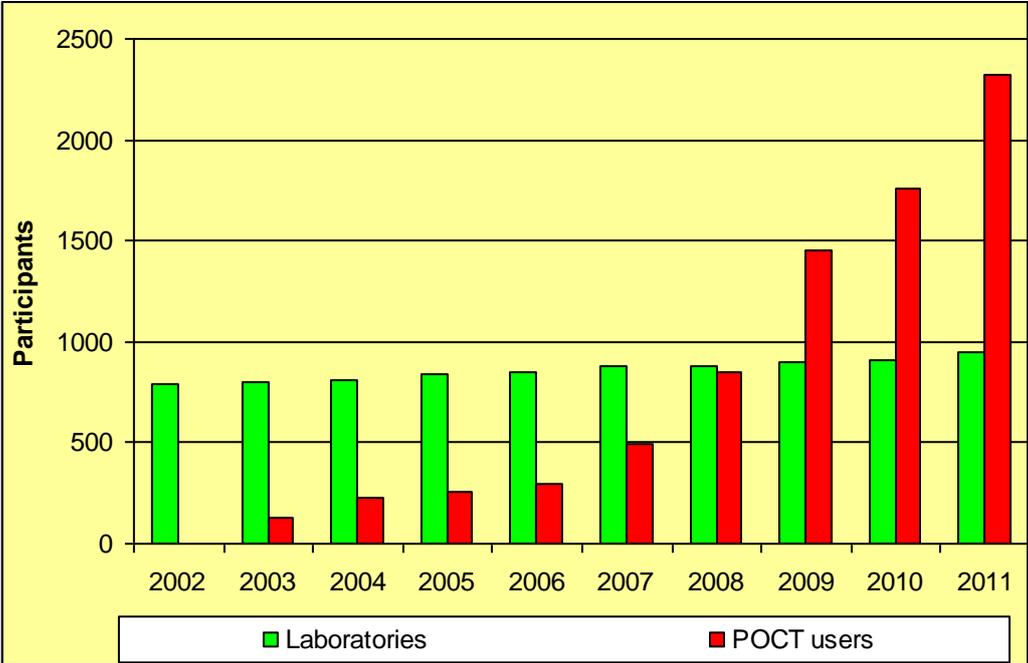
The EQA programme for PT INR determination with POCT device users was included in the system in 2006 (35 participants). Four cycles are currently run each year, in which over 600 participants take part.

In all, CoaguChek and INRatio POCT systems are significantly represented. The CoaguChek users receive special samples, while INRatio users are given a special batch of strips. The results of the quality control integrated in this strip are evaluated in the EQA programme.

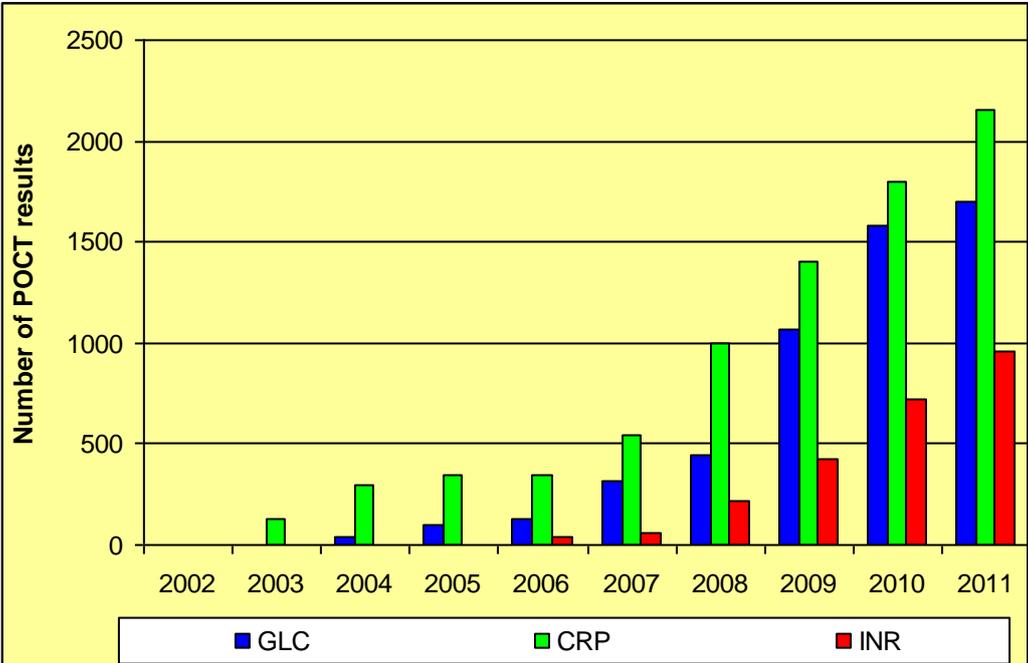
The results are evaluated in groups according to the POCT type ($D_{\max} = 20$ %).

Total successfulness over the long term ranges above 90 % depending on the POCT system used. With regard to the samples used, neither a comparison of the POCT systems nor a comparison with the results of other laboratories is possible. Total reproducibility lies within a CV interval of 5 to 10 %.

10-year history showing the growth of participants (both laboratories and POCT users) in our EQA system



10-year history showing the results received from POCT users



External quality assessment of prothrombin time determination on POCT systems – the evaluation of the postanalytical phase

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Background: The clinical interpretation of the INR is as important as the accuracy of the measurement. The addition of the postanalytical phase to the analytical phase as a subject of external quality assessment (EQA) in the case of point-of-care testing (POCT) of INR is beneficial.

Aims of the study: To evaluate the usefulness of the interpretational phase involvement in the EQA of INR testing.

Participants: 629 healthcare professionals participating in 4 rounds of EQA.

Methods: Each participant received two samples of control plasma with two brief case histories. The results of INR determination and the answers to 3 questions concerning warfarin dosing and frequency of INR monitoring were evaluated. The results were classified as good (leading to optimal treatment) acceptable (leading to suboptimal, but not harmful treatment) and incorrect (leading to potentially harmful modification of warfarin treatment). Good and acceptable results were considered as successful.

Results: The INR determination was successful in 96 % of measurements. Both answers to the questions concerning adequacy of warfarin dosing were successful in 84 %, one answer was successful in 14 %. Both answers to the questions concerning dose adjustment were successful in 81 %; one answer was successful in 17 %. Both answers to the questions concerning the interval to the next INR determination were successful in 56 %, one answer was successful in 35 %. Only 40 % of participants answered correctly to all 6 questions.

Conclusions: High proportion of participants recommended unacceptably long intervals to the next INR determination in unstable patients with high risk of thrombotic complications. Our next educational activities should be focused on this problem. The involvement of the postanalytical phase in EQA scheme seems to be beneficial.

Tools & experiences for POCT Practice.

Viviane Van Hoof¹, Edith Van Loock¹, Myriam Christiaens¹, Vera Verhaeghen¹, Marleen Truyers¹, An Hennebel¹, Hugo Cluckers¹, Dirk Maes², Pierre Rombouts¹, Geert Vandenheede¹, Marc Flothmann³, Katrien Lesage³, Kristien Van Brussel⁴. ¹Department of Clinical Chemistry, Antwerp University Hospital, Edegem, Belgium, ²Directory of nursing, Antwerp University Hospital, Edegem, Belgium, ³ICT Department, University Hospital Antwerp, Edegem, Belgium, ⁴Quality Department, University Hospital Antwerp, Edegem, Belgium.

Minimizing turn-around-time for critical parameters is the driving force for the implementation of POCT in our hospital. The needs for POCT are indicated by the clinicians and discussed with the laboratory. In agreement with the hospital direction, use of POCT is limited to parameters for which the advantage for the patient of a short TAT is demonstrated. If POCT is an option, a core working group (laboratory, clinicians, hospital purchaser) explores the market and selects potential candidate systems. Tenders are subject to a cost/benefit calculation. Analytical quality of candidate systems is evaluated by the laboratory and ease of use is tested by the hospital department(s) that are involved. Pilot departments are selected for hospital wide implementations. Final choice of equipment is made by the core working group. The laboratory has the final responsibility for all POCT in the hospital. Presently, +/- 25% of all lab results are generated through POCT. The integrated set-up of the POCT instruments in use is shown in Fig. 1. In our experience (> 10 years) key issues for a successful implementation are: (1) connectivity with the lab information system (LIS) and hospital information system (HIS), (2) correlation with central lab results, (3) internal and, if available, external quality control procedures, (4) traceability of patient results, (5) traceability of the user, (6) user's training and (7) 24 hour back-up by the laboratory. This way compliance with regulatory guidelines concerning traceability, training and patient safety is assured.

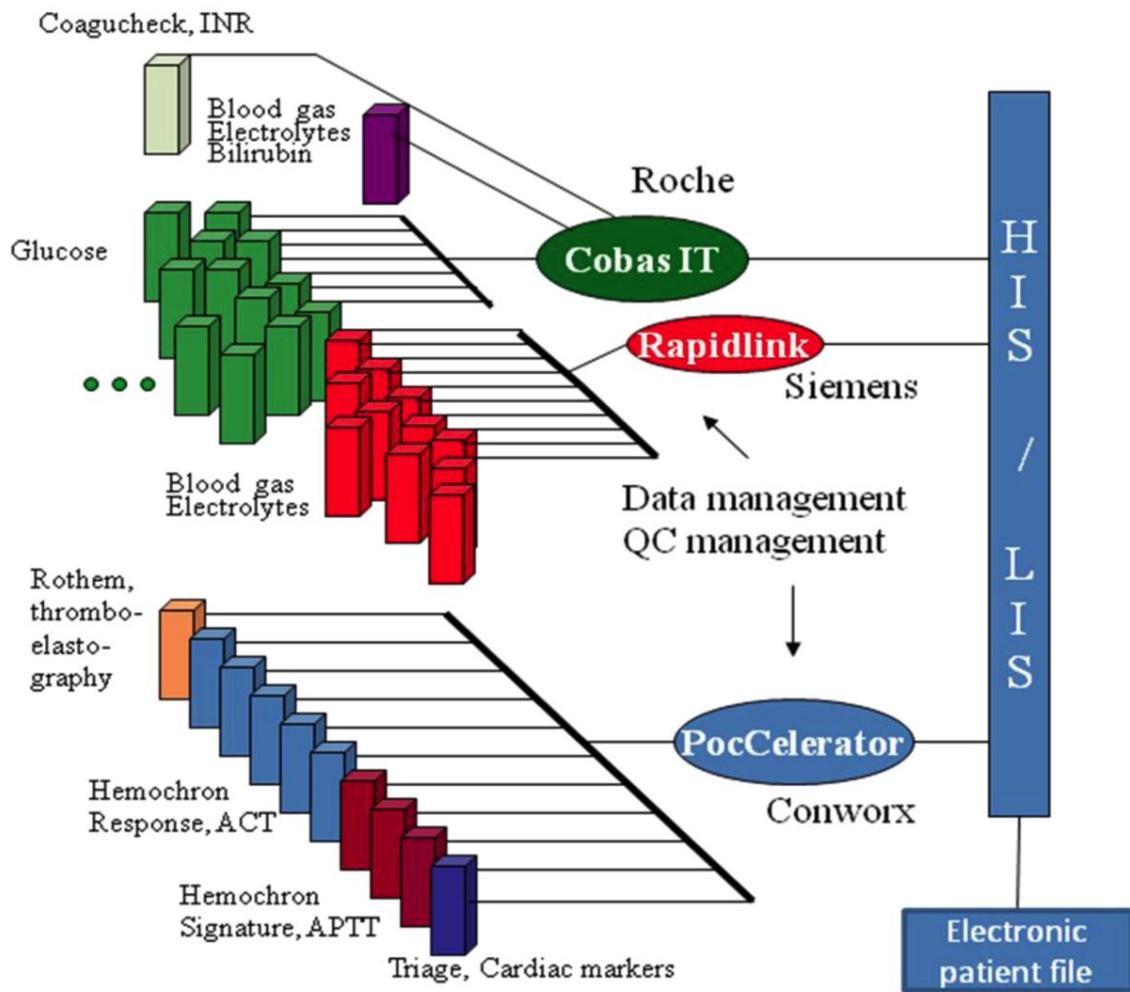


Figure 1: integration of point-of-care testing in the Antwerp University Hospital.

Point of care testing and laboratory medicine: which evidence? A systematic review.

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Point of Care testing (POCT) had rapid technological development and their use is widespread in clinical laboratories to assure reduction of turnaround time (TAT) and rapid patient management in some clinical settings where it is important to take quick decisions. Until now the works about the POCT have focused the attention on the reliability of the technology used and their analytical accuracy. The use of POCT to provide a more efficient healthcare is become important, because the devices provide more services with less expense to improve a healthcare systems centered on patients.

Purpose: To conduct a systematic review of the evidence to support POCT, focusing on clinical outcomes.

Methods: We searched in Medline. Two independent reviewers assessed the eligibility, extracted study details and assessed the methodological quality of studies.

Results: We analyzed 109 studies for five POCT types: neonatal bilirubin, troponin, blood gas analysis, intraoperative parathyroid hormone and procalcitonin. Most of the included studies (75%) were comparative, only 7 (6%) are RCTs, and 25 studies considered important patient's outcomes. Most of the included studies were about correlation between POCT and laboratory, 31% were studies about diagnostic accuracy and 24% studies evaluated the impact of the POCT on the clinical practice. Only 3 studies reported economic evaluation. Moreover the incomplete outcome data were not adequately addressed. We have performed meta-analysis about TAT and LOS for troponin POCT.

Conclusions: POCT reduced the time taken to make decision on patient management but the clinical outcomes have never been adequately evaluated. Our work shows that, although POCT has the potential to provide beneficial patient outcome, further studies may be required.

P11

Relationship of activated clotting time to heparin dose depends on the type of cuvette used with the Hemochron® Signature Elite. Lisa Senzel,¹ David Fiorella,² Henry Woo,² and Jay L. Bock.¹ Departments of ¹Pathology and ²Neurosurgery, Stony Brook University, Stony Brook, New York 11794 USA.

Background: The activated clotting time (ACT) is a widely used point-of-care test for adjusting heparin dose during interventional procedures. In early 2010, clinicians from our cerebrovascular, vascular, cardiac and cardiothoracic divisions noted they were using substantially higher doses of heparin to achieve target ACT values. Potency standards for unfractionated heparin (UFH) manufactured in the United States had been modified a few months prior to this time. We investigated whether details of the ACT measurement might relate to the apparent difference between ‘new’ versus ‘old’ heparin.

Methods: We measured ACT on blood spiked with ‘old’ and ‘new’ heparin using both the regular (ACT+) and Low Range (ACT-LR) cuvettes for the Hemochron Signature Elite (ITC, Edison, NJ). We also compared concurrent ACT+ and ACT-LR values during 10 neurointerventional procedures.

Results: We found differences in the ACT responsiveness to ‘new’ vs ‘old’ heparin. Hemochron ACT-LR cuvettes were more sensitive than ACT+ cuvettes to any given dose of either heparin. Target ACT values were more easily achieved using ACT-LR cuvettes than ACT+ cuvettes, particularly when using the ‘new’ heparin. After 50 to 80 Units/kg of ‘new’ heparin, most patients achieved ACT-LR values of 250 to 300 sec, but ACT+ values remained at 150 to 200 sec.

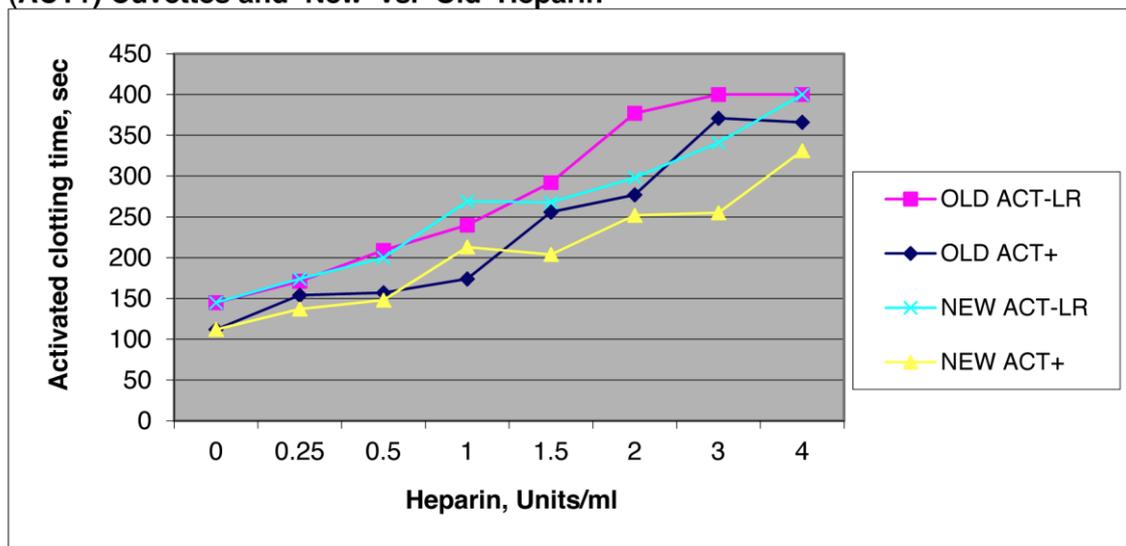
Conclusion: Clinicians need to be aware that target values for ACT during interventional procedures must be tailored not just to the Hemochron and Medtronic devices, but within the Hemochron system, to the tube method as well as the two types of cuvettes.

Heparin Dose Response: Spiking study comparing Low Range (ACT-LR) vs. Regular (ACT+) Cuvettes and ‘New’ vs. ‘Old’ Heparin

450 400 350 300 250 200 150 100
50 0
OLD ACT-LR OLD ACT+ NEW ACT-LR NEW ACT+
0 0.25 0.5 1 1.5 2 3 4

Heparin, Units/ml
Activated clotting time, sec

Heparin Dose Response: Spiking study comparing Low Range (ACT-LR) vs. Regular (ACT+) Cuvettes and ‘New’ vs. ‘Old’ Heparin



P12

Effect of delay time on measurement of lactate in unpreserved whole blood. Jay L. Bock,¹ Jirina Vasek,¹ and Peter Viccellio.² Departments of ¹Pathology and ²Emergency Medicine, Stony Brook University, Stony Brook, New York 11794 USA.

Background: Rapid measurement of blood lactate is needed for the assessment and management of sepsis. Unless collected with a preservative, blood specimens generate lactate *in vitro*, and so must be analyzed immediately to obtain accurate results. In some settings, however, even with use of point-of-care technologies, specimens must be transported and some pre-analytical delay is inevitable. In our institution specimens from the Emergency Department (ED) are transported to a satellite ED stat laboratory, where general chemistry profiles, including lactate, are performed on whole blood using electrode analyzers (Critical Care Xpress, Nova Biomedical, Waltham, MA). We sought to determine if these lactate results, though expected to have variable positive error related to pre-analytical delay, still had useful predictive value for initial assessment of sepsis in ED patients.

Methods: The study examined all lactate tests performed on ED patients at our institution over a 54-day period in 2012. For every patient where a possible diagnosis of sepsis was considered, a tube of blood with oxalate anticoagulant and fluoride preservative (OFP) was collected, along with a whole blood tube containing only heparin anticoagulant (HWB). Plasma from the OFP tube was tested for lactate in the main Chemistry Laboratory using a colorimetric method on a P-Modular Analyzer (Roche Diagnostics, Indianapolis, IN). The HWB tube was transported to the ED stat lab via pneumatic tube and tested using the Nova analyzer. Lactate results above 2.0 mmol/L were considered elevated, and if the HWB result was not elevated the test on OFP was omitted. Pre-analytical delay times were estimated from draw times and lab receipt times entered in the laboratory information system.

Results: A total of 1136 HWB chemistry profiles were performed in the ED stat lab during the study period. In 319 cases the lactate result was elevated (>2.0 mmol/L), and lactate was then measured on the concurrently collected OFP specimen. On average, the HWB result exceeded the OFP result by 0.59 mmol/L, and by 27.4%. The OFP result exceeded the HWB result by more than 0.1 mmol/L in only 2 cases (0.6%). When the HWB result was in the range 2.1-3.0, 3.1-4.0, or >4.0 mmol/L, the percentage of OFP results that exceeded 2.0 were, respectively, 50%, 95%, and 98.6%. The median transport delay was 20 min., and the increased lactate in HWB compared to OFP correlated modestly with the delay time ($r=0.35$, $p<0.000001$).

Conclusions: Delay in analyzing unpreserved whole blood specimens caused, as expected, a substantial and unpredictable increase in measured blood lactate. Nevertheless, low results on unpreserved specimens can rapidly rule out hyperlactatemia, whereas sufficiently elevated results indicated a high likelihood of hyperlactatemia in our setting.

EVALUATION OF THE ACCURACY OF GEM PCL PLUS FOR MEASURING ACTIVATED CLOTTING TIME (ACT) IN OPERATING ROOM.

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Introduction. The activated clotting time (ACT) has been the first bedside system employed in the monitoring of anticoagulant therapy in patients undergoing catheterization treatments. In cardiac surgery a high dose heparin is needed to prevent thrombosis of circuits used during extracorporeal circulation. Thus, an important issue is to rapidly monitor the degree of heparin-induced anticoagulation and its reversal. ACT determination has been made in the cardiac operating rooms of our hospital for several years, but without the supervision of laboratory staff. Now our hospital has two GEM PCL Plus for the analysis of ACT. This year the laboratory professionals responsible for hemostasis POC testing have taken control of the quality control of ACT equipment in operating room and our work is to ensure analyzer quality and establish a routine QC program in operating room. The recommended specifications for the ACT test are of a CV less than 14% according to literature.

Objectives. Check the precision, veracity and accuracy of the point-of-care (POC) devices used in cardiac surgery to monitor the anticoagulation by heparin in our hospital.

Methods. During 14 days was carried out a trial for imprecision with lyophilized whole blood controls. Outliers were eliminated by the Grubbs test and the coefficient of variation, systematic error and total analytical error were recalculated.

Results. CV were 7% for the normal level and 2% for the abnormal level, both cases less than 14% recommended by the literature and less than 10% recommended by the manufacturer.

Conclusions. We found that GEM PCL Plus has a CV less than recommended for coagulation values determinations and a CV lower than recommended by manufacturer, therefore their determinations are suitable for clinical use.

Efficiency of POCT-management in the hospital: a survey among 19 Dutch hospitals

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Introduction:

In Dutch hospitals the central laboratory is in charge of Point-of-care testing (POCT). The laboratory is responsible for device and user management. The aim was to investigate how different hospitals organize their POCT policy.

Materials and Methods

A questionnaire was sent to the operational staff of POCT of 19 hospitals (approximately 20% of total number of hospitals). Estimation of the time used for device and user management was asked. Device management (mean 38 (17-67) devices per hospital) included maintenance time, quality control, trouble shooting and stock management of strips/cuvettes of glucose-and haemoglobin devices. User management (mean 932 (350-2000) users per hospital) included training and re-certification as well as administration of users. The service level of the laboratory was determined by two aspects: whether the laboratory performs QC control for hospital departments and whether the users are trained by the POC-team. The automation level was determined based on whether there is an automated periodic recertification of users.

Results

The average total time for POCT per week was 21.8 minutes (21 minute per device and 0.8 minute per user). 7(37%) of hospitals used more than average total time. 4(21%) hospitals provided maximal service level. All hospitals had automatic result management. However, automated periodic recertification of users was organized in only 2(11%) hospitals. 6(32%) hospitals had no recertification procedure at all.

Conclusion

The hospitals who automated their process while providing the highest service level with total POCT time per week lower than average were considered to have the most cost-effective policy.

The relation between laboratory and POCT in Malopolska province, Poland.

P. Tomasik, B. Mrózek, K. Sztefko

Introduction: In Poland there are no binding regulations regarding the point-of-care tests (POCT). It is unclear who has the qualifications to run the POCT, as well as who should supervise the process of obtaining the results of bedside tests and their QC. Only the ISO 22870 standard, introduced to the Polish legislative in 2006, suggests some solutions. This European standard indicates, among other, the need of supervision over POCT examinations run in hospitals. The supervision should be a responsibility of the hospital laboratories. Such a solution guarantees high quality of the carried out examinations and high credibility of the results.

Aim: The aim of this study was to evaluate the role of hospital laboratories in Malopolska province in supervising the POCT procedures and the practical application of the ISO 22870 standard.

Material and method: The research was carried out in hospitals in Malopolska province by survey given to the heads of hospital laboratories. Complete responses were obtained from 67% of the initial number of subjects. The evaluation regarded, among other, the POCT equipment, the kinds of carried out tests, staff training in test running and supervision by the laboratory, including quality control.

Results: Hospital wards most often use in the POCT mode glucometers (81% of facilities), some (23%) possess blood-gas analyzers or analyzers suitable for troponin or D-dimer testing. At some facilities (38%) it is acceptable to use glucometers brought from outside. In most of the facilities (87%) there were no any supervision over the carried out tests, and no any relation between POCT and laboratory.

Conclusion: The lack of competent supervision over POCT examinations might results in their low quality and credibility, also due to lack of quality control. It is necessary to set up government act that would broaden the responsibility of the hospital laboratories for the measurements performed in POCT mode in hospitals.

Application of Risk Management Methodology in Improving the Performance of Point of Care Testing

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Background:

Risk management methodology might be considered a specific problem solving methodology for quality improvement projects which focus on safety or prevention.

Healthcare Failure Mode and Effect Analysis (HFMEA) is a systematic method of identifying and preventing process problems before they occur. HFMEA includes five steps: (1) team selection, (2) process identification, (3) process flow diagram preparation, (4) failure mode identification and scoring based on risk priority numbers, and (5) determination of an action plan. A failure mode is an area where the process can break down and cause poor outcomes. Point-of-care testing (POCT) is defined as performance of diagnostic testing occurring at or near the site of patient. Laboratorians possess a wealth of scientific and technical knowledge that is used daily within the laboratory. In case of POCT, specimens are procured, analyzed and resulted at or near patient bedside which puts the POCT operator in the position of being responsible for all stages in the specimen workflow path. The process design needed to be adjusted so that the quality of POCT services remained optimal even when the volume of requests is high.

Aim:

To describe the application of Healthcare Failure Mode and Effect Analysis (HFMEA) and the subsequent process changes made to reducing errors at the point of care testing system

Methods:

A multidisciplinary team was assembled which mapped out the steps involved in processing blood glucose level using POCT glucometers: pre-analytic, analytic, and post-analytic phases of testing process. For each step, sub-processes were also identified and a detailed flowchart was created. The team identified failure modes; each of these failure modes was listed with its consequence and consecutively numbered. Numeric values and rating scales were created and assigned to each category: severity of failure and likelihood of failure (occurrence rate), For severity of failure, a rating from 1 to 4 was assigned indicating a situation categorized from a near miss (1) to a catastrophic event (4). Similarly, the occurrence rate was scaled from 1 to 4 according to the probability of occurrence, which categorized from remote (1) to frequent (4).

A risk priority number (RPN) was then calculated as the product of the severity and occurrence rate.

Results:

Based on the Pareto principle the failure mode with the highest RPN was selected for action. "Critical values reporting mechanism" scored (16) as the severity rating of that failure categorized as catastrophic (4) and the probability of occurrence categorized as frequent (4). Corrective action was discussed and implemented. This took the form of including critical values reporting policy & procedure in the training conducted for POCT operator, as well as in the initial and ongoing competency assessment check list, and the recommendation of supplying all POCT stations by flowchart describing the steps involved in reporting panic values. The team tracked the RPN overtime for 3 months to see whether changes being made to the process were leading to improvement. After 3 months there was improvement in reporting critical values by POCT operators as well as a 50% reduction in RPN for that selected failure mode.

Summary

Healthcare Failure Mode and Effect Analysis (HFMEA) can be applied to point of care services to identify and address possible weaknesses within the system. Implementation of changes and reassessment of risk after implementation of changes can provide numerical changes of value and can be used for quality assurance processes.

Haemostasis Point of Care testing- INR Proficiency testing programme

DP Kitchen, S Munroe-Peart, I Jennings, S Kitchen, TAL Woods, ID Walker.

UK NEQAS for Blood Coagulation, 3rd Floor Pegasus House, 463A Glossop Road, Sheffield S10 2QD , UK.

Many aspects of haemostasis can be tested using specifically developed Point of Care (POC) instruments. In recent years, there has been a major shift from laboratory International Normalised Ratio (INR) testing to guide coumadin (vitamin K antagonist oral anticoagulant) dosing to INR monitoring using POC devices. Whether performed by a biomedical scientist in a laboratory or by a non-scientist in a POC setting, these tests need to have a robust quality control system in place and for this both Internal Quality Control (IQC) and External Quality Assurance (EQA) is required.

UK National External Quality Assessment Scheme for Blood Coagulation (UK NEQAS BC) have been providing EQA programmes for haemostasis tests for more than 30 years and introduced a specific POC EQA scheme for INR testing in 1996. Currently there are over 3300 centres enrolled in this POC INR testing programme with 79% of these sited in General Practices (doctors' offices) where testing is performed by nurses or by General Practitioners.

The programme circulates four surveys (sets of samples) per year with 2 samples per surveys. Samples are mailed to participating centres with a deadline of 17 days for results to be returned by post or electronically. After the survey has closed to result entry, data is analysed to calculate for each sample the median INR value and for each individual participant the percentage deviation from the respective median for each of their results. 15% deviation around the median value is set as acceptable performance. Centres with results 15% or less from the median are defined as "within consensus" and results further away then 15% from the median are considered "outwith consensus". Failure to return a result in any survey is also considered to be "outwith consensus". Centres that have results "outwith consensus" in 3 consecutive surveys are defined as "persistently outwith consensus" and are contacted by the UK NEQAS BC offering support and help to resolve any technical difficulties.

Participation in an EQA programme in the UK, is not mandatory for POC test providers so only centres that are aware of the need for EQA will have entered the programme. Of those registered in the UK NEQAS BC POC testing INR programme, there is a lower percentage return of results than for the laboratory programme (on average 86% for POC compared to 95% for laboratories for the same time period). For the year April 2011 to 2012 the average percentage "outwith consensus" was 6.6% however centres that are persistently experiencing testing problems are very few (only 0.1% of users).

In conclusion Point of Care INR testing can be a reliable method to monitor patients INRs providing quality issues are addressed and correct procedures to monitor the devices are in use. General Doctors and nurses are able to perform EQA testing and in the UK NEQAS BC programme persistent problems with testing using these devices are very rare.

Impact of Blood Collection Devices on Carboxyhemoglobin Measurements

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Background: Blood collection devices (syringes and evacuated blood collection tubes) with different anti-coagulants are routinely used in hospitals and clinical laboratories for clinical chemistry assays. Instrumentation Laboratory (IL) has recently learned through a customer evaluation that blood samples collected in BD Vacutainer® tubes containing lithium heparin and gel separator can significantly elevate the carboxyhemoglobin (COHb) levels. Different blood collection devices commonly used in hemoglobin measurements are compared in this study to assess their impact on carboxyhemoglobin.

Methods: Blood samples from healthy volunteers were collected in different blood collection tubes and syringes (listed in table below) were used for COHb measurements in three CO-Oximetry analyzers (GEM Premier 4000 and IL 682 from Instrumentation Laboratory and ABL 837 from Radiometer) in triplicate measurement from each device.

Results: Impact of different blood collection devices and the sample draw volume on Carboxyhemoglobin is shown below:

Blood Collection Device	COHb % of Total Hemoglobin* Bias vs. Arterial Syringes	
	Donor 1 Full Draw	Donor 2, Short Draw (1 mL)
Syringe, Westmed, Heparin 3 cc	-0.01	0.01
Syringe Vital Signs Heparin 3 cc	0.01	-0.02
BD Vacutainer® EDTA liquid (7 mL –Glass)	-0.26	0.07
BD Vacutainer® EDTA dry (6 mL)	0.25	2.50
BD Vacutainer® Heparin (6 mL)	0.57	3.81
BD Vacutainer® EDTA with gel (5 mL)	0.72	3.74
BD Vacutainer® Heparin with gel (8 mL)	1.04	5.17
BD Vacutainer® Heparin with gel (3 mL)	1.34	3.53

*Results are average of GEM Premier 4000, IL682 and ABL 837

- On a full draw, carboxyhemoglobin is slightly elevated (+ 0.5 -1.5 units) in heparin or dry EDTA tubes compared to syringe collection or EDTA tubes containing liquid.
- However, short draw (1 mL) showed significant impact on the COHb results (+ 2- 6 units bias) with different blood collection tubes except liquid EDTA tubes.
- Based on the syringe and liquid EDTA COHb values and draw volume impact, it is hypothesized that the presence of low levels of carbon monoxide as the likely source of COHb elevation.

Conclusions: Blood collection tubes with separator gel showed elevation in COHb compared to the arterial syringes. Sample draw volume variations in plastic blood collection tubes can cause pre-analytical errors in COHb measurements. Based on the significant elevation in COHb, plastic blood collection tubes with separator gel are not recommended for CO-Oximetry based whole blood hemoglobin measurements. Heparinized arterial syringes are recommended for accurate COHb measurements.

Bacterial contamination of glucose test strips: does the packaging matter?

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Introduction:

The role of fomites in bacterial transmission is still debated and need further investigations. We previously reported the putative role of the glucose test strips (GTS) as a reservoir for bacteria and a way to cross contamination between patients if the recipient was shared (Vanhaeren *et al.*, *Am J Infect Control* 2011). Nevertheless this study concerned only one type of packaging and its role was not evaluated.

Purpose of the study:

We aim to explore the bacterial contamination of GTS available in three different packaging, i.e., two multi-uses vials (A and B) and one unitarian packaging (C).

Material and Methods:

GTS from three different brand names were collected from three different teaching hospitals from the Assistance Publique – Hôpitaux de Paris (AP-HP) network.

In different wards, opened vials or boxes of GTS containing less than a half of the initial number of strips were collected and centralized in the same laboratory (Department of Bacteriology and Infection Control, CHU Antoine Béclère, Clamart, FRANCE). Each strip was placing in 1 ml of 0.9% NaCl and vortexed during 30s. One hundred microliters of the suspension was cultured on Colombia colistin nalidixic acid and Drigasliki. Viable bacteria were counted after 24 h and 48 h of culture at 37°C. Bacterial contamination was reported as a number of bacteria per strip. The inside of the box containing unitarian strips (C) was swabbed, the swab released in 1 ml of 0.9% NaCl and 100 µl inoculated as previously reported. Once empty, 1ml of 0.9% NaCl was added to the inside of vials of the multi-uses packaging (A, B); cultures were performed as previously reported.

Results: The percentage of strips yielded a positive bacterial culture were 2.5% (C, 5/196) for the unitarian packaging, 5.2% for the first multi-uses vial (A, 5/97) and 11.6% for the second multi-uses vial (B 17/146). No bacteria was isolated from the packaging of the unitarian strips (0/2) but viable

bacteria were obtained from the vial of the two multi-uses packaging (2/8 and 3/9 positive vials, respectively).

The median number and ranges of bacterial counts for positive GTS were 10 per positive strip / [0-10] for the unitarian packaging (C), 56 per positive strip / [10-230] for the first multi-uses vial (A) and 135 per positive strip [10 - 900] for the second multi-uses vial (B).

Discussion / Conclusion

Indeed packaging of GTS matters in their bacterial contamination during use. Hidden sources of bacteria could lead to cross contamination between patients if the GTS recipient was shared. Strict hand hygiene and/or unitarian packaging constitute simple measures to control GTS bacterial contamination.

Rapid test Quantum Blue[®] faecal calprotectin as predictor of relapse in patients under maintenance treatment with Infliximab[®]

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Background: In inflammatory bowel disease (IBD), predicting relapse by measuring non-invasive biomarkers could allow early treatment adaptation. Few data exists about the usefulness of close monitoring of calprotectin to predict relapse. The aim of the study was to evaluate the predictive value of rapid test for faecal calprotectin levels for flares in patients with IBD under maintenance treatment with Infliximab[®].

Methods: A prospective study was designed. Inclusion criteria were IBD patients (Crohn's disease (CD) and ulcerative colitis (UC)) in clinical remission under a stable 5mg/kg Infliximab[®] therapy. Rapid test for fresh faecal calprotectin in a lateral flow immunoassay was measured the day of the infusion, received in gastroenterology office. Clinical examination was performed two months later infusion. Relapse was defined as a as a Harvey-Bradshaw score >4 in CD patients and as a Mayo score >2 in UC patients. U-Mann Whitney test, Chi square test, Odds Ratio, ROC analysis and Logistic regression were performed in IBM[®] SPSS 20.

Results: 43 patients were recruited (mean age 46 years \pm 11.9), 23 (53.5%) were female, 62.8% had CD and 37.2% UC. After two months, 35 (81.4%) patients remained in clinical remission and 8 presented a relapse.

In patients in remission median calprotectin levels were 115.6 mg/kg of faeces. Patients who flared had significantly higher calprotectin levels at the moment of flare (median calprotectin levels of 278.9 mg/kg). (U-MW $p < 0.001$)

Further ROC analysis (flare vs remission) suggested that a calprotectin level of 110.5 mg/kg indicated as the best cut-off point showed high sensitivity (100%) and high specificity (74.3%) to model flare. Area under the curve was 0.875 with good accuracy ($p = 0.001$ SE: 0.053 CI 95%: 0.772-0.978). For a value of calprotectin over 110.5 mg/Kg an OR= 1.889 ($p < 0.001$; CI 95%:1.207-2.957) was obtained. Logistic regression analysis showed a 0.6% increase risk per unit of calprotectin ($p = 0.047$) in a model adjusted for age and sex.

Conclusions: In IBD patients under infliximab maintenance therapy calprotectin levels highly correlate with prediction of a relapse. Remission is associated with low levels. More studies and an increased number of patients should confirm the utility or usefulness of calprotectin rapid test to modulate therapy in consultant office.

Values for umbilical cord blood gas. Biochemical metabolic acidosis in newborn.

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Background: Arterial cord blood values provide a useful tool for the assessment of respiration and metabolic state of the newborn. As a general concept umbilical arterial blood gas values represent the metabolic status of fetal tissues oxygenation. We tabulate all cord blood gases data realized in the Delivery Department over the period of 06-02-2012 to 20-04-2012 for his evaluation and subsequent assessment of ranges of reference in our hospital. Fetal blood sampling taken from the cord is considered the gold standard in the analysis of biochemical status of the fetus, with an objective assessment of the risk of neonatal asphyxia. Respiratory acidosis occurs through the accumulation of CO₂ due to umbilical cord compression, decreased heart rate or insufficient placental perfusion. Metabolic acidosis occurs in the later stages of fetal hypoxia, when the O₂ to the fetus is insufficient and carbohydrate metabolism becomes anaerobic lactate production. So as the lactate is good predictor of the severity of neonatal hypoxia, which is one of the causes related to neonatal encephalopathy, and for being a way of assessing the severity of cerebral hypoxia, our aim is to know the percentage of acidosis metabolic (represented by increased lactic acid and parallel determination of base excess) in neonates of our Hospital.

Results and methods: 461 samples of umbilical arterial blood were collected. The samples were taken from the umbilical cord (double clamp) in sodium heparin syringes. They immediately were processed in situ. pH, pCO₂, pO₂, bicarbonate, lactate and excess of bases were determined in an automated blood gases analyzer (GEM4000 IL). The statistical analysis of the data was conducted with the program IBM SPSS 20. Results before analyzing the data found that they followed a normal distribution. We obtained the following results for umbilical arterial blood: pH = 7.24 (SD = 0.08), pCO₂ = 53.8 (SD = 11.4), pO₂ = 16.92 (SD = 11.66), bicarbonate = 23.08 (SD = 2.67) and base excess = - 4.18 (SD= 3.17). Considering as criteria of metabolic acidosis in fetal blood: pH <7.20, EB ≤ -7.2 and Lac > 3.7 mmol / l (only if they meet the three criteria in the same sample), 50 samples meet biochemical acidosis criteria (11% of samples).

Conclusions: Obtained results correspond with those in the literature. We find a high correlation between Apgar score and metabolic acidosis status due compliance with pre-analytical methods, with the consequent improvement of analytical results.

Quality Assurance of Blood Gasses using Certified Reference Materials.

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We report an external quality assessment study of blood gas analyzers using certified reference materials (CRM), which are made by Reference Material Institute for Clinical Chemistry Standards (ReCCS) in Japan.

A total of 124 laboratories in Hokuriku area (Toyama, Ishikawa, and Fukui prefectures) were participated in this study. The number of gas analyzers examined was 135 (Radiometer:77, Siemens:41, Techno Medica:12, AVL:3, i-STAT:2). The CRM is composed of two materials with a different level of pH, $p\text{CO}_2$,

or $p\text{O}_2$. One set of these materials were sent to each laboratory under a frozen condition below -30 degree centigrade, preserved at 4~6 degree centigrade, and examined within 3 days. The stability was checked under the same condition and was satisfied at every levels in every parameters of pH, $p\text{CO}_2$, and $p\text{O}_2$.

Table 1 shows the data for pH, $p\text{CO}_2$, and $p\text{O}_2$ at each level. Mean and SD values are those of all analyzers, and "N*/N" values were 90.4% to 95.6%.

We conclude that the CRM is more convenient method than the using tonometry method to maintain the quality of blood gas analyzers and it is also useful for a large scaled study.

Table 1. Accuracy evaluation of pH, $p\text{CO}_2$ and $p\text{O}_2$

	Level	Certified Value	Mean \pm SD	Bias	N*/N(%)	N*/N: Number of analyzers within acceptable ranges, total number of analyzers
pH	I	7.286 \pm 0.04	7.2874 \pm 0.01266	0.001	128/135 (94.8%)	
	II	7.499 \pm 0.04	7.4936 \pm 0.01490	0.0046	129/135 (95.6%)	
$p\text{CO}_2$	I	57.1 \pm 4.0	55.49 \pm 1.964	-1.61	122/135 (90.4%)	
	II	27.2 \pm 2.0	27.27 \pm 1.117	0.07	123/135 (91.1%)	
$p\text{O}_2$	I	41.7 \pm 3.0	40.96 \pm 1.756	-0.74	117/135 (86.7%)	
	II	74.8 \pm 4.0	75.49 \pm 3.508	0.69	95/135 (90.4%)	

Achieving quality POCT results in primary health care settings

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Karolinska University Laboratory, provides services for quality assurance of point of care testing (POCT) in hospitals and primary health care settings. During the last 5 years the laboratory has developed a quality assurance program for POCT for primary health care providers.

The program consists of two phases:

The initial establishment phase comprises presentation of the services provided, signing of formal agreement, training of health care personnel and issuing of certificate for personnel responsible for POCT in health care unit.

The second administrative phase comprises audit, support, monitoring of control results and annually recurring education for health care personnel responsible for POCT.

Methods: POCT methods chosen for quality assurance program are validated and approved by the Karolinska University Laboratory. Current methods include analysis of Hemoglobin, Glucose, C-reactive protein, HbA1C, Prothrombin time, D-Dimer, group A beta-hemolytic Streptococcus, Mononucleosis (heterophilic antibodies) and Urinalysis.

Control programs: all methods are subject to internal and external control programs. Monitoring of internal control runs is done through the web-based QC program "Unity Web" (BioRad).

Results:

Participants of the quality assurance program show good compliance with external and internal control programs. The fraction of external control runs that deviate from the accepted limits decreased with time in the program from 4.5 % to 1.8 % over a period of 5 years.

A survey run 2011 showed that 100 % of the participants in the quality assurance program thought that the program met their expectations, 85 % felt more secure about their POCT results than prior to entering the program, and 90 % would recommend the program to others.

The amount of participants in the program has increased since the start in 2007 and is currently more than 50 health care providers within the Stockholm County.

Strategy for continuous quality improvement of the whole analytical POCT cycle

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Background

In our hospital POCT was implemented in 1995 and showed a spreading in the following years despite massive initial quality problems. Therefore, we started a continuous process of quality improvement according to PDCA cycle. On the clinical and laboratory side, we are focused with errors over the whole analytical process. On the manufacturer side, we are still waiting for better accuracy and precision of devices and uniform connectivity standards.

Methods

A POCT hospital-wide inventory was performed in 2001. Structured interviews were carried out regarding the following sections: devices, tests, QC, patients, documentation, users, trainings, activity recording and accounting for services.

Results

Different device types	-> uniforme devices
No or poor pre-analytical knowledge	-> brief manual instructions and training of <i>users</i>
No labeling of blood gas syringes	-> direct labeling of blood gas syringes bedside
Air in blood gas syringe samples	-> venting of blood gas syringe samples
Insufficient verification of test stripe lots	-> validation of new test stripe lots by the laboratory (glucose)
No uniforme training of users	-> training of users by biomedical laboratory assistant or super-user
No user-ID and patient-ID	-> mandatory user-ID and patient-ID -> Introduction of patient wrist bands
No uniforme validation procedures	-> uniforme validation procedures
No uniforme QC measurements	-> uniforme QC procedures
Transfer of patient results manually	-> online result transfer
No connection of devices with LIS	-> connection of devices and transmission of results to the LIS
No graphical trend in the LIS patient data and monitoring system	-> online POCT results and trends in the LIS and the patient data monitoring system
No traceability	-> traceability of results, reagents, devices and users

Conclusion

Based on the answers given in the different categories, quality improvements were introduced and the results were checked in 2011. The implementation of a hospital-wide POCT requires a continuous PDCA cycle-driven quality improvement, which includes the total POCT process and has to be tightly controlled by a laboratory POCT coordinator.

Use of a needs assessment and utilization tool in building a quality Point of Care Testing program in a pediatric hospital system

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OBJECTIVE: To develop a tool for use in determination of satisfaction level of clinical care providers with laboratory turn around time and their desire for and potential utilization of both currently available and newly developing laboratory Point of Care Testing (POCT) modalities.

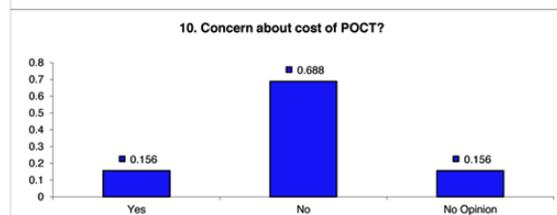
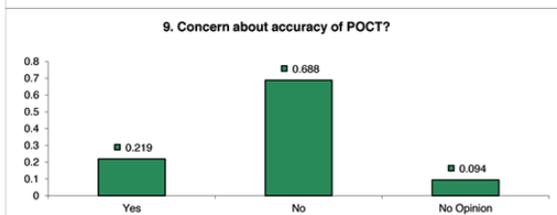
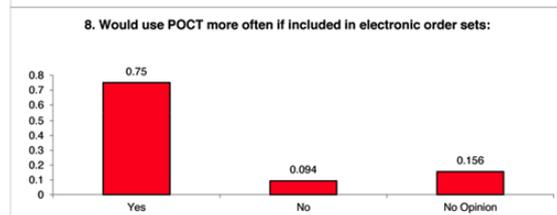
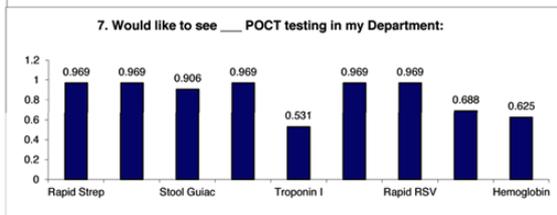
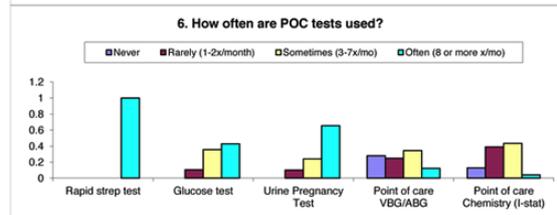
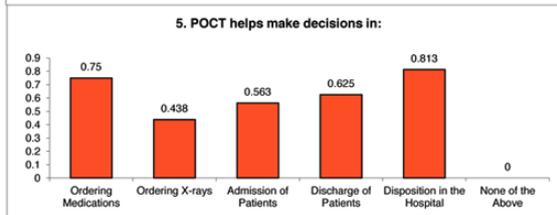
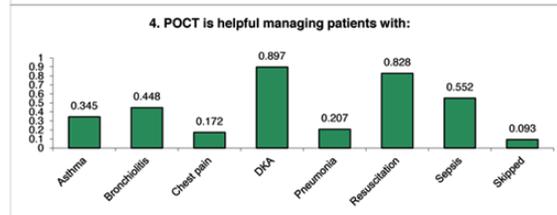
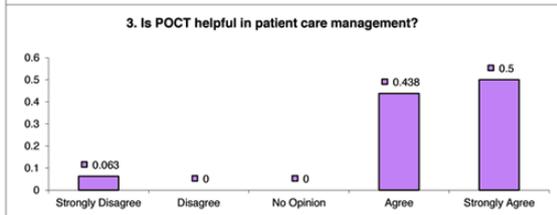
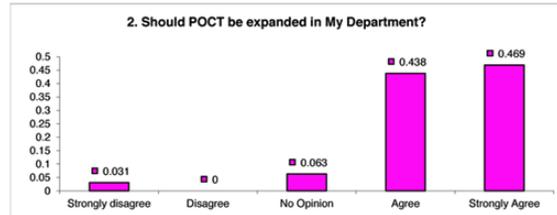
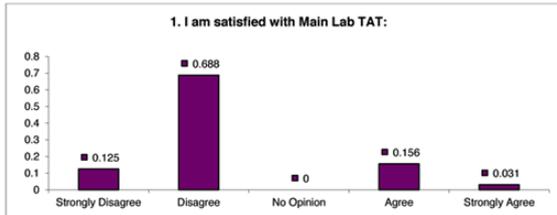
METHODOLGY: A 10 question Survey Monkey survey was sent to all physicians, and pediatric nurse practitioners working in the emergency departments of the hospital regarding their satisfaction with lab turn around time for frequently ordered tests, asking which tests they currently use for POCT testing and frequency of use; and asking how the POCT tests influenced their care of the patient. In addition, questions were asked pertaining to their concerns about POCT accuracy, cost and ease of ordering.

RESULTS: 52 providers were sent surveys via hospital e-mail delivery system. One follow up e-mail was sent regarding the survey. Thirty-two recipients responded, 6 recipients never opened the e-mail by the time of conclusion of the survey, 14 did not reply. Of the recipients who did open the e-mail we received a 69.5% response rate. All responders completed the 10 survey questions.

The results of the questions were graphed and percentages of answers were calculated from the responding group total. All answers were tabulated and trended, and all comments collected without identifying the respondent.

Results of the survey were then presented to the ED medical directors, and to the POCT coordinator for the hospital system in addition to being presented to the staff as graphic results for comparison with future POCT changes and repeat surveys. (See graphs in separate attachment.)

CONCLUSION: Pediatric clinical care providers see an important role for POCT in the pediatric emergency department and would prefer to expand testing modalities as they become available. They perceive a use for POCT in common respiratory illness management as well as management of critically ill patients. POCT assists providers in decision-making for medication orders, radiography and patient disposition. There is some concern about the accuracy of the testing which needs to be addressed with providers as these tests are introduced to the emergency department setting. Incorporation of POCT options in the electronic order sets may improve utilization of point of care testing by reminding providers of this option in patient care.



Assuring the quality of Point of Care Testing results through participation in External Quality Assessment programmes.

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The United Kingdom National External Quality Assessment Service (UK NEQAS) has established Point of Care Testing (POCT) External Quality Assessment (EQA; Proficiency Testing) for in excess of 5,000 registered participants both within and outside the UK. The quality of results obtained from a POCT device needs to be seen to be ensured, so that clinical decisions may be taken with confidence. Tests should have a robust quality assurance system in place, requiring both Internal Quality Control (IQC) as well as EQA. Currently, UK NEQAS offers POCT EQA programmes in:

- Blood Coagulation
 - Capillary reagent prothrombin time/international normalised ratio (PT/INR)
 - CoaguChek XS / XS Plus series of systems for PT/INR
 - HemoChron PT/INR
 - HemoChron activated clotting time (ACT+) systems
- Clinical Chemistry
 - Urine dipsticks
 - Health Checks
 - Pregnancy Testing (urinary hCG)
- General Haematology
 - POCT programme integrated with the main laboratory EQA programme
- Microbiology
 - HIV programme

Demand for POCT EQA has increased substantially in recent years, assisted by endorsements for EQA to be carried out (where programmes exist for specific POCT tests) in various disciplines of pathology by the publication of guidelines or recommendations from experts in representative fields. The British Committee for Standards in Haematology guideline [1] on the use of EQA for POCT systems in haematology states that POCT should not be seen as a secondary type of testing service and therefore not be subjected to less rigorous EQA. Briggs et al for The International Council for Standardization in Hematology [2] includes the expectation for users of POCT and supervising laboratories to subscribe to an accredited EQA service. The American Association for Clinical Chemistry includes recommendations for (E)QA of POCT in a chapter on Management as part of The National Academy of Clinical Biochemistry Published Guidelines on Evidence-Based Practice for Point-of-Care Testing [3].

There is evidence in both primary and secondary care settings that EQA improves the quality of pathology test results and to ensure accurate and reliable results, EQA remains an important component of quality assurance for POCT.

References

1. Guidelines for point-of-care testing: haematology (2008)
British Committee for Standards in Haematology website: www.bcsghguidelines.com
2. Briggs C., Carter J., Lee S.-H., Sandhaus L., Simon-Lopez R., Vives Corrons J.-L. for The International Council for Standardization in Hematology (2008). ICSH Guideline for worldwide

point-of-care testing in haematology with special reference to the complete blood count. Int. Jnl. Lab. Hem. 2008, **30**, 105-116.

3. Nichols J.H. (Editor). Evidence-Based Practice for Point-of-Care Testing (2006). The National Academy of Clinical Biochemistry (2006; Archived). American Association for Clinical Chemistry website:
<http://www.aacc.org/members/nacb/LMPG/OnlineGuide/PublishedGuidelines/poct/Pages/poctpdf.aspx#>

Application of Quality Standards to Point-of-Care Testing for Hemoglobin A1c

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The Point-of-Care Testing (POCT) program at The Children's Hospital of Philadelphia covers twelve clinical services, oversees over 3000 health care professionals at over 100 testing locations located within the main hospital campus and ambulatory settings. POCT is managed by laboratory professionals in the Department of Pathology and Laboratory Medicine, which has full oversight and responsibility for all aspects of lab testing. The program is challenged with ensuring high quality, accurate test results rapidly and at the point-of-care to accommodate patient flow, decision-making, and optimizing precious time providers spend with their patients. The implementation of the hemoglobin A1c test at eight ambulatory locations exemplifies success in meeting this challenge.

Hemoglobin A1c results are an important tool utilized by Endocrinologists in the management of diabetes. Measurement of the percent glycosylated hemoglobin in blood is an indicator of the patient's blood glucose controls over the past two to three months and assists with letting providers, patients and families know how the diabetes treatment plan is working. The American Diabetes Association recommends testing patients twice per year at a minimum. The availability of the test result during the patient visit is an effective tool to provide discussion and potential adjustment of treatment plans in a real time manner. The efficiency of the process has resulted in family, patient and provider satisfaction.

The test methodology is based on latex immunoagglutination inhibition using the Siemens DCA Vantage analyzer. The laboratory validated the DCA method to gold-standard HPLC (Bio Rad Variant II) and an immunoassay on a main chemistry lab analyzer (Ortho Vitros 5600). The accuracy of Siemens DCA device was first determined by comparison of 53 patient specimens to the Bio-Rad Variant II ion exchange high performance liquid chromatography (HPLC) system. Deming regression analysis of these comparative results yielded a slope of 0.96 with an intercept of 0.196 ($R^2 = 0.986$). Comparison of 53 patient specimens on the Siemens DCA analyzer to an immunoassay on the Ortho Vitros 5600 platform yielded a slope of 0.98 with an intercept of 0.334 ($R^2 = 0.962$). All three methods were linear throughout their entire reportable range.

The POCT program quality standards were applied to this test. Competence assessment includes initial staff training by laboratory staff, or by designated staff trained by the lab. When the test was first implemented, additional steps to ensure adequate staff training was performed with testing previously tested patient samples and comparing results. A guide with tips for avoiding preanalytical errors related to specimen collection was provided to testing staff. After that, rotation of quality control tests and a proficiency test program with three events per year is used for competence assessment. Analyzers are configured with features to meet regulatory requirements for day of use quality control, new reagent lot quality control, and analyzer maintenance. Maintenance is performed and documented as per manufacturer's recommendations for quarterly optical checks and regular cleaning of parts and filters plus regular function checks performed by the Hospital Biomedical Department. Service maintenance agreements are in effect for rapid analyzer replacement in the event of a malfunction. Post analytical factors related to result reporting are reviewed frequently to keep the resulting process simple and efficient. A software upgrade being released in the near future will allow for the interface of analyzers to the patient electronic medical record to further streamline the process.

The components of our quality system collectively ensure test result accuracy. Key to success of the overall outcome is teamwork and good communication between laboratory and a diverse group of testing personnel. Oversight of the lab with regular on-site visits for documentation review, direct observations of test performance and interaction with testing staff has been the hallmark of the success of the POCT program.

Strategy for Quality of POCT Bilirubin-Results

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Introduction Monitoring of bilirubin levels in patients in neonatal care settings is important for managing and maintaining undangerous blood bilirubin concentrations to reduce the risk of severe hyperbilirubinemia. Hyperbilirubinemia is a typical, potentially dangerous symptom in hemolytic diseases and immaturity of the neonatal hepatic function with considerably elevated blood bilirubin levels. Point of care analysis by (POC) blood gas analysers is often routinely used for the measurement and management of bilirubin levels in NICU patients.

Recently we observed falsely elevated POCT bilirubin readings different from central lab results as every result from POCT that must be followed by therapeutic interventions must be verified by a value determined in our central lab.

Objective The aim of this study was to check the potential influence of matrix effects (whole blood versus cell-free quality control (QC) fluids) on the accuracy of bilirubin measurement in blood gas analyser systems.

Methods During daily routine in our Hospital bilirubin can be determined by two ABL835 blood gas analysers and on a Siemens dimension xPand. All results are stored in our lab information system. From all bilirubin results (n = 34.147) obtained from routine blood sampling between July 2007 and April 2012 we selected those samples, when in a single patient results existed from a POCT BGA as well as from the central lab. Those pairs were accepted, when time between POCT BGA and acceptance of sample in the laboratory differed up to 1 hour.

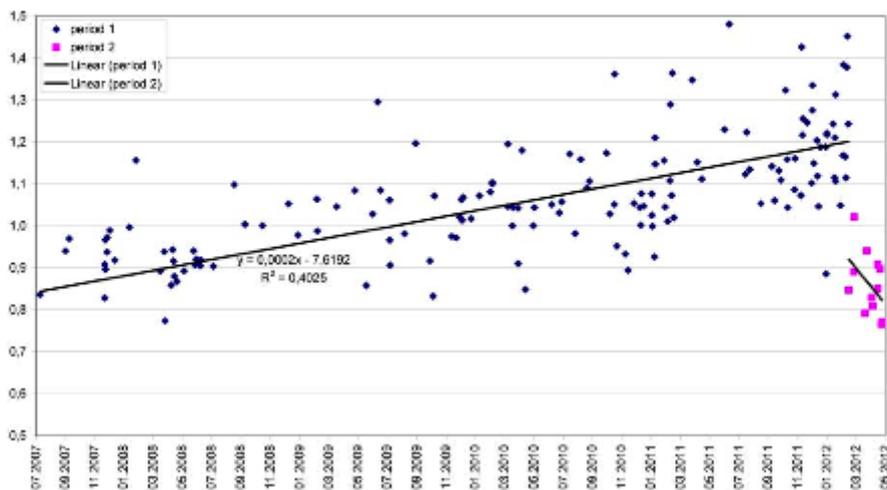
Thus, our sample consists of 1.381 retrospectively merged pairs. It is impossible to determine if both specimen came from the same blood sample, as the material type (arterial / venous / capillary sample) during the investigation period was not stored in the lab computer.

Results The accuracy of the bilirubin results obtained using both ABL835 blood gas analysers seems to be affected by "aging" of the hemolyzer and/or oximetry modul (tables 1 and 2). After replacing the hemolyzer modules in February resp. March 2012, the POCT readings were not excessive compared with the central laboratory.

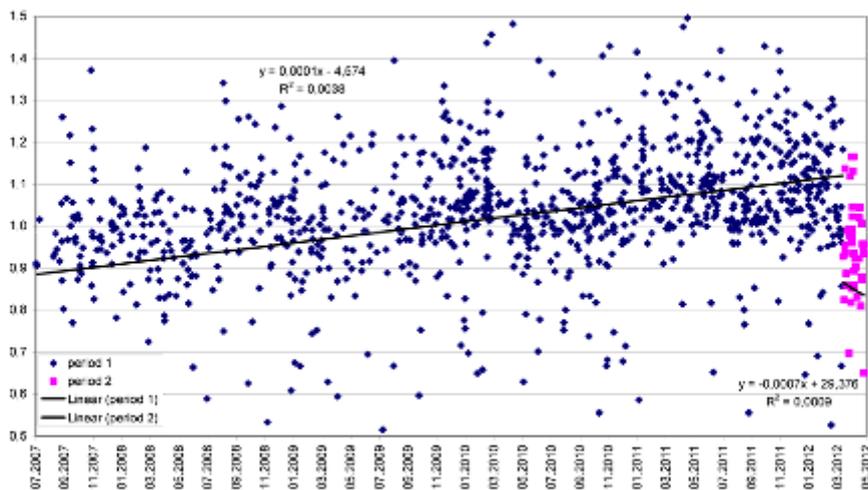
Conclusion Laboratory methods must be compared against each other in order to determine the in-house position values. Matrix effects (whole blood versus cell-free aqueous QC-fluids) can influence the accuracy of the hemolyzer and oximetry modul of blood gas analysers. This needs to be taken into account in neonatal care settings in order to manage hyperbilirubinaemia effectively and adequately.

The German Institute for Standardization is preparing a DIN 58964 "near patient's side emergency diagnostics (POCT) - Method Comparison - Minimum requirements for the comparison of POCT devices with devices from the laboratory".

Quotient POCT/Lab-Bilirubin Ward PNZ



Quotient POCT/Lab-Bilirubin Ward NGM



Analytical Performance of Three POC Analyzers for Pleural Fluid pH Analysis

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Introduction: Pleural fluid is collected for pH testing in the management of patients with exudative pleural effusions. Patients with low pleural fluid pH require chest tube insertion to drain the fluid. Reaching the correct clinical decision requires appropriate preanalytic and analytic considerations, such as use of a blood gas instrument as opposed to pH meters or litmus paper, which have been shown to significantly overestimate pleural fluid pH. However some laboratories are hesitant to use blood gas analyzers for pleural fluid analysis because sample viscosity increases the potential for instrument clogging, resulting in instrument downtime and repair. Single use or multiple use cartridge-based blood gas devices would reduce downtime for troubleshooting caused by poor specimen quality, while potentially producing pleural fluid pH results clinically concordant with larger blood gas devices that have been traditionally used.

Objective: Compare the performance of three point of care methods for measuring pleural fluid pH to our current validated method.

Methods: An ABL 725 (Radiometer America Inc., Westlake, OH) previously validated by our lab for pleural fluid pH analysis was compared to an ABL 90 FLEX (Radiometer America), and an i-STAT 1 (Abbott Point of Care Inc., Abbott Park, IL) using the CG4+ and G3+ cartridges. Pooled residual pleural fluid samples from patients undergoing thoracentesis were analyzed to determine intra-assay precision (n=20). Inter-assay precision was determined using manufacturer provided quality control material (n=20) over at least 10 days. Method comparison samples were made with filtered pleural fluid spiked with 2% acetic acid (<10% volume change), mixed, and dosed on each instrument via non-heparinized or heparinized syringes (Portex 3.0mL dry lithium heparin, Smiths Medical ASD, Inc., Keene, NH). All methods were compared by measuring pH in duplicate within 30 minutes of preparation (n=40) across the analytical measuring range (pH: 6.30-8.00). An additional 10 samples were included in the method comparison from clinically ordered pleural fluid pH testing within the established stability of the sample (60 minutes on wet ice). Regression analysis (ABL 725, x-axis) was performed and the slope and intercept were calculated. Bland-Altman analysis was performed (comparative method – ABL 725) with acceptable limits of $\Delta\text{pH} \leq 0.02$. Clinical concordance was assessed using the ABL 725 as gold standard with a decision limit of <7.20.

Results: Inter-assay precision determined by using commercial QC material on each device demonstrated CVs < 0.1% on all devices (including the ABL 725) at pH values of 7.1 and 7.6. Intra-assay imprecision studies conducted using pooled pleural fluid samples on each platform yielded the following results. The ABL 725 demonstrated CVs of 0.3% and 0.1% at mean pHs of 7.15 and 7.69, respectively. The ABL 90 FLEX had CVs of 0.2% and 0.1% at mean pHs of 7.19 and 7.67, respectively. The i-STAT 1 with a CG4+ cartridge had CVs of 0.1% at mean pHs of 7.16 and 7.75. The i-STAT 1 with a G3+ cartridge had CVs of 0.1% and <0.1% at mean pHs of 7.16 and 7.75, respectively. Regression analysis yielded the following proportional and constant bias expressed as (slope, intercept): ABL 90 FLEX (0.97, 0.17), i-STAT 1 CG4+ cartridge (1.06, -0.36), and i-STAT 1 G3+ cartridge (1.06, -0.29). Bland-Altman plots demonstrated the bias was most significant between ABL 725 and each of the other methods at pH >7.7. Overall clinical concordance using a decision limit of pH 7.2 was 96% for the i-STAT 1 (CG4+), 98% for the i-STAT 1 (G3+), and 100% for the ABL 90 FLEX. Among rare discordant samples, the ΔpH was <0.02 for all i-STAT and ABL 90 samples compared to Radiometer ABL 725.

Conclusion: Both inter-assay (using commercial QC material) and intra-assay (using pooled pleural fluid specimens) precision on the single (i-STAT) and multiple use (ABL 90) cartridge-based blood gas instruments was comparable to the current validated method for pleural fluid pH analysis (ABL 725). Regression analysis confirmed that the methods compare with the ABL 725 having slopes = 1.0 +/-0.06. All three methods

displayed acceptable (> 95%) clinical concordance, with rare discordant samples still meeting analytical criteria of $\Delta\text{pH} < 0.02$ compared to the reference method. The i-STAT 1 is a single use disposable cartridge system, and thus the most convenient in terms of eliminating sample clots or clogs. The ABL 90 FLEX has accessible sample tubing to easily clear clogs, but relies upon a multiple use cartridge which could result in reagent waste if a cartridge becomes clogged after pleural fluid analysis. Neither i-STAT 1 nor ABL 90 FLEX are currently FDA-approved for pleural fluid testing, thus laboratories would need to validate these devices for pleural fluid testing.

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Use of POCT in the Emergency Department and Impact on Performance Metrics

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Background: The primary objectives of Emergency Medicine are to provide timely, efficient and high quality patient care. Removing barriers that prevent the patient from being seen by the Physician or making dispositions, are essential to accomplish these objectives. Once these goals are defined, process improvements can take shape. This requires a global vision of the entire Emergency Department visit. Addressing impediments to ingress and egress from the department, Point of Care Testing (POCT), and radiology throughput are critical to reaching desired endpoints. Presently, there is increasing pressure on all aspects of care where payers attempt to reign in expenses and improve care by offering incentives based on a pay for performance model (PFP). Several PFP goals involve specific Emergency Department throughput metrics and not meeting them will have significant negative financial impact.

Goal and Objectives:

- To improve Emergency Department experience at Mease Dunedin Hospital.
- Improve time to assessment by clinical provider to less than 30 minutes.
- Decrease time to disposition of patient.
- Reduce turn around times (TAT) for lab test results.
- Decrease patient length of stay in the ED.
- Minimize number of patients leaving without treatment (LWOT).
- Reduce diversions to other medical facilities.

Materials and Methods: To decrease disposition time in the ED, we incorporated the utilization of POCT including blood gas, whole blood electrolytes and metabolites, and cardiac markers to reduce TAT for blood tests. The measureable results were time from Physician assignment to time of disposition, which signified all laboratory, radiologic and therapeutic testing was complete. Data is captured in the electronic medical record (EMR). The EMR was queried to arrive at these data.

Results: Data was collected over a 10-month period on all patients who presented to the ED, demonstrating that the average time to clinical provider assignment was 22 minutes (national average 56 min). Time from clinical provider assignment to patient disposition averaged 1 hour 56 minutes yielding an average length of stay of just over 2.5 hours (national average is 4 hours 7 minutes). LWOT was 0.29% far below national average of 2%. POCT played an integral role in supporting the efficient care and throughput of patients in this ED. Specific patient case reports will be provided.

Conclusion: POCT is an integral component to reducing LOS and providing quality, efficient patient care in an emergency department setting.

Quality Improvement of Point-of-Care-Testing in a Large University Hospital

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Background

Point of care testing (POCT) is increasingly used in hospital wards, intensiv care units, emergency departments and operating theatres as clinicians often need to have the test results readily available in order to make prompt diagnosis, establish early therapy or make therapy changes. Global problems of point-of-care-testing in hospitals are the performance of the tests by clinical staff not systematically trained in laboratory medicine, the use of different devices for one test, the often troublesome and badly traceable documentation and the difficulty to apply common principles of quality control.

Approach

According to the international standard ISO 22870 "Point-of-care-testing - Requirements for Quality and Competence" the University Hospital Graz has defined internal regulations for point-of-care-testing. The University Hospital is structured in 21 clinical departments with 43 divisions covering all medical branches. Around 84.000 outpatients and 410.000 inpatients are treated per year. A governance model has been developed and responsibilities and competences have been defined. An interdisciplinary working group has been established and a POCT coordinator, POCT-representatives and POCT-users introduced. An obligatory training for POCT-user has been implemented and an online quality control assurance scheme has been established. All POC-methodes are evaluated in accordance to the methods in the central laboratory. All POC measurements are documented in the laboratory and hospital information system.

Results

By now about 3000 people of clinical staff have been systematically trained by a technician of the central laboratory, 1400 thereof on blood glucose devices Accucheinform II and 1600 on blood gas analyzers GEM 3000, GEM 4000, Cobas b221 and ABL 800. At the departments 62 glucose devices and 17 bloodgas analyzers mainly at intensive care units and operating theaters are in use. Only clinical staff who have been trained in POCT are allowed to perform testing. This is guaranteed by an obligatory user identification. In the training particular attention is paid to preanalytics, handling and quality control measurement. A trainingguide is available at every ward and in case of problems the POCT users can contact the laboratory via helpline. The quality and precision of POCT has markedly improved as shown by a drop of the rate of invalid quality measurements from 4.75 to 1.5%. POCT in our hospital setting is now a valuable complementation to centralized laboratory services. A good management system is required to ensure reliable results and overall benefit.

Performance of a POC blood ketone meter evaluated by comparison to a photometric method and to GC/MS analysis.

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Introduction: Rapid analysis of ketone bodies, namely acetone, acetoacetic acid and 3-hydroxybutyrate (3-OHB), in human blood is vitally important in the diagnosis and treatment of various metabolic diseases. Its main application, however, is to monitor lipolysis in diabetes mellitus type-1 patients and several fatty acid oxidation disorders. In all conditions leading to an increased blood ketone level a decrease of blood pH poses the main threat, which may lead to ketoacidotic coma and death. Common methods for blood ketone testing are time-consuming and require a well-equipped laboratory. POCT instruments provide fast and accurate bedside measurement for immediate diagnosis and treatment utilizing minimal sample volumes, making these tests suitable for investigating metabolic diseases or DKA in neonatal or pediatric patients. However the reliability of POC methods can be affected by the calibration as well as the influence of sample matrix components (e.g. hematocrit concentration or drug medication).

Aim of the study: The aim of this study was to assess the analytical performance of a handheld POC device, the NOVA[®] StatStrip glucose/ketone connectivity meter (Nova Biomedical, Waltham, MA, USA), by comparison to a standard photometric method (RANBUT, Randox Laboratories Ltd., UK / spectral photometer DU-640, Beckman Coulter Inc., USA) and to GC/MS (TRACE GC Ultra / DSQ-II single quadrupole GC/MS, Thermo Fisher Scientific, USA) as the gold standard. The susceptibility to hematocrit, ascorbic acid and paracetamol was determined as well.

Method: The evaluation of the meter was performed by 'in vitro' tests, where heparinised whole blood from one donor was obtained and pooled. Samples were aliquoted and spiked with 3-OHB in increasing concentrations. For the interference study ascorbic acid or paracetamol were additionally added. All analyses were performed subsequently to avoid degradation of 3-OHB. Hematocrit interference was tested using three 3-OHB concentrations over a 22-60% hematocrit range.

Results: The POCT device correlated well with the photometric standard method ($R^2 = 0,9803$; $y = 0,9718x - 0,182$) over a wide concentration range of 3-OHB (0,5-7,5 mmol/L 3-OHB). The StatStrip meter performed also quite good ($R^2=0,9953$; $y=1,1081x+43,235$) when compared to the GC/MS results over the measuring range important for assessing neonatal and pediatric patients with metabolic diseases (0,1-1,6 mmol/L 3-OHB). Drug interferences: the StatStrip glucose/ketone showed no influences regarding the expected 3-OHB values over a wide range of hematocrit (22-60%), ascorbic acid (0-10 mg/dL) and paracetamol (0-10 mg/dL) concentrations.

Conclusion: POC methods for measuring ketones need to be reliable over the measuring range applicable for the target population to be investigated. For metabolic disease analysis the performance of POC meters needs to be reliable between 0,1-1,6 mmol/L 3-OHB. The StatStrip Ketone meter showed a good correlation to our GC/MS method over this range. For investigation of pediatric DKA a POC device needs to be reliable over a wider and higher measuring range and again the StatStrip Ketone meter showed good correlation over this range. Interference tests were

performed with agents mostly causing problems in neonatology due to the small blood volume in infants. The interfering agents tested did not cause any critical impact on the results. The analytical evaluation of the POC ketone device showed that it could be applicable for use in neonatal and pediatric patients, but this needs to be substantiated further testing real clinical samples.

Accuracy of the ProTime InRhythm™ Coagulation Monitor to International Standards of Thromboplastins

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Introduction: The ProTime InRhythm™ System¹ (InRhythm) is a point of care (POC) device for the quantitative measurement of PT/INR in patients treated with warfarin. The objective of this study was to (1) calibrate the InRhythm system against the international reference standard, which conforms to the World Health Organization “WHO” guidelines and (2) verify the accuracy of the INR calculation using the assigned ISI.

Method: The initial calibration study was performed against human thromboplastin International Reference Preparation (IRP) rTF/95 with ISI= 0.94 followed by a verification study to confirm the INR results using established calibration parameters. The studies were performed at Hemostasis Reference Laboratory “HRL”, Hamilton, Ontario, Canada, using a “split sample” testing matrix in which whole blood was tested on the InRhythm and plasma samples collected from citrate anticoagulated venous blood were tested with the tilt tube method using IRP rTF/95. The calibration study included 60 patients stable on warfarin therapy INR 1.5-4.5 only, and 20 healthy donors not receiving any form of anticoagulant (normal). The InRhythm system ISI was determined using the orthogonal regression analysis. The verification study used the established ISI calibration equation. The INR of the corresponding plasma samples were determined by using both the tilt tube method and the reference laboratory method Dade Innovin® and Sysmex® CA 1500 at HRL.

Results: All orthogonal regression lines of data from patients passed through the normal data and the CV of the slopes were below 3%, thus meeting the requirements of the WHO guidelines. The ISI and MNPT (Mean Normal PT) of the InRhythm was 0.94 and 11.9 seconds respectively. Calculation of INR using these values resulted in a good correlation with the INR from the tilt method INR; $r = 0.97$, $y = 1.04x + 0.05$, mean Bland-Altman bias = 0.14, 95% limits of agreement = -0.24 to 0.52. Similar results were obtained when the InRhythm system was calibrated to a secondary reference method that is traceable to rTF/95. Results from the verification study confirmed these results. The observed correlation coefficient was $r = 0.98$, $y = 1.0469x + 0.0162$ and mean Bland-Altman bias was 0.11 ± 0.17 , 95% limits of agreement = 0.07 to 0.15. Similarly, good correlation to the reference laboratory method using Dade Innovin and Sysmex CA 1500 was observed; $r = 0.97$, $y = 1.0576x + 0.0007$, mean Bland-Altman bias = 0.12 ± 0.18 , 95% limits of agreement = 0.08 to 0.16. Accuracy of duplicate determination with the ProTime InRhythm was demonstrated by the pooled SD (0.082), precision (CV = 3.9%) and a good correlation ($r = 0.99$, $y = 1.0034x - 0.028$). Further verification of the InRhythm calibration was achieved with rTF/09.

Conclusion: The overall results demonstrate the accuracy of the InRhythm to the WHO standard preparation of thromboplastins and to the laboratory reference Innovin/Sysmex method. Thus, the new ProTime InRhythm can be effectively used to monitor patients on oral anticoagulation therapy.

STRATEGIES FOR IMPLEMENTATION OF QUALITY POINT OF CARE FETAL SCALP LACTATE TESTING TO ASSESS FETAL STATUS DURING DELIVERY

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The current Canadian guideline on fetal health surveillance (JOGC 29 Suppl 4, 2007) recommends use of fetal scalp pH to assess the fetus during delivery. At our centre, a change to plastic sample collection rods and new laboratory instrumentation with minimum whole blood sample volume of 65uL led to problems with fetal scalp sample collection and unreliable pH results. Fetal scalp pH testing was discontinued from 2009 to mid 2011, and clinicians had to rely on electronic fetal heart monitoring coupled with digital fetal scalp stimulation to assess fetal compromise and need for operative delivery.

Recent international studies and guidelines have supported the use of fetal scalp lactate as a valid and viable alternative to fetal scalp pH. The laboratory was asked to implement the use of the Lactate Pro (ARKRAY USA, Inc., Medina MN) in the delivery suites, to provide an immediate indication of fetal status during delivery, using only 5uL sample. A combined effort by physicians, nursing and laboratory was initiated to support the implementation of fetal scalp lactate point of care testing.

Methods: Literature on fetal scalp lactate was reviewed. Roles and responsibilities of health care providers (physicians, nurses, laboratory) were defined. Laboratory evaluation of the Lactate Pro included a limited examination of lot to lot variation of test strips, between day precision, comparison of arterial or capillary and cord blood samples to the GEM[®] Premier[™] 4000 (Instrumentation Laboratory, Bedford MA) and assessment of operational factors. Clinical policy and procedure (physician and nursing), and Lactate Pro (laboratory) procedures were written and educational plans developed for clinicians and nurses.

Results of evaluation: Between day precision of aqueous QC at levels of 3.4 and 9.0 mmol/L ranged from 2% to 5% on different devices within one lot number and 3% to 5% across two strip lots. Comparisons to the GEM were significantly different for cord blood (Lactate Pro = 0.76*GEM + 0.3, r = 0.98, n = 18) and fresh arterial/capillary samples (Lactate Pro = 0.91*GEM + 0.17, r = 0.95, n = 11). Delay in testing (time out), incomplete sampling, and sample fill techniques for whole blood and aqueous quality control material were noted to compromise result reliability.

Ward Implementation: Published guidelines for fetal scalp lactate were adopted: normal <4.2 mmol/L; 4.2 – 4.8 mmol/L repeat within 30 minutes; and >4.8 mmol/L delivery is indicated. Carts were assembled with the device and supplies for sample collection and testing. 160 nurses were trained using an "Eduquik" that incorporated clinical and technical information, and a wet-lab to test quality control and a lithium heparin whole blood sample in duplicate. Competency check lists were used to document training. Physicians and residents were educated concurrently about the clinical practice change and trained in sample collection. A report form was developed for manual reporting

of quality control and patient results on the wards. Clinical use commenced 2 weeks from start of training, once core teams of nurses were trained. Results are now entered daily into the Laboratory Information System by the point of care office. Clinical experience was reviewed at 6 months and training adjusted. The wet lab was retained as sample application is critical for accurate results. The next phase will be ongoing competency review.

Conclusion: At BC Women's Hospital, fetal scalp lactate testing at point of care provides an immediate indication of fetal status during delivery. Preliminary review of interventions during delivery and clinical outcomes following fetal scalp lactate testing has demonstrated that the method is successful. A one year review is currently being conducted.

Qualitative Cardiac Fatty Acid Binding Protein POC-Test in an Estimation of Myocardium Damages at Cardiosurgical Patients

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Objective. The aim of this study was to determine whether serum levels of cardiac type fatty acid binding protein (cFABP) are related to myocardium ischemia in patients undergoing cardiopulmonary bypass (CPB) surgery.

Methods. Serum levels cFABP by qualitative express test "КардиоБСЖК" (Russia) was measured in 40 patients: 10 – coronary artery bypass grafting (CABG) with CPB, 10 – CABG with beating heart CPB, 10 - CABG without CPB (of-pump CPB), 10 – valve replacements with CPB. cFABP was measured in blood before surgery, in start of CPB, in 12 hours, for 2 and 3 days after surgery.

Results. Before surgery the test was negative in all cases. At the start of CPB the test also remained negative with all patients. During CPB till 120 min it has not been revealed positive results of the test. In the end of operation in all cases the test has been regarded as positive. At patients after valve replacement surgery intensity of coloring of a test strip was considerably above, than at patients after CABG. Depending on a kind CABG expressiveness of coloring in the end of operation increased in the following sequence: of-pumpCPB < beating heart CPB < CPB. Among patients with CABG only at 2 from 10 persons changes on an electrocardiogram were marked. In 6 hours after surgery positive results of the test were marked at 70 % of patients after CABG, however only 43 % from them had changes on an electrocardiogram. At 30 % results of the test during this period were negative. The test remained positive at 50 % of patients in 12 hours after operation, and at 40 % from them changes on an electrocardiogram were marked. At one patient the test has been regarded as «poorly positive». The same picture was and for 2 days after surgery. For 3 postoperative days the positive test was registered at 20 % of patients against remaining changes on an electrocardiogram. At 80 % of patients the test was negative, including one patient with a peri-operative myocardium heart attack.

Conclusions. Intensity of coloring of a test strip is more expressed at valve replacement surgery that is connected with a straight line myocardium «surgical trauma». At CABG the maximum intensity of coloring is marked at the operations with CPB. At electrocardiograms-signs of a myocardium heart attack after cardiac surgery the positive test "КардиоБСЖК" can serve as a method of an estimation of necrotic process dynamics.

A Novel Technology for 5-Part Differentiation of Leukocytes Point-of-Care

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Introduction and technology: A new hematology system has recently been introduced by HemoCue®. The novel system uses state-of-the-art image analysis techniques to count the white blood cells and perform a 5-part differentiation. A microcuvette serves as a pipette, sample container and reaction chamber. A blood sample of approximately 10 µL is drawn into a cavity by capillary action. The blood dissolves the dry chemistry in the microcuvette, the red cells (erythrocytes) are hemolyzed and the nucleuses of the white blood cells are stained. No dilution is required. When the microcuvette is inserted into the analyzer the measurement starts automatically. A fix volume used in the test is defined by the length of the cavity in the microcuvette and the size of the image (no. of pixels). A camera moved by a high precision motor to achieve an exact and repeatable movement is used to capture images of the stained white blood cells. As the camera moves throughout the cavity of the microcuvette, it takes more than 30 images of each cell. Image analysis technique is used to decide when a cell is in focus, and all focused cells are merged into one final image. By vision technology the cells are then classified into neutrophils, lymphocytes, monocytes, eosinophils, basophils, pathological white blood cells (blasts and immature granulocytes) and others.

The analyzer will flag all samples containing pathological white blood cells. An advanced inbuilt QC-system will check for correct filling of the microcuvette, dirt, improper light, unsharpness, reagent stability etc. The system is factory calibrated and needs no further calibration by the user.

HemoCue® has in the development of the algorithms used state-of-the-art vision technology. More than 30 different features (size, shape, texture, granules etc) have been identified for each cell type and translated into a mathematical algorithm that has been implemented in the analyzer.

Results: The HemoCue® WBC DIFF has shown to give reliable results comparable to laboratory cell counters. Performance including studies from two hospitals and three outdoors doctor's offices will be presented in the poster.

	ADVIA® 2120 (Växjö Central Hospital)	Beckman Coulter® LH750 (Malmö University Hospital)	Sysmex® XS-1000i (Three doctors offices)
Total leukocytes	$y = 0,93^*x - 0,17$ $r = 0,993$ $n = 119$	$y = 0,98^*x - 0,23$ $r = 0,996$ $n = 116$	$y = 0,97^*x - 0,18$ $r = 0,997$ $n = 114$
Neutrophils	$y = 0,87^*x + 0,02$ $r = 0,994$ $n = 101$	$y = 0,94^*x + 0,02$ $r = 0,994$ $n = 84$	$y = 0,98^*x + 0,05$ $r = 0,989$ $n = 92$
Lymphocytes	$y = 0,96^*x + 0,18$ $r = 0,94$ $n = 101$	$y = 0,99^*x + 0,10$ $r = 0,96$ $n = 84$	$y = 1,01^*x - 0,01$ $r = 0,98$ $n = 92$
Monocytes	$y = 1,2^*x - 0,16$ $r = 0,69$ $n = 101$	$y = 0,63^*x + 0,01$ $r = 0,58$ $n = 84$	$y = 0,51^*x + 0,01$ $r = 0,76$ $n = 92$
Eosinophils	$y = 0,92^*x + 0,02$ $r = 0,76$ $n = 101$	$y = 1,13^*x + 0,00$ $r = 0,86$ $n = 84$	$y = 1,11^*x - 0,02$ $r = 0,91$ $n = 92$

Table 1. Data from comparison against three different cell counters

Conclusion: The novel POCT HemoCue® WBC DIFF technology is built on state-of-the-art vision technology. The results from the system are accurate and precise and correlate well to laboratory cell counters.

A white blood cell count including a 5-part diff at the point of care will increase the availability of already well established and frequently used lab parameters. Rapid and easy access will be a valuable tool for physicians in making direct and more well informed decisions in several clinical conditions.

Novel POC analysis for determination of total and 5-part differential WBC count among a US population, in comparison to Beckman Coulter LH750

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Introduction: The purpose of the study was to evaluate the HemoCue WBC DIFF system on both total and 5-part differential WBC count in comparison to Beckman Coulter LH750 when analyzing samples from a US population.

The study was performed at Quest Diagnostics' Hematology Laboratory in Baltimore, MD, USA. A total of 366 different, leftover blood samples were analyzed in one replicate on four different HemoCue WBC DIFF analyzers. Two different batches of microcuvettes were used. As reference method, all samples were analyzed in one replicate on a total of nine different Beckman Coulter LH750 instruments. The study was performed according to CLSI EP9-A2.

The study period ranged over five working days in July 2011. All fresh samples received during the afternoon/evening were included in the study. Some older samples were selected to obtain the sample distribution according to EP9-A2.

Results: A summary of the results from regression analysis for the WBC DIFF system in comparison to Beckman Coulter LH750 is presented in table 1. Basophils could not be evaluated due to very low absolute counts. Scatter plot (least linear regression) for HemoCue WBC DIFF versus Beckman Coulter LH750 for total WBC count is presented in figure 1 and scatter plot (orthogonal regression) for HemoCue WBC DIFF versus Beckman Coulter LH750 for neutrophils is presented in figure 2.

Table 1: Summary of results from regression analysis between WBC DIFF and Beckman Coulter LH750

Cell type	N samples	Correlation coefficient r	Intercept (with 95 % CI) (10 ⁹ /L)	Slope (with 95 % CI) (10 ⁹ /L)
Total WBC	362	0.988	-0.22 (-0.31 to -0.14)	1.01 (1.00 to 1.02)
Neutrophils	343	0.984	0.17 (0.09 to 0.26)	0.98 (0.96 to 1.00)
Lymphocytes	343	0.968	0.13 (0.07 to 0.18)	0.91 (0.89 to 0.94)
Monocytes	343	0.564	0.06 (0.02 to 0.10)	0.51 (0.43 to 0.59)
Eosinophils	343	0.885	-0.01 (-0.02 to 0.01)	1.08 (1.02 to 1.14)

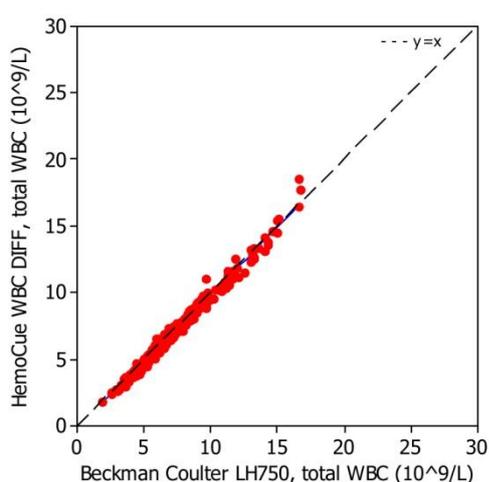


Figure 1: Scatter plot for total WBC

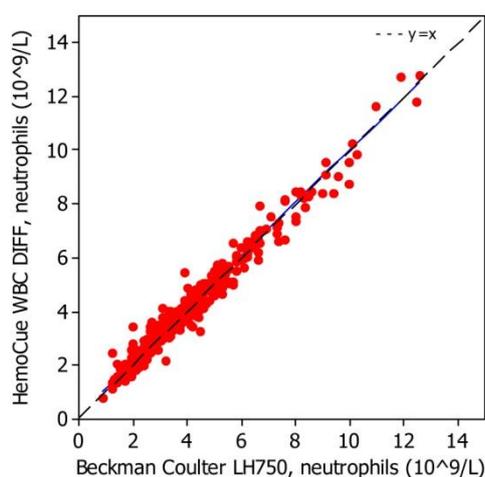


Figure 2: Scatter plot for neutrophils

Conclusion: The novel HemoCue WBC DIFF system for total and 5-part differential WBC count correlates well to Beckman Coulter LH750 when analyzing samples from a US population.

IMPROVING CLINICAL OUTCOMES BY SPLIT CENTRAL VENOUS SAMPLING OF PARATHYROID HORMONE

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Keck Medical Center of University of Southern California is a private, non-profit, 400-bed research and teaching facility located in Los Angeles and staffed by the faculty of USC's Keck School of Medicine. In recent years, many of our endocrine surgeons have requested the rapid intra-operative parathyroid testing as a necessary adjunct to the gold standard of four-gland exploration as a way to exclude multi-glandular disease. The parathyroidectomies performed at our hospitals are assisted and monitored by Intra-Operative Intact Parathyroid Hormone (IO I-PTH) testing. The current IO I-PTH methodology is an immunochemiluminescence assay (ICMA) manufactured by Future Diagnostics that uses a two-antibody sandwich technique for measuring the intact chain (1-84 amino acid) parathyroid hormone molecule. For the past eight years, we have averaged about forty to forty-five parathyroidectomies per year. We have noticed a remarkable decrease in cases of unexplained persistent hypercalcemia after parathyroidectomies.

The availability of the IO I-PTH has been especially crucial with cases of unrecognized ectopic or multiple adenomas, unrecognized supernumerary glands, insufficient excision of hyperplastic tissue, and occasional difficulty encountered in histological differentiation between hyperplastic and adenomatous glands. Yves Chapuis in France (1990) and George Irvin in Miami, Florida (1991) independently reported the use of IO I-PTH monitoring as an adjunct to parathyroidectomy in patients that had positive pre-operative localization with Technetium-99-Sestamibi scintigraphy or high resolution ultra-sonography. The surgical technique requires a pre-incision peripheral IO I-PTH level followed by a post-gland removal level obtained ten minutes after the pathologic parathyroid tissue has been removed. The criteria used to predict post-operative normocalcemia in single gland disease is a drop of fifty percent in the pre-incision hormone level at five or ten minutes after gland excision. These criteria are predictive of a cure in 95% of patients. Weber et al have shown that in patients with four gland hyper-plasia, a 90% drop in IO I-PTH from baseline may be required to confirm excision of Hyper-functioning Parathyroid tissue.

With the advent of the Internet, many patients are doing their research prior to their initial specialist visit. Patients are increasingly requesting minimally invasive surgeries (MIS), limiting the popularity of the four-gland exploration. Using the MIS technique, the patient heals faster and the majority of surgeries are performed as outpatient, saving resources for the hospital. For performance of MIS parathyroid surgery, it is essential that the patient have pre-operative localization of the abnormal parathyroid tissue (solitary adenoma) which then directs a targeted operative approach leaving normal parathyroid tissue undisturbed. Our present study describes the technique of using split venous IO I-PTH samples obtained from the right and left internal jugular veins in patients undergoing parathyroidectomy that have failed to localize an abnormal gland pre-operatively with a Sestamibi scan or high definition ultrasonography. One hundred sixty-six patients underwent neck exploration for hyperparathyroidism at the Keck Hospital of USC between July 2005 and December 2009. Of these patients, a cohort of 66 individuals had IO I-PTH levels drawn from the right and left jugular veins. These 66 consecutive patients represented a change in protocol designed to minimize the extent of surgery and to determine the value of the split central venous PTH levels in verifying the side of the adenoma. Ten of the 66 patients had secondary hyperparathyroidism and were excluded from the study. The peripheral vein sample obtained after induction of general anesthesia served as the baseline pre-operative PTH level. The two internal jugular vein samples were compared looking for a gradient between the right and left sides. Thirty-three patients had positive pre-operative localization of the abnormal parathyroid tissue by Technetium-99-Sestamibi scintigraphy and confirming high resolution neck ultrasonography. The split sample IO I-PTH gradient was used to confirm the side indicated by pre-operative localization studies. Twenty-three patients failed to localize abnormal parathyroid tissue pre-operatively by conventional imaging. In this latter group, the split internal jugular vein samples were compared looking for a gradient in the absolute PTH value which then directed the initial side of surgical exploration. If an abnormal gland was identified, it was removed and the IO I-PTH was determined ten minutes later from a peripheral vein. Failure of the IO I-PTH to drop greater than 50% from the baseline value resulted in a bilateral four gland exploration. Our studies show that the greater the absolute value of the gradient between the left and right IJ samples, the more likely the gradient was to predict the side of the tumor. Furthermore, it is evident that a gradient greater than 200 correctly predicted tumor side with 100% accuracy. For values between 20 and 200, the gradient correctly predicted tumor side in 15 of 17 (88%) patients. In summary, identifying the correct side of parathyroid gland pathology allows the surgeon to perform a more focused and less invasive operation without compromising results and minimizing the morbidity of bilateral surgery.

An Economic Model Incorporating a Point of Care Platelet Function Assay: A Quality Improvement and Value Assessment Tool

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BACKGROUND: Dual antiplatelet therapy with a P2Y12 inhibitor and aspirin is the standard of care for secondary prevention of major adverse cardiovascular events (MACE). These medications are used to prevent platelet activation and aggregation, thereby reducing the chance of thrombus formation and subsequent MACE. It is well documented that not all patients respond equally to their antiplatelet medications, and percutaneous coronary intervention (PCI) patients who do not respond adequately may be at significantly greater risk for heart attack, stroke, death, and associated 30-day hospital readmissions. Patients on antiplatelet therapy are also at increased risk for bleeding, contributing to the risk for surgical procedures such as coronary artery bypass graft (CABG) or orthopedic surgery. Previously, guidelines recommended that surgical candidates have their antiplatelet medications discontinued 5 to 7 days prior to surgery. While waiting for the effects of these medications to diminish, many of these patients were occupying hospital beds. Surgical guidelines now provide for the incorporation of a point of care platelet function test (PFT) to help assess the risk of potential bleeding due to the presence of these antiplatelet agents, thereby preventing delay of necessary surgery. The objective of this study is to examine the economic impact of the incorporation of a PFT on PCI and CABG patient populations.

METHOD: We designed a Quality Improvement and Value Assessment Tool incorporating a PFT to estimate and model the potential impact of integrating PFT into cardiovascular patient care. Specifically, we examined two clinical scenarios: 1) the potential reduction in 30-day hospital readmissions following stent procedures, resulting from the measurement of platelet reactivity and modification of antiplatelet therapy to achieve a target level; 2) the potential reduction in pre-op medical admission days for CABG patients, resulting from measurement of platelet reactivity and determination of when CABG patients would no longer be displaying an antiplatelet effect following discontinuation of a P2Y12 inhibitor.

RESULTS: Using this model with a typical US hospital performing 650 PCI patients per year and 225 CABG patients per year, the Quality Improvement and Value Assessment Tool estimates that integrating a PFT into patient care protocols could yield 3.3 fewer 30-day readmissions, 80 fewer pre-CABG medical admission days, and cost avoidance of over \$120,000 per year, for a 3-year total of \$365,000. In comparison, the associated cost of the instrument and reagents for the system used in this model is estimated at \$30,000 the first year, and \$63,000 over 3 years. Models are available that can be adapted to other cost metrics and in different currencies. The PFT costs used in this model are specific to the VerifyNow® Point of Care System.

CONCLUSION: The incorporation of PFT into clinical practice may contribute to decreased 30-day readmissions and pre-CABG admission days. This represents a significant cost savings while reducing readmissions and preventing delays in needed surgery.

Study of whole blood patient samples using point-of-care cardiac troponin I assay based on Magnotech technology

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INTRODUCTION

Cardiac troponin I (cTnI) testing is a key element in the evaluation of patients with chest pain and suspected acute coronary syndromes with a recommended turnaround time (TAT, time from blood draw to reporting of result) of ≤ 1 hour. Point-of-care (POC) testing for cTnI in the emergency setting may offer a solution when central lab testing does not meet the 1-hr TAT requirement. We are developing a novel cTnI POC test using Magnotech technology on a handheld device that allows testing from a single droplet of whole blood in less than 10 minutes. The objective of this study is to show that full recovery of cTnI is obtained using whole blood compared to its plasma in patient samples.

METHODS

The cTnI POC test is a one-step sandwich immunoassay that is completed in a compact plastic disposable cartridge with on-board dry reagents and superparamagnetic nanoparticles. With this Magnotech technology the amount of bound nanoparticles, proportional to the amount of cTnI in the sample, is optically detected [1]. A filter (to remove red blood cells) has been incorporated into the cartridge and signals from fresh cTnI positive patient samples (whole blood and plasma) have been compared with and without filter. This study has been performed using 40 patient samples from 3 different sites. All samples (whole blood with filter, plasma with filter, plasma without filter) were tested in 5 replicates. Cartridge filling time was measured and related to patient hematocrite values. In addition, whole blood stability was studied for 24 hours on a subset of patient samples.

RESULTS

cTnI positive patient samples were measured on cartridges with filter. The average recovery percentage between whole blood and plasma was close to 100%. Cartridge filling time increased with patient hematocrite value but time-to-result remained below 10 minutes. It was also found that whole blood samples can be stored for several hours before testing without significantly impacting the observed TnI concentration.

CONCLUSIONS

The current development status of the Magnotech technology-based cTnI POC assay shows high recovery of cTnI in patient blood samples. The development of this rapid (<10 min) bedside assay for emergency care is ongoing, and future steps will be to obtain similar performance to a cTnI assay on a central lab system.

REFERENCES

Dittmer WU, et al. Clin Chim Acta. 2010; 411: 868-73.

Next generation, fast and accurate point-of-care test for NT-proBNP based on Magnotech technology

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INTRODUCTION

In the emergency care setting, where time is of the essence, there is a need for fast and reliable information on NT-proBNP levels for diagnosis and management of acute dyspnea [1]. Rapid NT-proBNP testing near the patient has the potential to streamline the process of care, but only if it is robust, fast and accurate enough to operate safely at the point-of-care (POC) [2]. Here we report on the development of a novel NT-proBNP POC test which can be entirely carried out in a handheld device. This test has the potential to be rapid (less than 8 min), easy to use, and with good accuracy compared to state-of-the-art automated lab assays currently on the market.

METHODS

This new NT-proBNP POC test under development is based on Magnotech technology. A one-step sandwich immunoassay is performed in a compact plastic disposable cartridge with on-board dry reagents and magnetic nanoparticles. After a short incubation step the amount of bound nanoparticles, proportional to the concentration of NT-proBNP in the sample, is detected optically [3].

The precision of the assay was determined for plasma samples with NT-proBNP levels at clinically relevant values of 125 ng/L and 411 ng/L (10 replicates). Assay accuracy was determined by measuring 104 patient samples (lithium heparin plasma, NT-proBNP levels from 20 to 5000 ng/L) on both the handheld device and the bioMérieux VIDAS lab system, and comparing results by Passing and Bablok regression analysis.

RESULTS

Assay precision was characterised by CV levels of less than 10%. NT-proBNP results correlated well with VIDAS ($r=0.89$), with a corresponding slope of the regression line of 1.12 (95% CI 1.01 to 1.22) and an intercept of 64.04 (95% CI -73.50 to 109.83). In the current format under development, the NT-proBNP assay time with plasma samples is only 5 minutes. We are in the process of adding a filter that will allow measurements from whole blood directly. Flow experiments show that the filling time of the cartridge with whole blood is less than 30 seconds, resulting in a total assay time of less than 6 minutes, and a time-to-result of less than 8 minutes.

CONCLUSIONS

In its current implementation the Magnotech-based NT-proBNP assay shows promising performance for rapid, reliable NT-proBNP testing at the point of care in emergency settings. Development work is presently focused on the integration of a blood filter into the cartridge, to allow fingerprick tests.

REFERENCES

1. Januzzi JL, et al. Am J Cardiol. 2008; 101 (Suppl.): 29A-33A.
2. Alehagen U, et al. Eur J Heart Fail. 2008; 10: 260-6.
3. Bruls DM, et al. Lab Chip. 2009; 9: 3504-10.

Evaluation of the HemoCue WBC DIFF system for point-of-care counting of total and differential white cells in pediatric samples

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Introduction: Point of Care Testing (POCT) accelerates the availability of critical labtest information that clinicians require to make rapid treatment decisions and monitor a patient's response. Especially, in pediatric environments, the ability to perform multiple tests with just a few drops of blood is precious. Leukocyte count and differentiation is an important tool in diagnosing infections. Recently, HemoCue launched a POCT analyser, able to count and differentiate white blood cells (HemoCue WBC DIFF system) in 10 μ L finger prick blood using a microcuvette. In the cuvette red blood cells are lysed and white blood cells are stained. Cells are counted and analyzed by using image analysis.

Methods: The total leukocyte and differential counts of 199 capillary EDTA blood samples from children up to 12 years of age were tested in parallel by the HemoCue WBC DIFF system to assess the precision and accuracy designed according to CLSI EP9-A2. Reference counts were obtained by a standardised Sysmex-XE5000 automated cellcounter (Sysmex Corporation, Kobe, Japan).

Results: In the tests for precision, the HemoCue DIFF system showed for the total WBC count a maximum CV of 3.6% and for the differential WBC count a maximum CV of 7.6% (neutrophils, lymphocytes) or a maximum SD of $0.07 \times 10^9/L$ (monocytes, eosinophils and basophils), fulfilling the acceptance criteria for pediatric samples (see Table 1). In the tests for accuracy, orthogonal regression analysis ($y=b+ax$; b =intercept and a =slope at 95% confidence level) and measurements of correlation coefficients (r) showed good results for total WBC ($-0,2+1.02x$, $r=0.98$), neutrophils ($0.2+0.95x$, $r=0.97$), lymphocytes ($0.02+1.10x$, $r=0.94$) and eosinophils ($0.002+1.01x$, $r=0.93$) between the HemoCue DIFF system and Sysmex XE5000. The result for monocytes was $0.06+0.52x$, $r=0.61$, while calculations for basophils were not performed due to a low count. The flagging frequency was 15%, acceptable compared with standardized automated cellcounters. Samples regarding ages of children up to 12 years were equally distributed.

Conclusion: The HemoCue WBC DIFF system is reliable for counting and differentiating WBCs in pediatric samples. It correlates well with the Sysmex-XE5000 automated cell counter with acceptable flagging frequency. It is simple to use and provides a rapid provision of results that could facilitate adequate decision making leading to improved clinical outcomes.

Table: Precision of total and differential WBC on the HemoCue WBC DIFF system

Cell type	Number of samples	Range ($10^9/L$)	SD/%CV	Limits of acceptance
Total WBC	7	2.5 – 3.5	CV 3.3%	CV $\leq 10\%$
	169	3.6 – 20.0	CV 3.6%	CV $\leq 5\%$
Neutrophils	66	1.5 – 3.5	CV 7.2%	CV $\leq 15\%$
	80	3.6 – 19.3	CV 4.3%	CV $\leq 8\%$
Lymphocytes	95	1.1 – 3.5	CV 7.6%	CV $\leq 15\%$
	48	3.6 – 8.2	CV 6.1%	CV $\leq 8\%$
Monocytes	142	0.1 – 1.0	SD $0.07 \times 10^9/L$	SD $\leq 0.3 \times 10^9/L$
Eosinophils	145	0.0 – 1.0	SD $0.06 \times 10^9/L$	SD $\leq 0.3 \times 10^9/L$
Basophils	146	0.0 – 0.1	SD $0.01 \times 10^9/L$	SD $\leq 0.3 \times 10^9/L$

CAPILLARY BLOOD SAMPLE (DILUTED), PNEUMATIC TRANSPORT SYSTEM AND HIGH SENSITIVITY CRPH SYNCHRON® SYSTEMS ASSAY (BECKMAN COULTER) : A NEW RELIABLE AND ECONOMICAL ALTERNATIVE TO (USUAL) POINT-OF-CARE TESTINGS IN PEDIATRIC POPULATION, IMPROVED BY HEMATOCRIT CORRECTION

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Background. C-reactive protein (CRP) point-of-care testing methods (POCT) were found valuable to differentiate bacterial and viral infection, but require new equipments, clinical staff training, time consuming and are costly. Utilising the ultra sensitive Synchron®CRPH assay (Beckman Coulter) in (diluted) capillary blood sample and our hospital pneumatic transport system, we developed a new reliable alternative procedure to POCT, incorporating a hematocrit correction.

Materials. Glass capillaries (20µL) with plug and plunger; microtubes: Minicollect® Closure Cap with Cross Cuts (Greiner Bio-One) containing 100µL of haemolysing solution: Triton- X100 (0.3%) and anti-foam B (0.1%) in PBS (0.01M:Sigma-Aldrich®).

Procedure. After pricking and filling the glass capillary, the blood is applied in microtube by pushing through the cap (useless wiping). After vigorous shaking and being carried by the pneumatic system in laboratory, CRP is directly determined (neither transferring sample nor removing cap) with CRPH Synchron® assay and haemoglobin by a home-made adaptation of the SLS method of Oshiro and all. (giving equivalent performances, thus valid haemoglobin concentrations) on the Unicel® DXC 880i (Beckman Coulter), the results corrected for the hematocrit (calculated according to Wennecke).

Methods. Diluted whole bloods from hospitalised patients were analyzed by our new procedure (pneumatic transport included) according to the techniques validation protocol VALTEC (of the SFBC); the whole blood results (n=67) were compared with those of their plasma.

Results. Intra-assay CV's were 7.9% and 5.3% and Inter-assay CV's 8.1% and 6.7% at 10g/L and 60g/L respectively, with detection limit <2 mg/L and linearity >400mg/L; no hook-effect, no interference with bilirubin nor turbidity in the conditions of the protocol and excellent correlation between whole blood and plasma : the Passing-Bablok regression equation is $Y = 1.02X + 0.34$ (r=1.00), with no rejected point in Bland-Altman plot.

Conclusion. The superior accuracy achieved with the correction of the hematocrit (especially in extreme values) and the good performances of this procedure: simple and robust (very few and easy manipulations), hygienic and economical (very cheap reagents for SLS method), and usable in all the clinical services, thus allow us to use this one. Clinicians can consult the results in less than 30mn, time-limit a little longer than near-patient tests, but compatible with clinical practice, and the main goal is to reduce the venous blood samplings in this particular population.

Evaluation of Roche Cobas b123 as Blood Gas POCT

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Background

The objective of this study was to verify the analytical performance of the new blood gas analyser launched by Roche Diagnostics in 2011; Cobas 123. Our team also evaluated the suitability of this instrument to be used as a POCT setting.

Methods

The analytical performance of the instrument was verified for imprecision and method comparison. Imprecision was carried out by measuring three levels of QC material (COMBITROL PLUS B supplied by Roche) in triplicate over five days in accordance to CLSI EP5-A2 guidelines. The accuracy for pH, pCO₂, pO₂, electrolytes, ionised calcium and lactate was compared against the central laboratory blood gas analyser Roche Omni C and Abbott iSTAT using 36 patient samples while total haemoglobin and haematocrit were compared against the central laboratory Sysmex XT1800 using 26 patient samples. Two parameters including ease to use and safety-related factors were used to assess the suitability of this instrument for POCT purpose.

Results

The total imprecision was satisfactory; coefficient variation of less 4% were obtained for all the test parameters. The method comparison results showed good correlation between Cobas b123 and other comparative methods. Excellent correlation coefficients between 0.92 and 0.99 were achieved for most parameters except for sodium and ionised calcium with $r = 0.82$ and $r = 0.80$ respectively. Survey conducted on 10 nurses of different grades who had hand-ons experience on a trial unit for 2 weeks showed that the instrument is easy to use and virtually free of maintenance. The availability of “auto-lock” functionality, automated QC, clot detector and connectivity makes the instrument safe to use and ideal for POCT setting.

Conclusions

Cobas b123 showed satisfactory performance in analytical studies and suitable to be used as POCT in hospital critical care setting.

An evaluation of the ChemPac XDM Complete Blood Counter for Point-of-Care Testing in the Emergency Department

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The ChemPac XDM is a newly developed point-of-care testing instrument for CBC, i.e. hemoglobin, total leucocytes, granulocytes, lymphocytes, monocytes, platelets, red blood cells and MCV. It uses one drop of blood in a single-use disposable cartridge, and results are available three min. after insertion. We tested the performance with venous samples from 92 patients admitted to the Emergency Department of Herlev Hospital. An Advia 2120 from Siemens served as reference instrument, using the same EDTA sample.

	Difference		unit	Correlation	
	Mean	SD		coefficient r	slope
Total leucocytes	0.3	± 0.7	10 ⁹ /L	0.99	0.99
Granulocytes	0.1	± 0.6	10 ⁹ /L	0.99	0.97
Lymphocytes	0.4	± 0.5	10 ⁹ /L	0.73	0.78
Monocytes	- 0.2	± 0.2	10 ⁹ /L	0.64	0.38
Platelets	40	± 39	10 ⁹ /L	0.97	0.96
Hemoglobin	0.5	± 0.4	mmol/L	0.96	1.13
Red blood cells	0.1	± 0.1	10 ¹² /L	0.98	1.08
MCV	- 2.9	± 5.6	fL	0.68	0.50

In the emergency department an important clinical task is to rule out severe bacterial infection, so the patient can be discharged. This requires a high sensitivity (few false negatives). The ChemPac XDM detected all the 35 samples with total leucocytes above 10.0⁹/L and 41/42 samples with granulocytes above 8.0⁹/L. One patient with 8.3⁹/L granulocytes by the Advia 2120 and 7.9⁹/L by the ChemPac XDM was misclassified. The specificity was also high with few false positives, correctly classifying 50/54 with leucocytes ≤ 10.0⁹/L and 47/48 with granulocytes ≤ 8.0⁹/L. Three patients with granulocytes < 1.8⁹/L were correctly classified, of importance for patients with sepsis or receiving chemotherapy. Another clinical task is to rule out thrombocytopenia. The sensitivity for thrombocytopenia was 100%. All 11 samples with platelets < 150⁹/L by the Advia 2120 were correctly detected by the ChemPac XDM. The specificity for thrombocytopenia (i.e. few false positives) was 66/71, which was acceptable. A normal result by the Advia 2120 would soon be available, and the misclassified patient could then be discharged based on the normal result. The final task is to rule out clinically important anemia. The positive bias decreased the ability of the ChemPac XDM to detect mild anemia determined by the Advia 2120. The sensitivity for hemoglobin < 6.0 mmol/L was only 18/24. However, two patients with more severe anemia and hemoglobin < 5.0 mmol/L were correctly classified by the ChemPac XDM. The accuracy and diagnostic sensitivity to anemia can probably be improved by re-calibration. Red cell indices can be used to diagnose the cause of anemia, which however is irrelevant in the clinical setting of an emergency department. The correlation between red blood cells by the two instruments was good with r = 0.98.

The ChemPac XDM results for leucocytes and granulocytes can be used to rule out severe bacterial infection or leukemia, and there is no need to wait for the Advia 2120 results before discharging a patient with suspected bacterial infection and normal results by the ChemPac XDM. Life threatening thrombocytopenia can also safely be ruled out based on the ChemPac XDM result. Mild anemia can not be ruled out, and the diagnosis of mild anemia must await the Advia 2120 result. However, provided the clinical condition allows it, the patient can be discharged, and a low hemoglobin result by the Advia 2120 can be dealt with later by the patient's physician at home.

Predictive End Point Methodology for Reducing Time to Result in POC Analyzers

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Rapid report of clinical parameters such as blood gases and metabolites is important in critical care areas for prognosis and clinical outcome. Typically, such measurements are accomplished by blood analyzers using various electrochemical and enzymatic sensors and the result is reported when the sensor output has reached an end point which is close to an equilibrium or steady state level. However, reaching an end point for sensors with diffusion controlled response characteristic, such as pO₂ and glucose could cause delay in reporting the sample results.

This paper describes a methodology for reducing time to result by predicting the end point through signal extrapolation before the sensor response reaches equilibrium or steady state. This is accomplished by fitting the generated voltametric or amperometric sensor signals with a logarithmic function of response time. The methodology allows for using a simple linear or quadratic curve fitting equation for end point prediction. In contrast, the conventional curve fitting methodologies require finding roots of non-linear equations which is computationally intensive and requires high CPU time and potentially reduced throughputs.

Evaluation of the predictive end point methodology was accomplished by using sensor response in the GEM® Premier 4000 analyzer (Instrumentation Laboratory, Bedford, MA). Sensor output was collected at one second intervals and the response from 15 to 30 seconds was used to predict the end result at 55 seconds. Data from six GEM Premier 4000 analyzers running five levels of quality control materials over a period of four weeks were pooled and processed. Examples of the predicted and actual end points for various sensor types including amperometric (pO₂) and enzymatic (glucose and lactate) are summarized in the Table. There is a good agreement between the predicted and actual values. This study demonstrates capability of the new predictive method for reducing time to result in clinical analyzers.

Analyte	QC Level	Average of Actual	Average of Predicted	Average of Delta	SD of Delta
PO ₂	1	35	32	-2.5	0.36
	2	51	49	-2.1	0.24
	3	91	90	-1.5	0.22
	4	262	263	0.8	0.96
	5	565	571	6.2	0.89
Glucose	1	17	17	0.07	0.9
	2	94	94	0.20	1.3
	3	194	195	0.69	2.3
	4	472	472	0.46	6.2
	5	676	674	-2.01	7.1
Lactate	1	0.4	0.4	0.01	0.04
	2	0.9	0.9	0.00	0.03
	3	4.3	4.3	0.03	0.05
	4	10.3	10.4	0.08	0.11
	5	15.3	15.4	0.11	0.13

Performance of cassette-based blood gas analyzers to monitor blood glucose and lactate levels in a surgical intensive care setting

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INTRODUCTION: Strict maintenance of normoglycemia (between 80-110 mg/dL) via intensive insulin therapy reduces in-hospital mortality and morbidity of surgical intensive care unit patients (1). Blood gas analyzers (BGA) are suitable point-of-care systems for accurate monitoring of glycemia (2). The classic BGA validated for intensive insulin therapy on ICU (1) have been superseded by cassette-based (“all-in-one”) BGA. As little is known about the analytical reliability of cassette-based BGA to monitor patient’s metabolic status in an ICU setting, we performed a method comparison study to assess the analytical performance of cassette-based BGA.

METHODS: Skilled nurses drew via an indwelling arterial line 149 heparinized blood gas and fluoride oxalate samples from patients hospitalized in a surgical intensive care unit over a period of 1 week. Blood gases were analyzed within 5 minutes after sampling on a classic BGA: ABL800 (Radiometer), and on two cassette-based BGA: RP500 (Siemens) and ABL90 (Radiometer). All BGA use glucose oxidase and lactate oxidase to measure glucose and lactate. The order of analysis on the BGA was randomized to cancel systematic differences due to delayed analysis. All analyses were performed within 14 min. A fluoride oxalate sample was drawn immediately after the arterial blood gases, and centrifuged within 5 min. Centrifugation was for 10 min at 4 °C to separate plasma from cells and transfer of the supernatants to a fresh vial secured stability of the metabolites to be measured. On the latter samples glucose and lactate were measured by reference methods on Modular P (hexokinase glucose 6-phosphate dehydrogenase - Roche Diagnostics) and on Dimension (lactate dehydrogenase - Siemens), respectively. All correlations were expressed versus the reference method, using orthogonal regression analysis and residual plot analysis. Sufficiency of the accuracy was evaluated on the basis of preset acceptance criteria. For glucose we allowed a total proportional error of 8% for all values (Boyd and Bruns (3)). For lactate we allowed a total error of 0.15 mmol/L and a proportional error of 30.4% for values below and above 0.5 mmol/L, respectively (desirable specs, Ricos (4)). Imprecision (repeatability) of glucose and lactate measurement on BGA was assessed on quality control material as well as on whole blood.

RESULTS:

The average repeatability estimated from duplicate (n = 124) measurements on clinical samples on the reference analyzers was 1.0% at 108 mg/dL (range of 52-274 mg/dL) and 3.5% at 2.01 mmol/L (range of 0.52–16.16 mmol/L) for glucose and lactate, resp.. The estimated average repeatability for glucose measurement on the BGA was 1.1%, 0.8% and 2.4% for the ABL800, ABL90 and RP500, resp.. The estimated average repeatability for lactate on the BGA was 4.0%, 4.2% and 5.6% for the ABL800, ABL90 and RP500, resp. .

The following regression equations (y = system tested *versus* x = reference method) were found for glucose. For ABL800: $y = 0.439 + 1.031 x$ ($r^2 = 0.987$); for ABL90: $y = - 0.580 + 0.969 x$ ($r^2 = 0.990$); and for RP500: $y = - 4.618 + 1.014 x$ ($r^2 = 0.980$). For lactate the following regression equations were found ; for ABL800: $y = 0.088 + 0.855 x$ ($r^2 = 0.940$); for ABL90: $y = 0.032 + 0.896 x$ ($r^2 = 0.953$); and for RP500: $0.186 + 1.034x$ ($r^2 = 0.851$).

The following percentage of results fell within the preset acceptance limits: for glucose: 98.7%, 100% and 98.7% and for lactate: 100%, 98.7% and 98.7%, each time for ABL800, ABL90 and RP500, resp..

CONCLUSION: The cassette based systems tested here were capable of measuring glucose and lactate levels, within the predefined error range. We conclude that cassette-based BGA can be used for reliable monitoring of patient’s metabolic status in an ICU setting.

(1) Van den Berghe G et al, Intensive insulin therapy in the medical ICU. *N Engl J Med.* 2006 Feb 2;354(5):449-61.

- (2) Vlasselaers D et al, Blood glucose measurements in arterial blood of intensive care unit patients submitted to tight glycemic control: agreement between bedside tests. *J Diabetes Sci Technol.* 2008 Nov;2(6):932-8
- (3) Boyd JC et al, Monte Carlo simulation in establishing analytical quality requirements for clinical laboratory tests meeting clinical needs. *Methods Enzymol.* 2009;467:411-33.
- (4) Ricos C et al, Current databases on biologic variation: pros, cons and progress. *Scand J Clin Lab Invest* 1999;59:491-500.

Evaluation and Performance of StatStrip® Glucose meter

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INTRODUCTION

Point-of-care testing glucose meter usage are on the increase, and is widely used in monitoring hospitalized patients as well as by patients for self-monitoring. A major concern is the accuracy of glucose meters in different clinical settings. StatStrip® (Nova Biomedical, Waltham, MA, USA) is a new generation glucose and quantitative ketone meter designed to correct for common biochemical interferences and measuring and correction for haematocrit.

AIM

Our aim was to assess the analytical performance of the StatStrip® (Xpress and Connectivity) to two Accucheck Active® meters (Roche Diagnostics, Mannheim, Germany), currently used in monitoring glucose in-hospital and by patients in the public health sector in South Africa. Plasma glucose by the glucose oxidase method on the Siemens Advia 1800 (Siemens Diagnostics, Munich, Germany) was used as the reference method.

METHODS

Haematocrit Interference:

Haematocrit interference was evaluated using 3 glucose concentrations over 5 different haematocrit levels (22 -67%).

Chemical Interference:

Interference studies were performed with ascorbic acid, maltose, xylose and acetaminophen. Whole blood samples were used with different glucose levels spiked with different concentrations of interferents.

Method Correlation:

Heparinised venous whole-blood samples were collected from patients attending the medical outpatients department and measured and compared to the reference method. Accuracy was assessed by comparison to ISO15197 glucose performance criteria.

Ketone Measurement:

The StatStrip[®] meter quantitates ketones (β -hydroxybuterate) as well. A limited interference study testing haematocrit and ascorbic acid interference was performed.

RESULTS

Haematocrit Interference

The Accucheck Active[®] meters were affected by abnormal haematocrit levels showing significant bias with both low and high haematocrit levels (5.85 to 21.24%). The StatStrip[®] meters were unaffected by abnormal haematocrit levels.

Chemical Interference

At all levels of maltose and xylose interference the Accucheck Active[®] demonstrates significant interference. Ascorbic interference was demonstrated at low and normal glucose levels on the Accucheck Active[®]. The StatStrip[®] meters remained unaffected by these chemical interferences.

Method Correlation and Accuracy

StatStrip[®] correlated best to the reference method and demonstrated the lowest bias. It was the only meter to satisfy the requirements of ISO15197 performance criteria.

Ketone Measurement

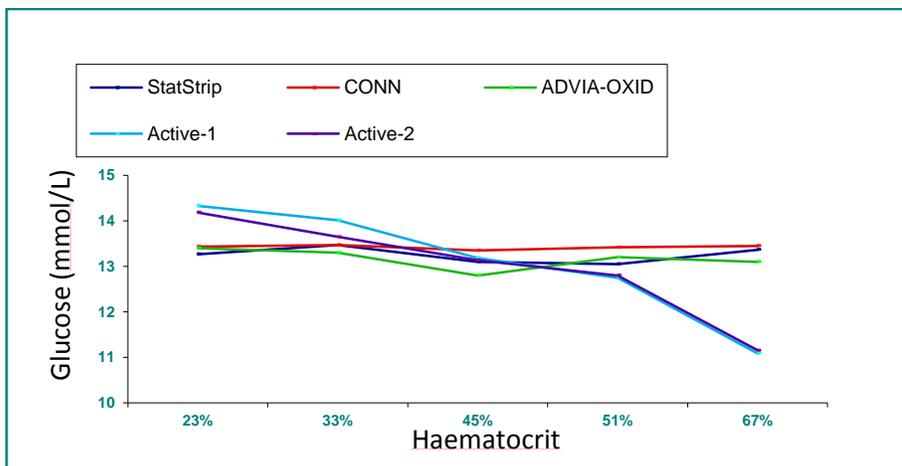
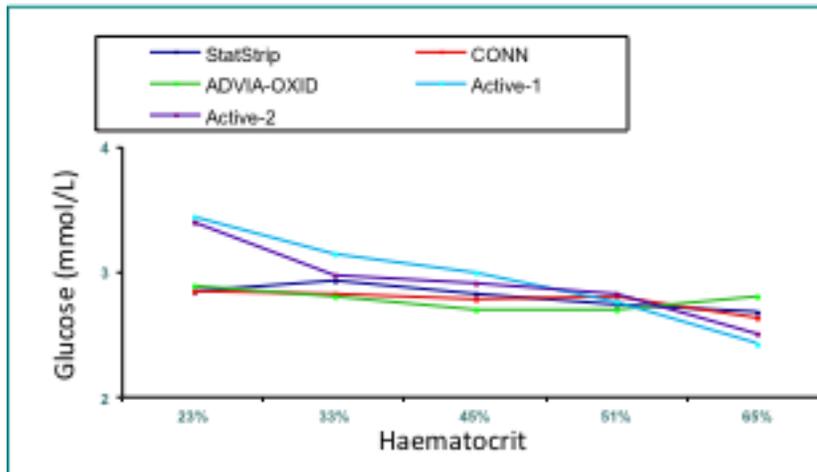
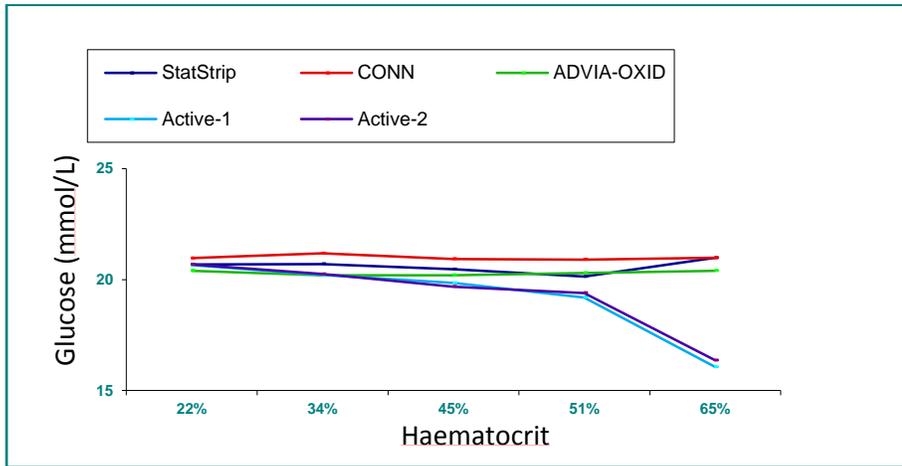
The StatStrip[®] meter ketone measurement was unaffected by haematocrit and ascorbic acid interference.

CONCLUSION

The StatStrip[®] glucometers demonstrated acceptable correlation when compared to the reference method, and was not susceptible to common interferences observed on currently used glucometers. Our current glucometer is not suitable for use in patients with anaemia and the neonatal population, as demonstrated by the haematocrit interference study. We are aiming to continue evaluating the StatStrip[®] glucometer in different clinical settings, e.g. high care, outpatient diabetic clinics and in the primary health care units to verify our laboratory evaluation findings.

Evaluation and Performance of StatStrip® Glucose meter (Graphs)

Haematocrit Interference



Multiplexed fluorescence immunoassay system for comprehensive serologic testing at the point-of-care

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MBio Diagnostics is developing a multiplexed immunoassay platform capable of simultaneous detection of serologic disease markers from a single drop of blood. Here we demonstrate the system in the context of HIV and AIDS-related co-infection testing. Multianalyte testing at the time of HIV diagnosis is essential for individualized management of HIV infection.

Unfortunately, co-infection testing is costly and too complex for most POC environments, particularly in resource-limited settings where disease burden is highest. The MBio POC System is designed to address the unmet need for timely and cost-effective co-infection testing.

The MBio multiplexed immunoassay system is based on single-use disposable cartridges and an inexpensive reader. Cartridges designed for simultaneous detection of antibodies (Abs) against HIV-1, hepatitis C virus (HCV), and *T. pallidum* from a single drop of whole blood sample were tested in an HIV clinic setting. Samples from participants representing various co-infection combinations were evaluated on the MBio system.

Ab reactivity results (pos or neg) were reported by the MBio system for 67 samples. 63 HIV Ab reactive samples were correctly reported as HIV Ab reactive on the MBio assay. 3 HIV Ab neg samples were correctly reported neg on the MBio assay. One sample was from a HIV-pos individual known to have initiated antiviral therapy during seroconversion; this sample was neg on both MBio and an FDA-approved HIV-1/2 rapid test. The MBio HCV Ab assay correctly reported reactivity for 12 of 13 known pos, and correctly reported no reactivity 49 of 50 known negs. The MBio treponemal Ab assay correctly reported reactivity for 20 of 23 TPPA pos samples, and correctly reported no reactivity 35 of 39 TPPA negs. The MBio system returned indeterminate results for 4 HCV samples and 4 syphilis samples.

The MBio POC system showed good concordance with reference methods on a cohort of complex co-infection samples, using a simple, disposable cartridge test format. Multianalyte testing from unprocessed whole blood at the POC should enable improved therapeutic decision making, particularly in limited resource settings.

Analytical Evaluation of Pleural Fluid as a Sample Matrix on GEM® Premier 4000 Analyzer
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Pleural fluid is found between the layers of tissue that line the thoracic cavity to lubricate the pleura and facilitate breathing. An excess amount of this fluid, known as pleural effusion, can complicate a range of pulmonary and non-pulmonary diseases such as heart failure, pneumonia, and autoimmune diseases such as rheumatoid arthritis. Alternatively with lung cancer, pleural effusion is quite common, and can be benign or due to the spread of lung cancer cells into the pleural cavity (malignant pleural effusion).

Measurement of pleural fluid pH is useful for diagnosis and management of patients with pleural effusion. pH of normal pleural fluid is approximately 7.6. Low pleural fluid (pH <7.3) may be used in identifying lung diseases such as pneumonia and cancer, and indicates the need for immediate therapeutic action. Several publications state that only pleural fluid pH values provided by blood gas analyzers are accurate enough for clinical decision making.

In order to evaluate the ability of the GEM Premier 4000 (Instrumentation Laboratory, Bedford, MA) to report pH of pleural fluid, preliminary testing was conducted to quantify analytical performance with a proposed reportable range from 6.90 – 7.60. To establish precision, pleural fluid adjusted to 3 pH levels, representing normal and pathological medical decision levels, was run twice daily over 20 days per CLSI EP5-A. Samples were assayed on four GEM Premier 4000 analyzers, and two classic blood gas analyzers using glass pH electrodes: ABL735 (Radiometer Medical, Denmark) and two Synthesis 1740 (Instrumentation Laboratory, Bedford, MA). Precision performance of the GEM Premier 4000 was not significantly different than either classic glass electrode pH design (alpha=0.05).

Table 1: GEM Premier 4000, ABL 735, and IL Synthesis Analysis of Pleural Fluid Precision

pH Target	Within Run SD GEM 4000	Within Run ABL 735	Within Run Synthesis
7.10	0.010	0.010	0.015
7.30	0.013	0.012	0.013
7.50	0.012	0.016	0.013

In addition, a matrix evaluation was conducted per CLSI EP14-A2. Frozen patient samples from critically ill patients were provided by St. Patricks Medical Center (Missoula, MT). Samples were thawed, equilibrated with pCO₂ to span a pH from 7.30-7.55 and evaluated on three GEM Premier 4000 analyzers and an ABL 735. In-house whole blood from healthy adults was manipulated to span the same analytical range. No significant difference between the mean bias of pleural fluid as compared to whole blood was observed (alpha=0.05).

Table 2: Matrix Evaluation of Pleural Fluid vs Whole Blood using ABL 735 as reference

	Pleural Fluid	Whole Blood
Mean Bias (95% CI)	0.00 (-0.03 to 0.02)	0.01 (-0.02 to 0.00)

In order to establish claims and validate the process by which patient results could be reported, a full analytical evaluation would be required. From the testing completed, we conclude the GEM Premier 4000 will provide accurate and precise results for measurement of pleural fluid pH, comparable to classic sensor designs. Therefore expansion of sample types to include pleural fluid is a potential application for future system capability.

Evaluation of POC methods for measurement of ketones in metabolic medicine.

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Introduction: Glucose homeostasis is maintained by gluconeogenesis, reutilisation of glucose derived intermediates and fatty acid oxidation (ketone body production). Glucose is an essential source of energy for brain metabolism, ketones being an alternative source of fuel in prolonged fasting and hypoglycaemic states. Diagnostic fasts are an important investigation of hypoglycaemia of unknown cause. The procedure is potentially hazardous in children and requires close and reliable glucose monitoring. Patients require IV access during diagnostic fasts and venous samples are used for glucose, beta-hydroxy butyrate (BOHB) and non-esterified free fatty acids (NEFA) measurement. Clinical applications of POCT BOHB measurements include diabetic or alcoholic ketoacidosis, diagnostics fasts and assessing ketogenic diets in epilepsy. The accuracy of POCT glucose measurement using venous samples with glucometers had been previously questioned and it is essential that POC devices used for BOHB measurement are fit for purpose.

Aims of the study: (i) Analytical evaluation of the Optium Xceed (Abbott) and StatStrip (Nova Biomedical) Glucose/Ketone meters for BOHB measurement (ii) Assessment of the clinical acceptability of StatStrip meter in diagnostic fasts/corn starch load.

Method: A spiking experiment was performed on whole blood (LiHep) (BOHB range: 0 – 10.5 mM). Intra-assay precision was performed at low, medium and high concentrations. Spiked samples were tested using Optium Xceed and StatStrip meters. Following analysis, samples were centrifuged and plasma was analysed using the kinetic enzymatic Randox RANBUT assay set up on Roche Cobas Mira. Stored plasma/serum was also tested using StatStrip meter. Clinical study involved measurement of glucose and BOHB using StatStrip meter during diagnostic fasts. Fluoride/oxalate and LiHep samples were sent to central laboratory for glucose (Roche Modular P800), BOHB and NEFA (Randox) measurements as per routine management. Passing Bablok regression and bias plots were used for method comparisons.

Results: StatStrip ketone meter showed systematic positive bias against the lab method (StatStrip = 1.05 Randox + 0.19, n=23, $r^2 = 0.996$). Optium Xceed ketone meter showed systematic negative bias against the lab method (Optium Xceed = 0.97Randox - 0.21, n=23, $r^2 = 1$). StatStrip and Optium Xceed mean bias were 0.31 and -0.26 mM respectively. Passing Bablok equation, plasma versus plasma, was (StatStrip = 1.17 Randox + 0.18, n=23, $r^2 = 0.98$) with mean bias of 0.37mM. Intra assay precision performed on low (~0.6 mM), medium (~2.5 mM) and high (~6.5 mM) samples were < 5.8%, < 2.1% and < 4.2 % (n=10) for the StatStrip meter, and < 14.3%, < 1.8% and <1.8 % (n=10) for the Optium Xceed meter. Total of 138 samples were analysed from 26 patients (age ~1-15yrs; Glycogen Storage Disease n=7, hypoglycaemia n=11, corn starch load n=4, query ketolysis defect n=1, galactosamia n=1 unknown n=2) undergoing metabolic investigations. StatStrip meter showed systematic positive bias, whole blood vs plasma/serum, against the lab methods; StatStrip BOHB = 1.12 Randox – 0 (n=138, range: 0.1 - 3.3 mM, $r^2 = 0.997$), and StatStrip Glucose = 1.11 Roche – 0.01 (n=142, range: 2.2- 8.1 mM, $r^2 = 0.89$). Average bias was 0.11 mM and 0.43 mM for BOHB and glucose respectively.

Conclusions: The StatStrip meter performance was acceptable for whole blood monitoring of patients during diagnostic fasts. Both glucose and BOHB measurements provided useful information for nurses and Drs to monitor their patients during specialist investigations. Analysis of plasma/serum using the StatStrip meter was also acceptable and in agreement with whole blood findings. Assay bias differences

raised the questions on differences in calibration, which suggests lack of international standard for measurement of BOHB can be a contributory factor. Therefore, results obtained from different systems may have an impact on patient management where cut offs are used. It is essential that laboratory evaluations are designed within the clinical context. This study suggests that further work is required to establish the cause of systematic bias in BOHB measurements. We are also intending to test StatStrip Ketone meter in DKA setting using different matrices to ensure patient safety.

Analytical Validation of the Nova StatStrip Blood Glucose Monitoring System in a Pediatric Hospital

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Introduction:

There has recently been a considerable amount of concern regarding the accuracy of point of care glucose testing devices due to the increased use of these devices in intensive care units where they are often used in tight glycemic control protocols. Our objective in this study was to evaluate the analytical performance of the Nova StatStrip glucose monitoring system and determine whether glucose measurements performed on this glucose meter are as reliable as those performed by the clinical laboratory's primary methods (Siemens RapidLab 1265 and Siemens RapidPoint 400) and a whole blood glucose meter generally considered to be the gold standard (YSI 2300).

Methods: We compared the analytical performance of the recently introduced Nova StatStrip (Nova Biomedical, Waltham, MA) glucose monitoring system to several laboratory-based whole blood glucose analyzers, including the YSI 2300 (YSI Bioanalytical Products, Yellow Springs, OH), the Siemens RapidLab 1265 and Siemens RapidPoint 400. All analyzers tested use glucose oxidase to convert glucose and oxygen to gluconic acid and hydrogen peroxide. All analyzers were used as recommended by the manufacturers. Excess heparinized whole blood from patient samples submitted for blood gas analysis was used for glucose method correlations. The samples were initially analyzed on either the Siemens 1265 or Siemens 400 and subsequently analyzed on the Nova StatStrip and the YSI 2300. Hematocrit values were determined by conductivity on the Siemens 1265 analyzers. Plasma glucose results from the Siemens blood gas analyzers (1265 and 400) were compared to results with: (a) whole blood on the Nova, (b) whole blood on the YSI, (c) and in some cases to whole blood on the smaller Nova StatStrip Professional meter which is designed for physician office use. In order to obtain some elevated glucose levels it was necessary to add small volumes of 1.0 mol/L glucose to some whole blood samples prior to analysis.

Results:

Nova StatStrip vs. YSI 2300 and the Siemens Rapidlab 1265: The linear regression equations for 99 patient specimens (ranging from 22 to 578 mg/dL) were $y=1.00x + 2.21$ ($R^2=0.99$) and $y=0.99 + 5.52$ ($R^2=0.99$) for the YSI 2300 and Siemens RapidLab 1265, respectively. No relationship was found between meter glucose bias and hematocrit levels. The specimens had a mean hematocrit value of 37.1% (ranging from 20 to 65%). *Nova StatStrip vs. the Siemens RapidPoint 400:* The linear regression equations for 119 patient specimens (ranging from 32 to 323 mg/dL) were $y = 1.02x + 1.49$ ($R^2=0.996$). For the smaller Nova StatStrip Professional meter (physician office model) the linear regression equation for 89 patient samples (ranging from 32 to 323 mg/dL) compared with the RapidPoint 400 was $y=1.00x + 3.69$ ($R^2=0.993$).

Conclusions:

The Nova StatStrip glucose monitoring system showed excellent correlation with pediatric specimens relative to whole blood glucose measurements performed on the YSI 2300 and the Siemens RapidLab 1265 and RapidPoint 400 analyzers. The glucose measurements were independent of hematocrit over a wide range of values.

POC Lactate testing as an Alternative to Foetal Scalp pH

Gill Hall Trust Point of Care Testing Manger

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Background: The monitoring of babies in labour is important to identify foetal distress and manage complications. It is particularly important to identify hypoxia before it is sufficient to lead to damaging acidosis and long-term adverse outcome for the baby. Foetal blood sampling for determination of pH or base deficit (BD) in fetal scalp blood during labour is often routinely performed as an adjunct to an abnormal heart rate. However in our experience there can be a high failure and repeat sampling rate because of sample volume issues and this can be compounded by analyser downtime. Measurement of whole blood lactate, the major end product of anaerobic metabolism, has been shown to be a reliable alternative to foetal scalp pH as an indicator of the development of metabolic acidosis. However the use of blood gas analysers for foetal lactate testing is also restrictive because of sample volume challenges. The use of handheld POC devices utilizing small sample volumes provides an alternative rapid and easier to use approach.

Aim: The aim of the study was to evaluate the performance and practicality of using a handheld POC Lactate device developed specifically for hospital use.

Method: The precision of StatStrip Lactate (Nova Biomedical) was evaluated using QC controls and whole blood samples. A method correlation was performed using donated whole blood sample spiked with lactate to prepare samples across the measuring range. Foetal scalp and neonatal cord artery blood was used for comparison of the POCT lactate meter with a blood gas analyser Siemens RapidPoint 500 and our lactate laboratory method (Roche modular).

Results: StatStrip Lactate showed acceptable precision at a lactate level with QC control levels 0.9 mmol/L (5.6 %cv) and 6.1 mmol/L (4.4 %cv) as well as whole blood samples with lactate levels 1.8 mmol/L (4.4 %cv), 5.4 mmol/L (3.9 %cv) and 9.5 mmol/L (1.93 %cv). The POC method also showed good correlation with the laboratory method ($r=0.997$, $y=0.786x-0.084$) and the BGA method ($r=0.962$, $y=0.926x-0.056$). The three methods differed in their calibration alignment and StatStrip Lactate demonstrated a mean % bias of -24.12% compared to the laboratory method and a mean -10.46% bias compared to the Blood Gas analyser. Foetal scalp blood samples and neonatal cord artery blood are currently being assessed in order to determine cut-off criteria for POC lactate assessment and correlation to scalp pH.

Conclusions: StatStrip Lactate showed good agreement with the laboratory and blood gas analyser and is a suitable POCT device for the measurement of lactate. StatStrip Lactate required a small volume of sample and provides results in a quicker turn around time and as such will reduce sample failure rates and the risk of unnecessary caesarean sections. Further study is ongoing to establish cut-off levels for the StatStrip Lactate based on the correlation to scalp pH.

Model of the Laboratory Medicine Relief Coordinator using POCT devices after huge disaster at Japan.

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Japanese several Laboratory Medicine societies such as POC committee of the Japanese Society for Clinical Laboratory Automation, Japanese Society of Laboratory Medicine, Japan Association of Clinical Reagents Industries and Hyogo Association of Medical Technologists work together to support Laboratory Medicine affairs in the affected area of Great East Japan Earthquake which caused a tragic tsunami and resulted in serious damage to north region of Japan on March 11, 2011.

From the experience of the Great Hanshin Earthquake which occurred on January 17, 1995 we expected that laboratory testing demands would increase during the weeks following the disaster. We decided to support the use of Point-of-Care Testing devices. Many POCT devices use battery-powered analyzers with immunochromatographic reagents. This is a definite advantage for their use in areas with limited access to power and water supplies. We contacted many companies about the possibility of providing POCT devices, IVD reagents and/or any laboratory supplies including disposable materials. Finally, forty companies agreed to support this project and we received reagent materials for more than one hundred IVD tests. We entered this information on our web site and continued to update it as additional support was received. Once a request of support was received, a communication with that company's representative was made to confirm the amount of material, the method of shipping / receipt and if any specific training that would be required for its use at the testing site. This step is one of the critical steps to ship right materials to right place. Nobody can confirm where reagent and instruments reached if we send them without confirming. Another critical step is to make sure who can operate these devices at the affected area. We trained laboratory professions at the affected area if this is first time to use POCT devices. Because most of laboratory professions are not familiar with all kinds of POCT devices. These communication style similar to job description of POC coordinator in each hospitals. We gathered demands of laboratory medicine needs from the affected area and distribute this information to agreed supporters. We coordinated between needs and supportive offer, as if we are Laboratory Medicine Relief Coordinator.

Not only work as Laboratory Medicine Relief Coordinator but also we dispatched volunteer Medical Technologists for eight weeks to assist in the laboratory work at the temporary aid stations. Some of the crucial points in recruiting volunteer laboratory professions are expenses and accommodations. We prepared, accommodations, transportation methods, covered all expenses including insurance and meals. Our relief activities have shown that Point of Care laboratory medicine and Medical Technologists are useful in disaster-affected area.

In this conference we are going to present our activities for laboratory medicine support after the huge disaster for the future reference.

Comparison of neonatal bilirubin measurement on Radiometer ABL 837 blood gas analyzer with diazo assay on Integra 400 Roche

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Introduction: Neonatal bilirubin is fundamental examination in premature newborns and neonates. The most of the available methods for determining the concentration of bilirubin are performed in central biochemical laboratory. Serum is the preferred material, nevertheless, there is problem with quantity of material which is needed for such a determination in case of premature infants and neonates. The ideal solution is POCT analyser which can measure the concentration of bilirubin from a very small volume of whole blood.

Objective: The objective of this study is to compare the values of measured bilirubin determined in whole blood on POCT analyser ABL 837 Flex and the values investigated with commercially available method (diazo assay) performed in central biochemical laboratory.

Materials and methods: 155 serum samples and 46 samples of whole blood were collected with the cooperation of Neonatology department at University Hospital Motol either to the test tubes with precipitation accelerator for investigation in serum or to the 35 µl to capillary for investigation in whole blood. We tested Radiometer ABL 837 blood gas analyser, which computes total bilirubin concentration from multi-wavelength absorbance measurements of 35 µl undiluted whole blood and serum. Performance of the Radiometer ABL 837 blood gas analyser bilirubin method was compared with a proven Roche Diazo Method for Integra analyser.

Results: Results were expressed as median±SEM: Comparison of serum values: Serum - Integra 400 plus (Roche): (169.1±6.3) µmol/l, Serum - ABL 387 Flex (Radiometer): (164.0±5.9) µmol/l; Comparison of serum and whole blood values: Serum - Integra 400 plus (Roche): (197.8±5.4) µmol/l, Whole blood - ABL 387 Flex (Radiometer): (166.0±5.32)µmol/l.

When comparing the values between serums we observed a strong correlation (correlation coefficient = 0.997). The results obtained from whole blood analyser ABL 837 Flex were approximately 20 % lower than the values obtained in the examination of serum measured on Integra 400 plus analyser with correlation coefficient = 0.901.

Conclusion: Based on the results of correlation we can conclude that ABL 837 Flex whole blood neonatal bilirubin method is well approved for neonatal bilirubin investigation. Advantages of the ABL are the very small volume of blood and the short turn around time, nevertheless, bilirubin concentrations from nonchemical photometric devices that exceed 250 µmol/l should be confirmed by standard laboratory method.

Comparison of creatinine method on ABL 837 Flex with enzymatic method on automatic chemistry analyzer Advia 1800

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Introduction: Creatinine concentration plays important role in monitoring kidney function. The aim of this study was to compare whole blood creatinine levels measured on POCT analyzer ABL 837 Flex (Radiometer) and creatinine serum levels measured in central biochemical laboratory on automatic analyzer Advia 1800 (Siemens). Only a few studies compared results of POCT analyzers and methods used in central biochemical laboratory, usually only two different were types of POCT analyzers compared.

Materials and Methods: For determination of serum creatinine levels an enzymatic colorimetric method was used. Module ABL 837 Flex determines creatinine levels using enzymatic creatinase method, with double amperometric detection.

Comparison was performed on group of 67 patients (aged 3 - 80 years) having creatinine levels 20 - 360 $\mu\text{mol/l}$.

Results: Results were as follow: (median \pm SEM). Comparison: Serum - Advia: 73.0 \pm 8.1 $\mu\text{mol/l}$, Whole blood – ABL 837 Flex: 76.0 \pm 7.7 $\mu\text{mol/l}$. Levels measured on both analyzers were compared with correlation coefficient of 0.989.

Conclusion: We proved excellent correlation between creatinine levels determined by analyzer ABL 837 Flex and levels determined in central biochemical laboratory.

Towards Sustainable Point-of-Care Testing in Remote Australia

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Introduction

The Northern Territory (NT) in Australia is one of the most remote regions in one of the most geographically isolated countries of the world, with many of its communities being located hundreds or even thousands of kilometres from the nearest central laboratory service. Pathology samples may take from several days to several weeks to reach laboratories, with similar times reported for results to be returned to health services. There are also many significant health issues which affect the Territory's large Indigenous population in particular, including very high rates of chronic and acute diseases and the high incidence of preventable hospitalisations.

For the past 5 years, the Northern Territory Department of Health has partnered with the Community Point-of-Care Services unit at Flinders University to deliver quality-assured point-of-care testing (POCT) on the i-STAT device (Abbott Point of Care, Australia) for the provision of selected pathology services in 31 remote health centres in the Territory. The i-STAT provides a practical option for the provision of pathology services in remote NT communities, as tests are conducted on-site on a small blood sample, results for tests such as electrolytes, urea, creatinine, troponin I, blood gases and lactate, INR and haemoglobin are available in 10 minutes or less, and clinical management can be initiated 'on the spot'.

Materials and Methods

Remote area nurses and Aboriginal Health Workers were trained and received competency certification as qualified POCT operators through a program of primary workshops, mobile on-site training and access to on-line training resources and videos. A quality management program was implemented to routinely monitor the analytical quality of the i-STAT in field use, while telephone and newsletter support services as well as feedback reports for health centre managers were established. A research plan analysed the operational effectiveness, analytical quality, clinical effectiveness and satisfaction levels with the POCT service.

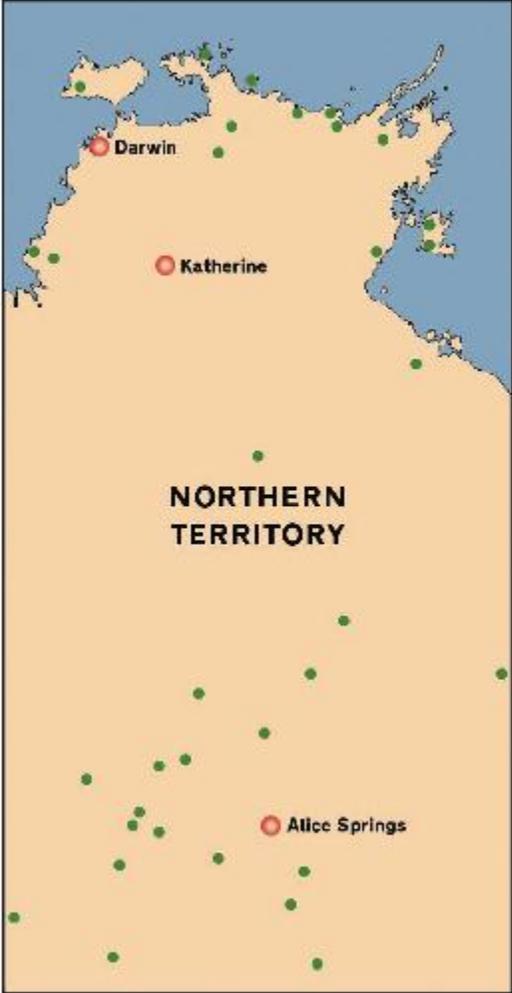
Results

Over 350 health professional staff have been trained as qualified POCT operators. More than 6200 i-STAT tests have been performed across the first three years of program operation. Patient testing on the i-STAT was highest for the INR (representing just over 40% of total testing). Analytical quality for POCT consistently met profession based analytical goals and/or state of the art laboratory performance for most tests, with the percentage of acceptable quality control results for all tests on the i-STAT averaging over 95%. Clinical case studies sourced from the i-STAT central data station (which electronically captured de-identified patient and quality data from all remote services) confirmed the clinical effectiveness of POCT for acute and chronic conditions. Community satisfaction with POCT was validated using qualitative surveys of device operators. Greater than 80% of respondents believed POCT was more convenient than the laboratory and assisted in the stabilisation of acutely ill patients.

Discussion

The Northern Territory POCT Program has proven operationally effective, analytically sound, clinically and culturally effective, and well-received by health professional staff. The main challenges for the program’s sustainability continue to be maintaining standards of training and analytical quality in the face of high staff turnover.

Figure 1. General location of remote health centres participating in the NT POCT Program.



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LOVE THY NEIGHBOR; A COMMUNITY CENTERED POINT OF CARE TESTING APPROACH IN A NEW YORK METROPOLITAN AREA

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Our presentation will focus on how our North Shore LIJ Health System strives to promote community wellness by providing services beyond the hospital walls.

Our integrated system is the nation's second largest, non-profit, secular healthcare system, servicing more than 5 million patients annually. The North Shore LIJ Health System was an early adopter of the ACO (Accountable Care Organization) model, which is strongly supported by the United States government. Accordingly, the system is aggressively shifting patient care to ambulatory facilities such as Urgent Care Centers, Faculty Practices, Wellness Centers, Community Health Fairs, Ambulances, Patient Service Centers, Nursing Homes and Home Care. This is a coordinated, integrated effort to keep the patient from entering the hospital by providing services that historically were performed only in a hospital setting.

North Shore LIJ Laboratories has designed new point of care approaches to be used as tools in concert with our health care providers for making real time decisions in improving patient outcomes in an affordable way. Our Department of Laboratories reached out to the system's Community Health Education Department and other community health care providers to promote our point of care testing system. Our initiative was quickly embraced and two (2) years later we have a comprehensive point of care division outside the hospital walls.

Within a year we performed one (1) million Point Of Care Tests in the local community which includes testing for diseases and disorders such as diabetes, cardiovascular and renal disease, prostate cancer, anemia, and coagulation disorders.

Our Laboratory point of care testing initiatives are so well recognized in the health care community that we were invited to perform point of care testing on a prime time TV show that was broadcast nationally.

We anticipate significant growth, as the System ACO model becomes embedded in our healthcare community. Our goal is to analyze existing patient data gathered from our point of care testing efforts, to better understand the health profiles of our patient population and achieve better patient care and outcomes, while minimizing hospital admissions. We are confident that this will lower the costs to both patients and providers. It is a symbiotic and synergistic program, a win-win situation that could be relatively easily replicated.

Performance of 6 home and 2 professional point-of-care urinary hCG tests

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Introduction: Point-of-care testing (POCT) for urinary hCG is frequently used for home pregnancy testing, but POCT analysis for hCG could also be used for professional in vitro diagnostics (IVD) (emergency department, surgical day care unit etc.) Many different urinary hCG tests are commercially available, including assays for professional IVD use only. We evaluated six of the most frequently used urinary home pregnancy testers (HPT) in Belgium, and 2 professional IVD only urinary hCG POCT assays. According to the product insert, seven of the 8 POCT assays have a sensitivity of $\geq 99\%$ for a urinary hCG of ≥ 25 U/L and one assay (Predictor early) has a sensitivity of $\geq 99\%$ for a urinary hCG of $\geq 12,5$ U/L.

Materials & Methods: A urine sample from a pregnant woman (hCG 4800 U/l) was diluted with a male urine sample to obtain hCG concentrations of 0, 5, 10, 18, 30, 57, 90 and 180 U/l. The urinary hCG was measured quantitatively on Modular E170 (Roche) as described by Nasser et al. (1). Tests were performed on the same day as the dilution series was prepared to limit effects of storage (e.g. nicking). The specificity was determined at 0 U/L and 5 U/L since the 97.5th percentile for urinary hCG in non-pregnant women <50 years is 3,1 U/l. (2)

Results: For each assay, 5 tests were performed for each of the 8 hCG levels. The test kits were interpreted at the advised reading time as positive or negative according to the manufacturer's instructions. Only 3 of 6 commercial home POCT assays and 1 of the 2 professional POCT assays had a sensitivity of 100% at 30 U/l as shown in the Table. No assay gave a false positive result at a concentration of 0 U/l or 5 U/l.

Conclusion: Although all manufacturers claim a sensitivity of $> 99\%$ for hCG ≥ 25 U/l, only 3 of the 6 home POCT and 1 of the 2 professional POCT assays for urinary hCG had a sensitivity of 100% for a urinary hCG of 30 U/l. The lack of sensitivity of some assays could result in false-negative results in early pregnancy.

Comparative Effectiveness of the VerifyNow P2Y12 Test and Light Transmittance Aggregometry for Assessing the Antiplatelet Effect of Clopidogrel

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Abstract:

Background: The VerifyNow P2Y12 Test (VN P2Y12; Accumetrics, San Diego, CA) is a rapid, point-of-care platelet function test that has been extensively validated as a tool for measuring the antiplatelet effect of P2Y12 receptor inhibitors. The test reports results as P2Y12 Reaction Units (PRU). The PRU result is highly specific for P2Y12 receptor blockade due to the effect of a P2Y12 inhibitor, and is more specific than light transmittance aggregometry (LTA) due to the presence of PGE1 in the assay, which minimizes the effect of the platelet P2Y1 receptor. The present analysis evaluates the comparative effectiveness of VN P2Y12 and LTA for the detection of a P2Y12 inhibitor effect, measured as reduced platelet reactivity to ADP. The sensitivity of detecting the antiplatelet effect of a P2Y12 inhibitor can be affected by 1) the time since the last dose, 2) the potency of the P2Y12 inhibitor therapy, and 3) inter-individual variability in the response to the drug. Factors such as genetics, concomitant disease, antecedent medication, and compliance can all influence the individual response to antiplatelet therapy. The ability to specifically detect the antiplatelet effect of P2Y12 inhibitors is important whenever the physician wishes to identify an antiplatelet effect in their assessment of the patient.

Methods: Participants eligible for the study had to 1) have a clinical indication to receive a P2Y12 inhibitor (clopidogrel), 2) be taking aspirin at least two days prior to enrollment, and 3) have at least two risk factors for developing vascular disease: family history of vascular disease; sedentary lifestyle; diabetes mellitus; hypertension; morbid obesity; known history of hypercholesterolemia; postmenopausal women; and smoking. VN P2Y12 and LTA measurements were performed from citrated whole blood samples collected prior to clopidogrel ingestion and either 24 hours after ingestion of a minimum 300 mg clopidogrel loading dose or 7 days after starting a 75 mg/day clopidogrel maintenance dose without the use of a loading dose. ROC curve analysis, sensitivity and specificity calculations were based on the ability to correctly identify the presence of a P2Y12 inhibitor.

Results: For the detection of a clopidogrel effect, as evidenced by a decrease in platelet reactivity to ADP, the area under the ROC curve for VN-P2Y12 PRU results was significantly greater than percent aggregation by LTA (0.95 vs. 0.90, $p = 0.0067$). The optimal decision point from ROC curve analysis for detecting the presence of a P2Y12 inhibitor was VerifyNow P2Y12 Test PRU < 208, which showed 79% sensitivity and 97% specificity for detecting the antiplatelet effect of clopidogrel. The lower limit of the PRU reference range (194) showed 72% sensitivity and 98% specificity for detecting the antiplatelet effect of clopidogrel. **Conclusion:** The VerifyNow P2Y12 Test is superior to LTA for detecting the presence of a P2Y12 inhibitor, with significantly greater specificity. VN P2Y12 is suitable for use in clinical settings where it is necessary to identify a measurable effect of a platelet P2Y12 inhibitor.

Point-of-care athlete testing, a new approach of sport performance evaluation.

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Using point-of-care testings has profoundly modified the approach to athlete's evaluation, linking sport performance and physiological parameters to the metabolic substratum, basal conditions, functional costs and providing reproducible exercise / functional capacity descriptors.

Training testings, is defined as testing performance at or near the sites of training or competitions, in the precise conditions likely to be really experienced. In sports science, usually such tests are not as reliable as laboratory tests, but often have greater validity because of their greater specificity. These is invariably difficult to achieve as there are numerous factors experienced in competition which are at near to impossible to replicate in training or testing environment. A combination of regular field based test (because of the practical, and immediate nature of testing) together with occasional laboratory testing (because of accuracy, reliability and quality) is a good option for most sports.

The choice of testings will depend on the specific goals of performance evaluation in the athlete, namely exercise tolerance assessment and training-induced adaptations. In general, the analytical processes are influenced at the biological material collection, storage, transport and preparation.. We should be aware of pitfalls, to avoid data misinterpretation.

For the relevance in reflecting during exercise or post-exercise homeostatic changes and costs, we chose to investigate blood lactate and acid-base status, muscle damage markers and many other. In sport performance, excessive efforts to maintain internal homeostasis in normal limits may have limiting even negative effects on performance capacities. It is possible to appreciate sports specific energetic requirements (energy systems contribution and efficiency in supporting exercise), functional status in basal / resting conditions and exercise, exercise metabolic costs, post-exercise recovery evolution, using calculated functional indexes and blood tests values. Based on specific changes, we can appreciate performance capacity, reveal the metabolic / muscular / recovery costs, defining also recovery drive.

The possibility of point-of-care testings to be done in real sport-specific conditions has demonstrated a significant potential to change the way of monitoring sport trainings and recovery. Testings are done considering trainings / race specific environmental factors: run and bike – road, weather, hills, wind resistance; rowing, canoeing – water conditions, weather, boat friction / water resistance; altitude. Valuable coaching decisions could be taken. It is essential that the coach receive an experienced support from professionals who can manage the details of training / competition based testings. POCT can provide informations about athlete weakness or limitations, about developing and improving sport performance. These kind of testings respect specificity / specific and environmental factors, personal skills, experience and training status, age and sex. It is possible to create the athlete's profile, for training to performance. Point-of-care testing become point-of training testing.

An attempt to investigate handling and analytical performance of blood gas devices in a critical care system

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Background: The guidelines on Laboratory Quality Control Based on Risk Management (EP 23-A) have introduced the use of internal standards as suitable methods for monitoring of quality control. This allows the structures responsible for POCT devices to fully consider the introduction of cartridge instruments in hospital networks. In our hospital 24 blood gas analyzers (ABL 800 Radiometer, Copenhagen, Denmark) are spread over many buildings and are connected to a central unit and remotely supervised and managed by the Central Laboratory since 2008. In the present study the “in use devices” installed in an ICU were compared to a cartridge system (GEM 4000 I.L. Bedford, MA, USA) in terms of handling, analytical performance, clinical care and decision-making processes.

Materials and methods: A 10 beds Emergency ICU (about 3,000 blood gas /month) was chosen for the investigation. During the study, the operators (26 nurses) were invited to run blood gas samples on both instruments and to register all significant events occurred. Sampling reports of the two systems were classified as: device unavailability and delayed device availability (relapsed time more or less than 5 minutes); sampling errors (insufficient sampling, interference and pre-analytical error related messages); alarms and analytical flags. The information obtained from the operators were integrated and compared with data reported in devices system log. The analytical performances of the two systems were evaluated by samples analysed with time shift lower than 30 min. Samples with analytical flags were used for methods comparison. The results of all the tests included in analytical reports (pH; PO₂; PCO₂; Hct; K, Na; Cl, Ca²⁺; TBil; Lac; HB) from both the instruments were compared by Linear Regression and Bland Altman analysis (without reference methods). All the samples differing >20% on Bland Altman analysis were further investigated in detail on both instruments.

Results: during the study interval 2784 samples were run on ABL and in 214 (7.7%) analytical flags were observed. In the same time, 1205 samples were run on GEM; out of these, 83 (6.9%) were aborted by the system for sampling errors; no analytical flag was reported by GEM.

1157 samples were run on both instruments; 264 operator notes were reported in data sheets, 89 (33.7%) concerning ABL (28% sampling delay < 5min, 16% delay > 5min, 4 sampling errors, 46 analytical flags) and 175 (66.3%) GEM (50% sampling delay < 5 min, 13% delay > 5min, 35% sampling errors and 3 system flag).

In the same time 55 instrumental flags (55.4% of total flags) produced by ABL were not registered by the operators. Analytical performance evaluation was run on 1002 samples (87% of registered samples).

Following linear regression analysis and Pearson's, correlation coefficients ranged from 0.92 to =0.996, slope from 0.92 to 1.047 and intercept from -3.14 to 5.21.

A significant mean bias (-38.8%) was found for total bilirubin, all other measurements showing a mean bias <4%. Differences >20% were observed for pCO₂, SO₂, Ca²⁺, Lactate on 2, 3, 2 and 4 samples respectively.

Discussion: The instrument comparison confirm the good correlation of the results produced. The technological improvement of the devices makes them more and more suitable for the clinical use. The two instruments have a different approach when displaying data that can not be used clinically (darkening of the data or question mark on the figure); the impact of these questionable data on the clinical use in different contexts, such as in emergencies or in the various clinical levels of intensive care needs to be further investigated. Finally, the reliability of analytical results and the operator training appear to be an indispensable task.

COMPARISON OF TWO METHODS OF INTERVENTION FOR MONITORING INR RESULTS WITH HOME CARE PATIENTS AND THE IMPACT ON THE ORGANIZATION OF WORK

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Rationale: The Health and Social Services Centre Alphonse-Desjardins (CSSS AD) is located in Chaudière-Appalaches, on the south shore of Quebec city. The facility covers five (5) Regional County Municipalities (RCM), totalizing over 231,000 citizens. Through its mandate, the CSSS AD has become interested in the 10 % yearly growth of anticoagulated patients on its territory. It has raised concerns regarding the efficacy of the overall process. The actual patient follow-up requires the coordination of numerous healthcare professionals (HCP). This adds complexity in the management of care, services and monitoring of International Normalized Ratio (INR) results. To this day, no research has been carried out on the possibility of managing oral anticoagulated patients by home support service HCP using a portable coagulometer. This study seeks to explore this option by comparing two different types of intervention on patients using the oral anticoagulant Warfarin/Coumadin^{md}.

Research question: Can the use of portable coagulometers by home care nurses improve clinical management of patients taking Warfarin/Coumadin^{md}, while preserving the quality and security of their follow-up?

Objectives: To compare two types of intervention mode for monitoring and managing INR results and to validate the overall clinical impact and workflow of both intervention modes.

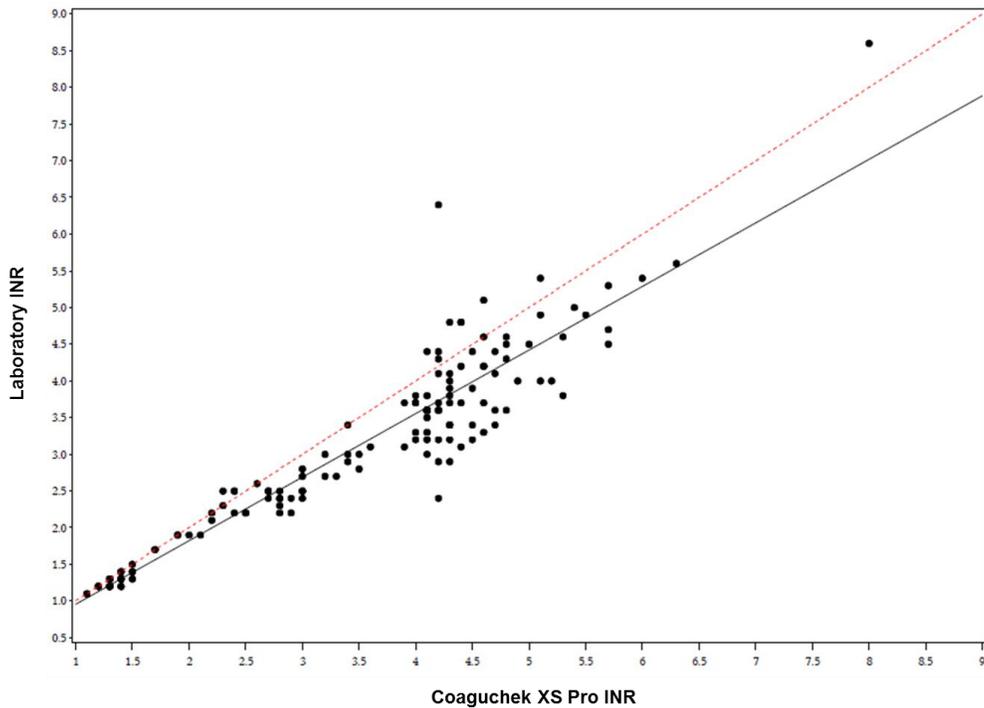
Methodology: The study population comes from both urban and rural area. Participants aged 18 years and older, are anticoagulated patients with limited mobility taking Warfarin/Coumadin^{md}. Three hundred and eighteen (318) people were initially recruited and 275 patients completed the study over a six months period between May and October 2011. Patients with atrial fibrillation represented 70.4 % of all study participants. The study approach is a cross-over model where each user becomes its own witness for two successive periods of three months. Capillary and venous samplings (or vice-versa) are respectively performed. When capillary sampling was performed, an INR result was recorded by the visiting nurse using a Point-of-Care (POC) Coaguchek XS Pro instrument (Roche Diagnostics, Canada). When venous sampling was performed by the nurse, the sample was transported to the regional hospital for testing on a Siemens BCS analyzer. To compare both intervention modes with respect to quality and security: temporal data, INR results, time within therapeutic range, number of samples were gathered by the home nursing staff for all samples (N = 4,192). Data to evaluate the nursing staff workflow in relation to each mode of intervention was also collected. A correlation between the laboratory analyzer (Siemens BCS) and the Coaguchek XS Pro was performed.

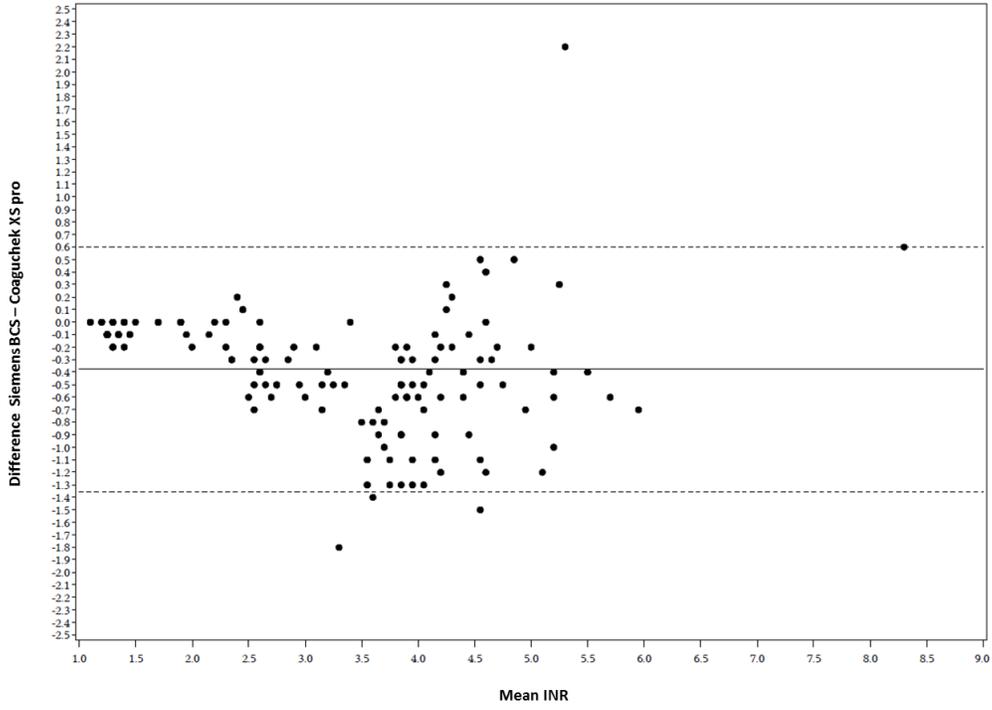
Study results: There was no increase in the number of samples related to each intervention mode (capillary vs venous). An average of 7.2 capillary samples and 6.9 venous samples, were recorded during a comparable three-month period. Patients achieved similar time within therapeutic range during both intervention modes (capillary: 67.6 %, venous 66.6 %; (OR 1.00; 95% CI 0.97-1.06) $p = 0.52$). Correlation was good to very good for INR results < 3.5; while POC analysis overestimated results (average difference = +0.38 s (SD± 0.49) for INR ≥ 4 (see attachment 1). For INR results within the targeted therapeutic range, three (3) and seven (7) steps were identified respectively for capillary and venous intervention modes. The mean time between sampling and transmission of the clinical decision was between 2-3 minutes (capillary) and between 4 hours 32 minutes to 5 hours 5 minutes (venous) (see attachment 2). For INR results out of the targeted therapeutic range, there were nine (9) steps identified for each intervention mode. The time between the transmission of the clinical decision and the sampling varied between 4 hours 53 minutes and 6 hours 37 minutes and between 6 hours 14 minutes and 6 hours 45 minutes respectively. According to a participant satisfaction survey, 85% were in favor of the Coaguchek XS Pro use.

Discussion: The nursing staff workflow analysis supports an estimated a gain of 25 hours a week on 151 patients followed by seven (7) nurses in urban areas and an estimated gain of 17 hours a week for 100 patients followed by eight (8) nurses in rural areas. Considering the very good correlation between the CoaguChek XS Pro and the laboratory analyzer, the establishment of a Warfarin/Coumadin^{md} dose adjustment collective prescription for INR results < 3.5 on AF patients would reduce the mean time to result from 6 hours to 15 minutes, improve the overall workflow while preserving the patient’s quality of life.

Conclusion: With the use of a portable coagulometer and a collective prescription by nurses, 93% of AF patients INR results could be managed directly by nurses during home visits. This includes managing with a protocol 68% of INR results within the targeted therapeutic range and managing 25% of INR results outside the therapeutic range with a collective prescription.

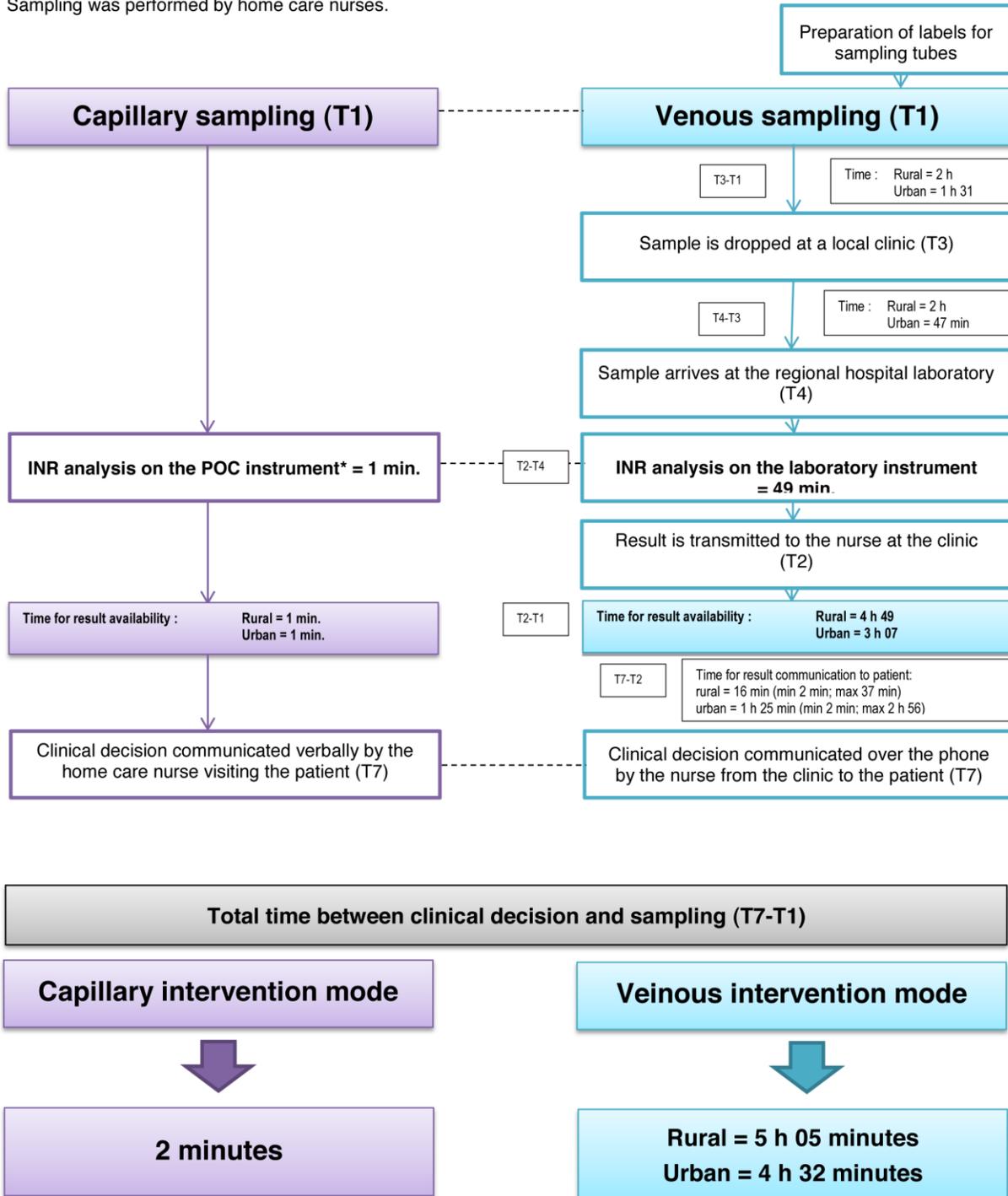
Attachment 1





**Capillary and venous sampling mode workflow comparison
when INR results were within therapeutic range**
(data based on 20 observation days)

Sampling was performed by home care nurses.



* POC results are transmitted to the regional hospital through a cobas IT1000 internet link.

POCT networks: verify of glucometer Accucheck Inform II performance by an External Quality Assessment processed by Central Laboratory.**Rapi S., Salti S., Peruzzi B., Veroni F., Messeri G.****Central Laboratory. Laboratory Departments. Careggi Hospital. Florence Italy.**

Background: In our Hospital a network of glucometers (AccuCheck Inform II. Roche Diagnostics. Mannheim. Germany) are spread over many building and are connected to a central unit and remotely supervised and managed by Central Laboratory since July 2010. POCT guidelines require to submit all POCT devices at external quality assessments or at a periodic evaluation of instrumental performance using control material different to normal reference. In our knowledge in Italy are not available programs of external quality assessments for POC glucometer. Aims of the present reports was to verify the performance of used devices. Create a strategy for external quality assessment operated by Central Laboratory in our hospital and investigate the overall working time of the used control strategy.

Materials and Methods: two pool of human serum was obtained by residual materials from inpatients known as not affected by viral infections (HIV, hepatitis at all.). The two different pools were obtained (20 ML of each levels) with glucose values of L1= 70.3 +/- 0.02 mg/dL and L2= 296 +/- 0.05 mg/dL (mean values and s.d by 8 runs) using Central Laboratory methods (ADVIA 2400, Siemens Diagnostics, NY. USA). Poll were stored at -20 until sending at the hospital units. Overall working time for sample preparations was registered by the laboratory operator. The two reference materials were analyzed in two different days (at least one month delay between the two evaluations) on 50 devices and results were used in order to obtain an evaluation of the analytical performance of single instruments and the bias of used POC glucometers. All samples were delivered at cure units directly by the laboratory operator. Working time of laboratory operators for pools preparation and samples delivery and of nurses time for samples running were registered for each instruments.

Results: mean values of all instruments results L1= 80.23 +/- 1.85 and L2= 308.3 +/- 8.3, bias between Laboratory methods and POC device (without reference method) results L1 = 6.59% and L2 = 2.03%. No total error over 15% were observed in the 200 of collected data; 1 data show a total error > 10% (L1); and 7 samples show a total errors more than 5% (both levels). Mean working time in hospital units for sample running was of 7 min +/- 5. The overall working time for laboratory operators were of about 15 min for single device.

Discussion: although the overall comparison confirm the good correlation a bias of more than 5% may be expected for low values between laboratory and used POC devices. Inter-devices variability of the used POC and the total amount of samples with significant standard error results very low. An accurate evaluation of available instruments may be performed in hospital setting starting from laboratory residual materials. In our experience the overall procedure is time consuming and is not so easy to perform in a hospital that spread over many building and probably results more and more difficult when the instruments are spread over the territory. Main difficult are related to sample selections and material delivered. A total amount of 24 working hours for nurses and 18 hours for laboratory operators was required for our program.

Assessing renal function in a community setting beyond the laboratory.

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In the UK 5.9% of the population originates from the Indian subcontinent. South Asian Indians (SAIs) are known to have lower rates of moderate chronic kidney disease (CKD) but faster progression, contributing to a greater need for Renal Replacement and healthcare costs. Early detection of CKD is therefore important in this population, which also has a high prevalence of other CKD-associated risk factors namely diabetes mellitus, hypertension and obesity. A Joint collaboration between H.E.A.R.T UK, The Royal Free London NHS Foundation Trust and Hindu temples was set up to screen for vascular disease, diabetes and CKD in a SAI population as part of UK Department of Health initiative.

We compared point of care (POCT) creatinine measurements (StatSensor meterTM, Nova Biomedical, UK) (n = 127) with laboratory based serum creatinine (SCr) measurement using an Isotope Dilution mass spectrometry (IDMS) traceable compensated (rate blanked) kinetic Jaffe assay using a Roche Modular P[®] analyser and Roche[®] reagents (Roche, Maidenhead, UK).

The mean age of the participants was 47.5 ± 10.6 years. The mean SCr (laboratory) was 71.5 ± 13 $\mu\text{mol/l}$ and POCT creatinine was 66.6 ± 11.8 $\mu\text{mol/l}$. The mean estimated glomerular filtration rate (eGFR) for lab based method was 86.7 ± 7.0 ml/min/1.73m^2 and for POCT was 86.6 ± 6.8 ml/min/1.73m^2 . The bias (Bland-Altman) in creatinine measurements was -4.5 $\mu\text{mol/l}$ (POCT was lower than laboratory value) and -0.2 ml/min/1.73m^2 for eGFR.

POCT measurements are comparable to laboratory measurements between SCr values of 47-108 $\mu\text{mol/l}$. POCT creatinine measurements can be used for CKD screening in the community as part of vascular health screen.

How accurate are blood glucose meters used for patient self testing

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Introduction: There is increasing concern being expressed about the accuracy of glucose meters used both in hospitals and for self-testing. A number of endogenous and exogenous substances can influence the accuracy of results and as such several bodies (ISO, IFCC, FDA) are looking at revised performance criteria for glucose meter performance. Since diabetes patients rely on self-monitoring of blood glucose [SMBG] meters to identify hyper- and hypoglycaemia and modify treatment accordingly, it is also important for patient glucose meter readings to be accurate and reliable in order to reduce the risk of inappropriate management. However it has been reported by the ADA that up to 50% of all SMBG readings may vary from their true value by more than 20% raising a question mark over their reliability.

Aim of Study: The purpose of this study was to challenge the design and analytical performance of commonly used SMBG meters in order to assess the impact of recognised interfering factors and to assess the accuracy of the best and worst performing SMBG meters when used to measure glucose in a diabetic patient population

Method: Seven SBGM meters (NovaMax plus, Glucofix Mio plus, Glucomen Lx plus, AccuCheck Aviva, Ascencia Breeze 2, Optium Xceed, and OneTouch Ultra 2) were tested. The meters were challenged with differing hematocrit levels and differing levels of non-glucose sugars (maltose, galactose, xylose) and at five different glucose concentrations (1.1-3.3, 5.5-8.3, 11.1-16.7, 18.1 – 22.2 and 23.6-27.8 mmol/L). Each individual sample was tested 6 times with each meter. Results were compared to the YSI reference method and the mean bias deviation calculated for each meter. The imprecision of each meter was determined at three different levels and this was used in conjunction with the bias deviation to calculate mean total error (%bias + 1.65 CV(%)). A method correlation was performed using a spiked sample panel. The meters showing the best and poorest total errors were selected for a study performed on capillary samples collected from self-testing diabetic outpatients. Glucose testing was performed on 130 patients attending outpatient diabetes clinics. Capillary blood (200ul) and was tested using the SMBG meters and YSI 2300 and for each patient the whole blood haematocrit level was determined

Results: The total error for the meters varied from 7.2% to 16.6% compared to the hexokinase method and the accuracy of several meters were affected by varying hematocrit and non glucose sugars. The Nova Max plus, Glucofix mio and Glucomen Lx were unaffected by the interferences assessed and demonstrated low and acceptable total error rates. The other meters were affected to varying levels by the interfering substances. The Nova Max plus, Glucofix mio and Glucomen Lx and One Touch Ultra were selected for diabetic patient testing.

The hematocrit levels seen in the diabetic patient population tested ranged from 37 – 59% and at the lower and upper range the accuracy of One Touch Ultra was affected. .

Conclusion: The accuracy of SMBG meters can be affected by haematocrit as well as non-glucose sugars. The results pattern seen in the analytical assessment for haematocrit also occurs with real patient samples. As the chronic disease population increases there is a growing trend for many of these patients to be managed and treated in the community and as a result there may be a likelihood of increased frequency of interfering factors present in patients that need to be considered in the use of SMBG meters. Inaccurate meters increase the risk of mis-management of diabetes and new performance criteria for SMBG meters need to take this into account.

Qualitative hCG Point of Care Tests Should Not Be Used to Rule Out Pregnancy

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BACKGROUND: Detection of early pregnancy in the healthcare setting is important for proper patient management. Healthcare delivery systems often utilize qualitative point-of-care (POC) human chorionic gonadotropin (hCG) testing to assess pregnancy status. Several studies have demonstrated that these devices perform extremely well, with diagnostic sensitivities and specificities >97%. However, the majority of patient samples analyzed by these studies had an hCG concentration >500 IU/L. There is a gap in the literature for evaluating patient samples with low, yet detectable hCG concentration using POC devices.

METHODS: Urine (n=289) and serum (n=269) specimens with hCG concentrations between 2 - >5,000 IU/L were evaluated by hCG POC testing. Approximately half of these had an hCG concentration <300 IU/L. All serum and urine specimens were evaluated using the OSOM and QuickVue+ POC hCG devices. Pregnancy status was evaluated by patient chart review.

RESULTS: The OSOM and QuickVue+ showed a diagnostic sensitivity of 53 and 78%, respectively for urine samples with an hCG concentration range between 20 and 300 IU/L. Serum samples with an hCG concentration range between 10 and 300 IU/L showed a sensitivity of 79 and 91% using the OSOM and QuickVue+, respectively. False negative results could not be attributed to the high-dose hook effect, the hCG variant effect, or the interpreters' evaluation of the qualitative test result. The mean gestational age for specimens corresponding to the false negative results ranged from 3-5 weeks, with a mean gestational age of 4 weeks.

CONCLUSIONS: The analytic and diagnostic sensitivity of two commonly used hCG POC devices is insufficient for the hCG concentrations observed in very early pregnancy. POC hCG assays should not be relied upon to rule out pregnancy. In cases where it is imperative to know pregnancy status, quantitative serum hCG testing should be utilized.

A Misleading Urine hCG

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A 16 year old, previously healthy, nulliparous female, presented to the Obstetrics and Gynaecology admissions department, complaining of lower abdominal pain and heavy per vaginal blood loss following a 14 week period of amenorrhoea. Initial work up included a bedside urine hCG strip test which proved negative. Due to a high degree of clinical suspicion the test was repeated by a more senior clinician using the same test kit but the result again proved negative. Quantitative serum hCG was then requested from the laboratory and returned as being 2 117 300 IU/ml. Ultrasound examination confirmed the suspicion of a molar pregnancy. Following surgery, the patient has been diagnosed with a high-risk choriocarcinoma for which she is currently receiving chemotherapy.

The most likely explanation for the initial negative urine hCG is that of the high dose hook effect. This is a well documented phenomenon affecting immunometric assays. A falsely low or negative result is obtained in the presence of excessive amounts of the measured analyte.

Our case highlights the importance of recognizing the limitations and sources of error inherent in point of care assays. Our laboratory staff are aware that dilutions of a serum sample should be made if an unexpectedly low hCG result is initially obtained in a patient suspected of having gestational trophoblastic disease. However, with the decentralization of the testing procedure, common sources of error may pass unnoticed. Laboratorians have a crucial role to play in ensuring the quality of near patient testing results. This includes educating and training the end users of these devices and offering an advisory service when results do not correlate with clinical findings.

Causes and Frequencies of Failed Electronic Transmission of Point-of-Care Test Results

Linda Sandhaus MD, Lois Schultz MT(ASCP), Karen Meyerson MT(ASCP), Ruth Natali MT(ASCP), Christine Schmotzer MD

Documentation of patient laboratory test results, including point-of-care test (POCT) results in the electronic medical record (EMR) is a high priority for health care organizations. At University Hospitals Case Medical Center, Telcor middleware is used to connect moderate-complexity POCT analyzers to SoftLab, the laboratory information system (LIS), which is interfaced to Eclipsys, the electronic medical record (EMR). These devices include ITC Signature Elites (22 in 7 locations), Radiometer ABL80 blood gas analyzers (5 in 2 locations), IL GEM4000 blood gas analyzers (11 in 6 locations), and Siemens Stratus (2 in one location). Test results that do not transmit to the LIS are displayed in a Telcor “exception” file. POCT coordinators monitor the Telcor exceptions daily and attempt to resolve them to enable transmission of the results. Resolution often involves contacting the device operator to provide correct patient information. The number of unresolved Telcor exceptions is a quality indicator in our POCT quality assurance plan. Data spanning an 18 month time period are tabulated below.

Month	Total Tests	Total Exceptions (%)	Unresolved Exceptions (%)
August 2010	3704	199 (5.4)	100 (2.7)
September 2010	3340	183 (5.5)	64 (1.9)
October 2010	3887	422 (10.8)	280 (7.2)
February 2011	4056	216 (5.3)	203 (5.0)
May 2011	3168	91 (2.9)	81 (2.6)
July 2011	3548	129 (3.6)	107 (3.0)
November 2011	2885	59 (2.0)	43 (1.5)
January 2012	3646	204 (5.6)	186 (5.1)
Mean	3529	188 (5.1)	133 (3.6)

Telcor exceptions are classified as system errors or operator errors. System errors are errors that are outside of the operator’s control, such as LIS down-time or incomplete patient data in

the admission/discharge/transfer system. Examples of operator errors include entering an incorrect medical record number or failure to download the device within the 3 day time window. A detailed analysis of 60 consecutive days indicated 39% system errors and 61% operator errors. The most frequent error was operator failure to download the Signature Elites. There were two spikes in system errors that were caused by an interruption in wireless connectivity and an LIS down-time.

In our experience, about 5% of POCT results do not initially transmit to the EMR; about 30% of these “exceptions” can be resolved. Electronic transmission of POCT results to an EMR has many points of vulnerability due to the numbers of people, device types, and interfaces that are involved.

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Interference of ethylene glycol with lactate measurement: a comparison study on new generation cassette-based blood gas analyzers.

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Background: Ethylene glycol poisoning is an acute toxicological event, requiring immediate clinical actions. Metabolites of ethylene glycol have been described to interfere with the analysis of lactate on some blood gas (BG) analyzers, whereas they do not on laboratory automates. The apparent “lactate gap” might accelerate the diagnosis of ethylene glycol, even before the result of the ethylene glycol dosage is known. However, it is not clear to what extent ethylene glycol metabolites interfere with the analysis of lactate on different BG analyzers, in particular the more recently developed cassette-based BG analyzers.

Methods: Venous blood samples were spiked with clinically relevant concentrations of glycolic acid, the most prominent ethylene glycol metabolite, and less prominent metabolites (glyoxylic acid, oxalic acid and formic acid). Spiked samples were analyzed on cassette-based BG analyzers of radiometer (ABL90), Siemens (RP500), Roche (cobas 123) and IL (Gem premier 4000) and classic BG analyzers of these companies.

Results: Glycolic acid, the most abundant ethylene glycol metabolite, and glyoxylic acid interfered with lactate measurement on the classic and cassette based BG analyzers of Radiometer, Siemens and IL. However, lactate measurement on the cassette-based as well as the classic BG analyzer of Roche is not sensitive to interference by ethylene glycol metabolites.

Conclusions: Physicians and laboratory personnel should be aware of the possible interference by ethylene glycol metabolites on BG analyzers of Radiometer, Siemens and IL to possibly to avoid misinterpretation of BG lactate and to speed up the diagnosis of ethylene glycol poisoning.

A Robust Technique for Assessing Analytical Imprecision on the Abaxis Piccolo

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Introduction: Assessment of the imprecision of tests performed at the point-of-care (POC) is critical for ensuring the clinical utility of the test result. Users of POC test devices typically obtain analytical performance expectations from the test manufacturer's kit insert or from imprecision estimates obtained by the user following repeated analysis of quality control material. Unfortunately, manufacturer's precision estimates, as well as those obtained by the end user, are typically obtained in a controlled setting, using quality control material measured on one or few instruments with a single lot of reagent, and at only two concentrations of analyte. Estimates of test imprecision obtained in this controlled environment fail to account for many of the factors that adversely affect imprecision when testing is performed at the POC. These factors include the use of multiple instruments operated by numerous different individuals, use of multiple lot numbers of reagents, and testing a heterogeneous mixture of patient samples spanning a wide range of analyte values.

In order to obtain a more robust estimate of test imprecision, we developed precision profiles for tests performed using the Abaxis Piccolo POC instrument using patient samples with a wide range of analyte values, tested using multiple instruments and multiple lot numbers of reagents.

Materials and Methods: We used several Piccolo POC instruments to test 16 different common chemistry tests. Plasma samples that remained following routine testing in the Clinical Chemistry laboratory were obtained within 2 hours following the completion of testing. Each sample was randomly assigned to testing using up to 7 different Piccolo instruments. Each of the different analytes was measured using 16 to 42 different lots numbers of reagent discs. The number of lot numbers used for each analyte varied due to differences in the test menu available on the different reagent discs.

Precision profiles were developed by plotting the average measured concentration of the analyte in each sample against the %CV calculated following repeated measurements of the sample with different lot numbers of reagent discs and different instruments. A power function curve was used to fit the resultant data points and to enable test imprecision to be assessed at each concentration of analyte.

Results: We developed precision profiles for 16 different analytes measured with the Abaxis Piccolo. The precision profile for creatinine is shown below. A total of 37 patient samples were used to construct the precision profile for creatinine, with mean creatinine concentrations ranging from 0.38 mg/dL to 4.87 mg/dL. Each sample was measured an average of 8 times (range 4 -12) using different lot numbers of reagent discs and different instruments (randomly assigned).

The shape of the precision profile demonstrates the expected increase in analytical imprecision with decreasing concentrations of creatinine.

Conclusions: Determining the imprecision of tests performed at the POC is critical for assessing the true clinical utility that the test will provide in this setting. We propose a robust method for determining

precision estimates that incorporate inter-instrument and inter-reagent lot variability, and obtained using actual patient samples. The Abaxis Piccolo showed good precision for the different analytes that were investigated.

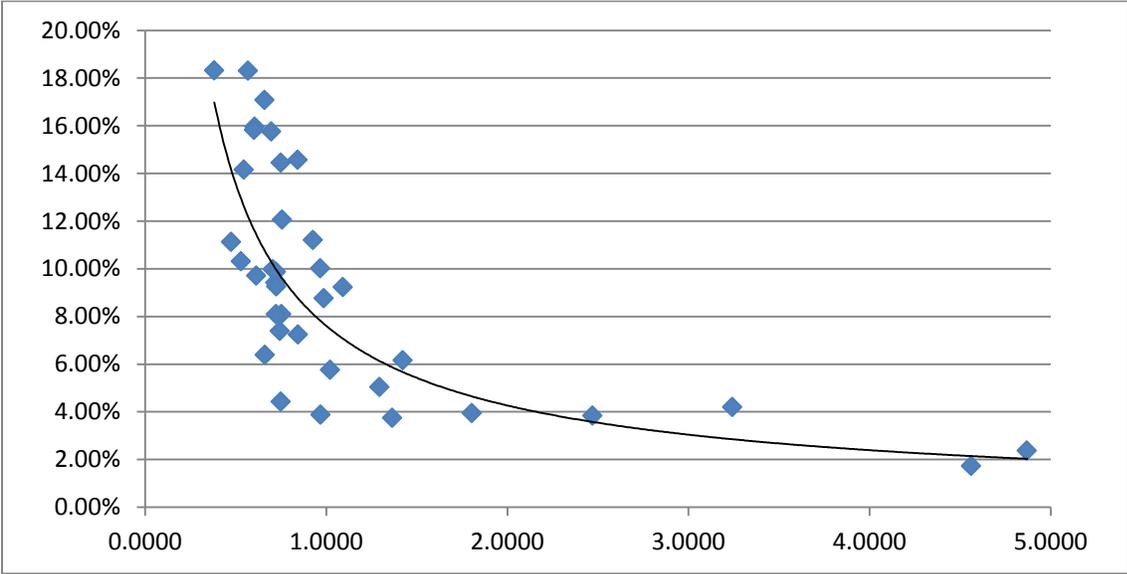


Figure 1. Precision profile for creatinine. Each data point is the mean of 8 separate creatinine measurements performed across up to 7 instruments and 12 different lots of reagent discs.

Comparison of Hospital Glucose Meters in Neonatal Care Unit

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Background: Glucose determination in the blood or plasma is used in the diagnosis, monitoring of persons with diabetes mellitus. Neonates and premature infants represent a mixed group of individuals in whom glucose monitoring is crucial and who have a physiology that differs significantly from older children and adults. So-called “normal ranges” are presumably dependent on the infant’s size, gestation and clinical condition, as well as the availability of energy sources and ongoing energy demands. Neonatal hypoglycemia cannot be defined by a single value of glucose, the proposed cut-off (repeated levels of less than 2,6 mmol/L) is recommended.

We compared the performance of two point-of-care glucose meters by using the spreadsheet program is designed for estimating the bias between two methods using patient samples.

Methods: The study was performed over a two week period using samples obtained from the Neonatal Care Unit of the Children Clinic of Tartu University Hospital. Method correlation was performed by analyzing 74 whole blood specimens on the Nova Stat Strip glucose meter compared to Hemoque glucose meter. 10 patient samples measured in duplicates and compared to blood gas analyzer ABL 825 in laboratory (samples prepared in laboratory, divided into 2 aliquots, all measurements were performed at the same time by 2 nurses and 1 technician). Mean glucose concentration was 4,59 mmol/L (range =1,8-10,0 mmol/L).

Results: Hemoque glucose meter had significantly lower results compared to Nova glucose meter ($p=0,001$). Linear regression analysis demonstrated a slope of 0,41/0,95/0,53, an intercept of 1,45/-0,75/1,23 mmol/L at the range 1,8-4,3/4,4-5,0/5,1-10,0 mmol/L, respectively. Maximum difference was 65% (-2,2 mmol/L) at the value 4,5 mmol/L. Mean difference was 1,0 mmol/L. Hemoque glucose meter demonstrated significantly lower bias

(-7,1%) compared to laboratory method ($p=0,034$). Nova glucose meter had not significant difference compared to laboratory method ($p=0,428$).

Comparison of glucose meters on cut-off value showed that number of infants with glucose levels less than 2,6 mmol/L was 5 times greater by Hemoque glucose meter (9 infants from 18). 2 infants from 18 had a glucose level below 2,6 mmol/L by Nova glucose meter. 2 low results by Nova /Hemoque meters was confirmed by laboratory and 7 results from Hemoque glucose meter had glucose value above 2,6 mmol/L compared to laboratory.

Conclusion: We conclude that Hemoque glucose meter was inadequate for monitoring glucose levels in neonates. Nova glucose meter is an accurate and precise alternative for near- patient testing in neonatal setting.

Data Management systems as a solution to help prevent errors in POCT testing.

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Our institution is an acute care institution with an active ED. We are also an open heart center and POCT for blood gases is an integral part of our daily routine. We have numerous testing personnel such as respiratory therapists, and cath lab personnel besides pathology lab testers. With blood gas and electrolyte determinations in an acute setting you get one chance to get a rapid answer off the blood gas instrumentation and you must have confidence in that answer. This means you must know the instrument is always ready and you also must know that any chance of error such as typographical, technical and pre-analytical has been mitigated. Studies indicate order entry errors can be as high 5% and other investigations on laboratory-associated errors found that preanalytical errors predominated, ranging from 31.6% to 75%, and postanalytical errors from 9 to 30.8%. Compliance with competency assessments is usually lacking about 10% of the time on laboratory personnel.

To help reduce these errors our solution has been a network connection to a Data Management System. The system we use is the Siemens RAPIDComm®. This system allows us to visualize the status of all our blood gas instrumentation throughout the institution. We always know by alert if an instrument is not ready for sample analysis. This allows us to correct the situation and to notify the staff to use another instrument while maintenance is being performed. Because the instrument results are interfaced the chance of typographic errors is essentially eliminated and to help us meet regulatory requirements all records of who did the testing and whatever maintenance is performed is also kept by the data management system. All controls run are logged into the system and can also be readily reviewed for troubleshooting and during any regulatory audit. All current operators are 100% competency assessed because the system locks out those who are not reviewed when required.

Because all our records are in one system it is now much easier to do monthly quality reviews of our systems. This eliminates the need to manually gather individual records from all the POCT sites for review. For our POCT coordinators the Data Management System provides real-time oversight of multiple blood gas analyzers from a single location. This includes the ability to remotely access and troubleshoot connected instruments, set alerts, manage operators, view live screens, generate QC reports, schedule and record maintenance activities, and to even take direct control of our RAPIDPoint® 405 blood gas analyzers from the laboratory or their office. It provides all of this for us with the most important function of helping to reduce errors.

Effect of high humidity on point-of-care glucose measurement

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Background: Point-of-care glucose meters are widely used to monitor treatment in diabetes patients. Siriraj hospital uses SureStep Hospital strips and SureStepFlexx meters which should be tested when the relative humidity between 30-70% according to the manufacturer's recommendation. However, Thailand has a tropical wet climate and the relative humidity sometimes exceeds this limitation. The objective of this study is to assess the effect of humidity on the glucose measurement.

Materials and Methods: SureStepTM Hospital glucose control solutions and test strips were used in this study. The control solutions of low and high levels contain glucose at approximate concentrations of 2.2 mmol/L (40 mg/dL) and 19.1 mmol/L(345 mg/dL) respectively. Glucose level in control solutions was measured at the relative humidity of less than 70% (control group, group 1, n=20). In the experimental groups, glucose level was measured at the relative humidity of approximately 80% (group 2, n=18) and 90% (group 3, n=20). All test results were performed by one operator using the same lot of test strips.

Results: The relative humidity was between 49-70%, 79-83% and 89-90% in group 1, 2 and 3, respectively. In low level control solution, glucose concentration was 42.35±0.32 mg/dL, 38.39±0.32 mg/dL and 36.55±0.39 mg/dL in control group, group 2 (relative humidity approximately 80%) and group 3 (relative humidity approximately 90%), respectively. In high level control solution, , glucose concentration was 356.10±1.58 mg/dL, 342.94±2.64 mg/dL and 339.50±2.46 mg/dL, respectively.

Conclusion: When the relative humidity exceeds the limit, the glucose concentration measured by glucometer significantly declines.

EVALUATION OF INTERNATIONAL QUALITY CRITERIA COMPLIANCE IN NOVA STATSTRIP® β -KETONE TEST (A. MENARINI DIAGNOSTICS).

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Introduction. Examinations performed beside the bed of patients ("Point-of care testing, POCT") provide immediate results and are simple to perform. The most common of these tests is the self control of blood glucose levels in diabetic patients. The determination of β -ketone in whole blood is very useful for the control of the diabetic patient because it can prevent the onset of diabetic ketoacidosis (DKA). DKA is a medical emergency, and without treatment it can lead to death. In recent years are appearing on the market glucometers which are also able to determine β -ketone in whole blood. STAT STRIP® Xpress-i™ (NOVA BIOMEDICAL marketed in Spain by A.MENARINI diagnostics) is an instrument which determines glucose and β -ketone in whole blood. Laboratory staff is responsible for assessing the quality of the analysis equipment implanted in all the hospital.

Objectives. The aim of this work is to assess the compliance of STAT STRIP® Xpress-i™ with international criteria of precision, veracity and accuracy to the β -ketone determination in whole blood.

Methods. Three levels of external glucose and β -ketone control solution were used in order to evaluate STAT STRIP® Xpress-i™. We followed the CAP protocol for verifying compliance with international criteria of precision, veracity and accuracy. To determine the intra-day variability were processed three levels of control solutions 20 times for three consecutive days, and to determine the inter-day variability were processed the three levels of control solutions for 20 consecutive days.

Results. The intra-day CV (%) obtained for control 1 (0.1-0.5 mmol/L), control 2 (0.5-1.4 mmol/L), and control 3 (1.7-3.7 mmol/L) were respectively 37.9%, 10.4% and 8.8%. The inter-day CV (%) obtained for control 1 was 37.8%, for control 2 was 9.7%, and for control 3 was 8.6%. Consequently the Total CV (%) obtained for each of the control levels were 53.5%, 14.2%, and 12.2%. The results for the systematic error (ES) were 27.5% in control 1, 16.8% in control 2, and 2.9% in level 3.

Conclusions. According to the CAP criteria the CV should be less than 14.7%, therefore STAT STRIP® Xpress-i™ meets the CAP criteria for the concentration levels of control 2 and control 3. In the case of ES, for the β -ketone determination, the CAP criteria allows values below 29.5%, thereby STAT STRIP® Xpress-i™ meets the CAP criteria for the concentration levels of control 1, control 2 and control 3. With these results we conclude that any medical significance criteria were violated, and STAT STRIP® Xpress-i™ is in compliance with international quality criteria.

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