13th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine:

"New Trends in Diagnosis and Monitoring using POC Instruments"

Inter-University Centre Dubrovnik,
Dubrovnik, Croatia
19-20 October, 2013

Organizers

Croatian Society of Medical Biochemistry and Laboratory Medicine (CSMBLM)
European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)
Slovenian Association for Clinical Chemistry (SZKK)
Inter-University Centre Dubrovnik (IUC)

Scientific and Organizing Committee:

Elizabeta Topic (chair), Croatia
Sverre Sandberg, Norway
Evgenija Homsak, Slovenia
Jasna Lenicek Krleza, Croatia
Pika Mesko Brguljan, Slovenia
Greta Strakl, Slovenia
Sanda Berzenji, Croatia

Welcome note

The thirteenth EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine: New Trends in Diagnosis and Monitoring Using POC Instruments

The Croatian Society of Medical Biochemists and Slovenian Association for Clinical Chemistry, together with the European Federation of Clinical Chemistry and Laboratory Medicine have organized 13th in a series of postgraduate weekend courses. These advance courses promote continuous postgraduate education of professionals in clinical chemistry and laboratory medicine, and bring the participants up to date with different topics in laboratory medicine.

This time the course is entitled "New Trends in Diagnosis and Monitoring using Point of Care (POC) instruments." In this Course the state-of-the-art on Point of care testing (POCT) in different medical fields is presented and discussed by well-known experts. The lecturers will try to cover the clinical and laboratory aspects of POCT and discuss the advantage and shortcomings of this tool in different clinical settings. The integrated knowledge of the lecturers and the material prepared especially for this course intend to provide updated information of high quality to the participants. As always, most important in such courses are the interactions and discussions between lecturers and participants both during the course and in the free time.

We hope that for all those attending the Course it will be an excellent opportunity to acquire new knowledge and exchange experience in the field.

Dubrovnik, October 2013

Elizabeta Topić & Sverre Sandberg

The role of POCT in modern medicine

Sverre Sandberg

The Norwegian Quality Improvement of Primary Care Laboratories (NOKLUS), University of Bergen, Bergen, Norway

Corresponding author: sverre.sandberg@isf.uib.no

Pont of care testing (POCT) is the most rapidly growing field in laboratory medicine. With increasing technological and analytical possibilities, an increasing number of analyses can now be carried out on POC instruments. Although the costs of POC instruments are less than hospital instruments, the number of users of POC instruments is much larger, ranging from wards in the hospitals, general practise (GP) offices, nursing homes, pharmacies and last but not least tests for self-measurements. With the increasing emphasis on patient empowerment, it is not surprising that POC instruments can be an important factor in this, from self-measurement of INR and glucose to a large and increasing marked of "over-the counter" sold tests. The ultimate goal of using POC testing is that patient outcomes should be improved and/or that it should be more cost-effective than the use of conventional laboratory testing. To achieve this, the role of POCT in the different clinical settings as well as the responsibility for introducing and manage the instruments and use of the instruments should be clearly defined. The main reason for using a POC instrument is that a rapid result is more useful than waiting for a result from a central laboratory.

Whereas it is without doubt that the laboratory is responsible for analytical results when they are produced within "their walls", it is not as obvious that the laboratory should have the responsibility for POC analyzing, and in many environments, this is not clearly defined. Therefore, the manufacturers in many cases will communicate directly with nurses and clinical doctors when promoting their instruments rather than use their time with laboratory people and the idea is that no professional laboratory knowledge is necessary to handle these instruments. The laboratory specialists therefore must be more proactive and move out of the laboratory and take responsibility for POC, even if it involves difficult discussions with clinicians and hospital managers. This way high quality POC can be ensured both for the pre-analytical, analytical and post-analytical phase and POC instrument can be a high quality service in modern medicine. In the present postgraduate course we will learn about POCT in different environments, hospital, GP offices and patients as well as different measurements procedures that are introduced on POC equipment to be used in a variety of clinical settings. In the future, there is probably no limitation to what tests can be performed on POC instruments, but the important task will be to define their usability (1).

References

1. Jani IV, Peter TF. How point-of-care testing could drive innovation in global health. N Engl J Med 2013;368:2319–24. http://dx.doi.org/10.1056/NEJMsb1214197

Hospital point of care testing network

Dunja Rogić

University Hospital Zagreb, Clinical Institute for Laboratory Diagnostics, Zagreb, Croatia

Corresponding author: drogic@kbc-zagreb.hr

Point of care testing (POCT) or near patient testing is defined as any *in vitro* diagnostic procedure done without the laboratory environment by non laboratory staff (1). Since it represents the fastest growing segment of in vitro laboratory diagnostics worldwide, it clearly remains an ongoing challenge for laboratory professionals (2). By its nature, POCT falls within the interest and responsibility scope of the laboratory personnel, however by its location and means of use it belongs to other areas of patient care. Only the successful blending of these two determinant factors ensures adequate testing quality and results reliability. Within hospital environment (which represents about 70% of POCT market) it has become an indispensable part of any unit that requires immediate access to results, whether for medical or logistic reasons (4). It is of utter importance that laboratory staff remains

recognized and involved in decision making about hospital POCT at all stages. The optimal approach towards this goal is establishing a hospital POCT committee which should consist of all interested parties' representatives: physicians who need the result, nurses who will do the testing, laboratory professionals who possess the required knowledge about technologies and operating procedures and last but not least, hospital administration who has to cover the costs. In terms of financial issues, it is highly advisable that cost coverage is clarified before any equipment is obtained – in other words, who will be covering the cost of equipment and/or consumables – generally this responsibility should not be taken by the laboratory but by the hospital department that needs POCT service (8). POCT instruments and equipment should be carefully chosen only after the committee has reached a consensus regarding specific clinical needs and available means of fulfilling them. The direct vending approach, whereby IVD industry representatives offer their POCT product directly to clinical staff should be strongly discouraged or if possible explicitly forbidden. When a particular POCT equipment has been chosen through the POCT committee, the laboratory should initially verify its performance and then organize education and training on site. If a parallel central laboratory procedure exists, the results comparability has to be checked and communicated to the end users. Clinical staff needs to understand the possible consequences of inadequate sample handling, as well as main interferences possibilities and other existing constraints (9). User identification should be introduced as an indispensable part of the training, since clinical staff has to stay aware of the fact that laboratory people will be responsible for the functionality of the instrument, while they will be held accountable for each particular patient result. Regarding instrument functionality, it can stay implemented usually mainly through continuous endeavours by laboratory POCT dedicated staff to maintain the same quality standards applied within the central laboratory – internal and external quality control, remote review of test and instrument data, supervising the regularity of cleaning and maintenance procedures together with constant education and

reeducation of clinical personnel. From this emerges the last but far from least general rule of good POCT hospital service network, which is that adequate and open communication between clinical and laboratory staff remains *a conditio sine qua non*.

References

1. *Nichols JH, Christenson RH, Clarke W, Gronowski A, Hammett-Stabler CA, Jacobs E, et al. National Academy of Clinical Biochemistry. Executive summary. The National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline: evidence-based practice for point-of-care testing. Clin Chim Acta 2007;379:14-28. http://dx.doi.org/10.1016/j.cca.2006.12.025.*
2. *Lewandrowski K, Gregory K, Macmillan D. Assuring quality in point-of-care testing: evolution of technologies, informatics, and program management. Arc Pathol Lab Med 2011; 135:1405-14. http://dx.doi.org/10.5858/arpa.2011-0157-RA.*
3. *Gregory K, Lewandrowski K. Management of a point-of-care testing program. Clin Lab Med 2009;29:433-48. http://dx.doi.org/10.1016/j.cll.2009.06.006.*
4. *Scalise D. Poised for growth. Point of care testing. Hosp Health Netw 2006;80:77-83.*
5. *Nichols JH. Quality in Point of care testing. Expert Rev Mol Diagn 2003;3:563-72. http://dx.doi.org/10.1586/14737159.3.5.563.*
6. *Schimke I. Quality and timeliness in medical laboratory testing. Anal Bioanal Chem 2009;393:1499-504. http://dx.doi.org/10.1007/s00216-008-2349-5.*
7. *Freedman DB. Clinical Governance: implications for point of care testing. Ann Clin Biochem 2001;39:421-3. http://dx.doi.org/10.1258/000456302320314421.*
8. *Magny E, Beaudeux JL, Launay JM. Point care testing in blood gas and electrolyte analysis: examples of implementation and cost analysis. Annal Biol Clin 2003;61:344-51.*
9. *Myers GJ, Browne J. Point of care hematocrit and hemoglobin in cardiac surgery: a review. Perfusion 2007;22:179-83. http://dx.doi.org/10.1177/0267659107080826.*
10. *Rogić D. Point of care testing management in a teaching hospital. Int Hosp 2011;37:26-8.*

POCT in critical care units in the hospital

Robbert Slingerland

Isala Clinics, Department of Clinical Chemistry, Zwolle, The Netherlands

Corresponding author: R.J.Slingerland@isala.nl

The quality of point-of-care tests (POCT) within different segments and between different parts of the health-care chain is currently insufficiently

harmonized. Status of guidelines regarding the different segments of POC glucose measurements as one of the most profound used POC test will be presented.

Connecting all POCT instruments in and outside a hospital to central databases is an essential step in improving the continuity of data in the health-care chain. This lecture will address the involved necessary and standardized requirements from a laboratory point-of-view.

Patient's privacy is at stake with increasing digital communication. The White House in the US has launched an initiative in 2010 to improve the privacy of patients and others in this market. The increased use of Wi-Fi and other digital applications in and outside hospitals makes this initiative even more relevant. The clinical chemistry society needs to be more involved in solutions invented for telecom and finance market because these solutions will in the end or do already enter the medical POC-market. Currently, telemedicine based on remote POCT is increasing rapidly. However, telemedicine can be a dangerous exercise if it is based on patient identification only. Patient authentication is an essential improvement for the near future. An example how to perform safe digital authentication with minimal patient credentials involved will be presented.

This lecture will show some validation topics to ensure the quality of POCT in the hospital, which may be useable in the whole health care chain. The challenges in the critical care setting will be described regarding e.g. continuous glucose monitoring *vs.* point-to-point glucose comparison studies, statistic parameters involved and power of these statistic parameters.

Differences between glucose measurements in a hospital *vs.* home-use setting and consequences for the quality of the glucose measurement will be presented.

External quality control by POCT

Sverre Sandberg

The Norwegian Quality Improvement of Primary Care Laboratories (NOKLUS), University of Bergen, Bergen, Norway

Corresponding author: sverre.sandberg@isf.uib.no

External quality control or quality assurance (EQA) is in principle used to monitor the trueness of a measurement method and to compare results between measurement methods as well as to evaluate the performance of a method in a single laboratory (1). In principle every measurement method, be it in a central laboratory, outside the central laboratory as in emergency departments, operating theatres, clinical wards, general practise offices or pharmacies should participate in EQA. In most laboratories, it is usual that most if not all measurements methods in the central laboratory participate in EQA. For measurements methods performed outside the central laboratory – e.g. POC instruments, this is not always the case and there is a very different practice between countries/EQA organizations as exemplified with the presence – or not presence of EQA schemes for INR (2). One of the reasons for this are the difficulties in finding adequate quality control materials for different measurements methods and also the opinion by some that EQA is not necessary for POC instruments. The most important problem with the control material is that it should be commutable between methods, patient like, stable and homogeneous. For POC methods, this can be especially challenging since many of them uses capillary or whole blood for their measurements and the number of POC instruments can be very large. The challenge of not having a commutable control material for POC instruments can be circumvented by the estimation of trueness of the measurement method and participant performance separately and the feedback report summarizes these results (3). The worst case is when the use of "poor" control material, introduce "errors" that are not present when patient-like material is used (4). EQA of POC instruments should also involve pre(pre)- and post(post)-analytical aspects. For POC instruments, this will probably be even more important than for

the central laboratory since the users usually have little formal laboratory education. It is therefore a challenge to set up EQA schemes for these phases. Since such schemes do not need control material, it is usual to circulate them only in a paper forms or as an electronic questionnaire/registration. This is done by e.g. KIMMS in Australia, but not for POC instruments (5). Post-analytical surveys of the interpretation and use of POC instruments have been carried out as surveys among European countries(6). Even if EQA might be difficult, EQA of self-measurements might be even more challenging and alternative ways of doing this should be explored.

References

1. Miller WG, Jones GRD, Horowitz GL, Weykamp C. *Proficiency testing/external quality assessment: current challenges and future directions. Clin Chem 2011;57:1670–80. http://dx.doi.org/10.1373/clinchem.2011.168641.*

2. Stavelin A, Meijer P, Kitchen D, Sandberg S. *External quality assessment of point-of-care International Normalized Ratio (INR) testing in Europe. Clin Chem Lab Med 2011;50:81–8.*

3. Stavelin A, Petersen PH, Sølvik UØ, Sandberg S. *External Quality Assessment of Point-of-Care Methods: Model For Combined Assessment of Method Bias and Single-Participant Performance by the Use of Native Patient Samples and Non-commutable Control Materials. Clin Chem 2013;59:363–71. http://dx.doi.org/10.1373/clinchem.2012.191957.*

4. Kristensen GBB, Christensen NG, Thue G, Sandberg S. *Between-lot variation in external quality assessment of glucose: clinical importance and effect on participant performance evaluation. Clin Chem 2005;51:1632–6. http://dx.doi.org/10.1373/clinchem.2005.049080.*

5. Key Incident Monitoring & Management Systems (KIMMS) project [Internet]. [cited 2013 May 6]. Available from: http://www.rcpaqap.com.au/kimms/, Accessed August 27th 2013

6. Skeie S, Perich C, Ricos C, Araczki A, Horvath AR, Oosterhuis WP, et al. *Postanalytical external quality assessment of blood glucose and haemoglobin A1c: an international survey. Clin Chem 2005;51:1145–53. http://dx.doi.org/10.1373/clinchem.2005.048488.*

QC net in hospital's POCT

Marija Prezelj

Institute of Clinical Chemistry and Biochemistry, University Medical Centre Ljubljana, Ljubljana, Slovenia

Corresponding author: marija.prezelj@kclj.si

Two decades ago, there was practically no electronic data management for POCT. All information, including tests results, material handling data, and result reporting comments, had to be manually entered into the patient chart, tables, and logbooks located on the patient care units. Documenting all this data is not only time consuming but also prone to errors, and extra care must be taken in verifying the entry of these data. Real-time data management and review POCT data was not possible. There also were no guidelines in place to ensure that all POCT devices were designed in a manner to be interfaced to electronic data management systems. The goal of CIC (Connectivity Industry Consortium), formed in 2000, was to develop standards for connectivity of POCT devices to permit bidirectional vendor-independent connectivity. Connectivity requirements have been described in the Clinical and Laboratory Standards Institute (CLSI) POCT Connectivity Approved Standard (POCT1-A2) and in the CLSI proposed guideline POCT2-P (POCT Connectivity for Healthcare Providers).

POCT connectivity devices [definition - devices with the ability to link point-of-care devices to each other, to laboratory information systems (LIS), or both (CLSI)] with a built in bar code reader is used to identify the test strips, for quality controls and to record the identification of the patient and operator. The device will not operate unless quality control has been performed. Quality control rules are built into the device software to ensure that patient testing cannot be performed unless the instrument is in control. Despite high level of technological sophistication in POCT devices today, the role of traditional quality control and external quality control remains significant confirmation for reliability of tests results. Quality control sample must be analyzed at a frequency recommended by the manu-

facturer and should be performed periodically as proposed in national guidelines for POCT. External quality control is desirable and required for POCT devices as stated in the international standard, ISO 22870 "Point–of-care testing (POCT) – requirements for quality and competence".

Quality control is immediate check on integrity of the POCT device and therefore the operator should record the result and take appropriate action in the time of testing. However, the POCT operational team of each unit should review the day-to day operation of POCT, the quality control and external quality control results.

Supervision of quality control measurements should be performed by the central lab, the best way is on the online connection of all POCT systems to the central lab via LIS/HIS network.

Institute of Clinical Chemistry and Biochemistry attempts the implementation of bidirectional HIS network of POCT devices in the Intensive Care Units of Internal and Paediatrics Division with two POCT servers and with LIS linkage.

References

1. *NCCLS. Point-of-Care Connectivity; Approved Standard.. NCCLS document POCT1-A (ISBN 1-56238-450-3). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.*
2. *Implementation of Point of Care Connectivity for Healthcare Providers; Proposed Guideline (POCT2-P).*
3. *Lewandrowski K, Gregory K, Macmillan D. Assuring Quality in Point of Care Testing. Arch Pathol Lab Med 2011;135:1405-14. http://dx.doi.org/10.5858/arpa.2011-0157-RA.*
4. *Gill JP, Shephard MDS. The Conduct of Quality Control and Quality Assurance Testing for PoCT Outside the Laboratory. Clin Biochem Rev 2010;31:85-8.*

Quality indicators of POCT

Ivana Baršić

Department of Laboratory Diagnostics, University Hospital Centre Zagreb, Croatia

Corresponding author: ivbarsic@yahoo.com

Point-of-care testing (POCT) or near-patient testing is performed near or at the site of a patient, with test results leading to a possible change in the care of a patient. These tests are performed outside the central hospital laboratory. Nevertheless, POCT main principles do not differ significantly from those governing the central hospital laboratory. We want to get the right test for the right patient, getting the right specimen and the right results in the right time, getting the right patient record and timely the right treatment. Therefore, we need to ensure good quality control and patient safety.

One way is to establish good quality management system and to develop quality indicators. As in the central hospital laboratory, it is preferable and important that indicators include all three phases in the working process: preanalytical, analytical and postanalytical. Quality indicators need to be designed to monitor processes that have the potential to put patients in risk so they should include a focus on patient safety and clinical effectiveness.

Quality indicators need to be clearly measurable so we need to establish what do we want to measure, can we get these information, how to analyze the obtained data, how often it will be done, etc.

There are still no clearly defined quality indicators for POCT so that each laboratory responsible for the organization and management of POCT should define its own.

Here are some POCT quality indicators: number of bad quality samples, number of wrong samples, samples without identification (no patient identification), sample handling errors (number of inadequate sample – haemolytic, clotted, insufficient sample volume, inappropriate collection container, etc.), education documentation (certification), critical values notifications, quality control performance (internal and external quality control), instrument management (instrument evaluation and validation, calibration verification, method correlation, instrument maintenance), inventory management (reagents and controls), incident reports, reporting patient results, number of missing patient results records, number of cases where operator didn't detect interference, reporting incidents, etc.

Ultimate goal is to ensure patient safety and optimal care. Finally, it is of great importance to ensure

good communication between the central hospital laboratory and staff performing POCT (non-laboratory staff). However, communication cannot be measured. Knowing that poor communication is a source of many mistakes, POCT requires its inclusion as an "immeasurable indicator" that will significantly improve the quality of POCT.

Maintaining high quality standards in POCT continuously proves to be a growing challenge for laboratory professionals.

References

1. *St-Louis P. Status of point-of-care testing: promise, realities, and possibilities. Clin Biochem 2000;33:427-40. http://dx.doi.org/10.1016/S0009-9120(00)00138-7.*
2. *Nicholas James H. Reducing medical errors at the point-of-care. Laboratory Medicine 2005;36:275-7. http://dx.doi.org/10.1309/NXXWJ31PWFHT7L1Q.*
3. *Baršić I. Point-of-care testing: advantages of informatization. Neurol Croat 2012;61:133-5.*
4. *Šimundić AM, Topić E. Quality indicators. Biochem Med 2008;18:311-9. http://dx.doi.org/10.11613/BM.2008.027.*
5. *Okorodudu Anthony O. Optimizing accuracy and precision for point-of-care tests. Available at: http://acutecaretesting.org/en/articles/optimizing-accuracy-and-precision-for-point-of-care-tests. Accessed August 14th 2013.*

POCT in celiac diseases

Jernej Dolinšek

Department of Paediatrics, Gastroenterology Unit, University Medical Centre Maribor, Maribor, Slovenia

Corresponding author: jernej_dolinsek@hotmail.com

Celiac disease (CD) is a systemic immune disorder triggered by the ingestion of gluten, a protein present in wheat, rye and barley in genetically predisposed individuals. The prevalence of CD in various populations around developed world is around 1%; however, the disease is largely underestimated in many regions. There is also evidence that diagnostic delays can reach more than a decade, especially in adult patients, which can have a major impact on their well being, and general health of population. Evidence also exists to show that the prevalence of the disease increases with the age, being more prevalent in adults and elderly than in children, which is in the contrast with previous belief that celiac disease is rather rare disease affecting only children.

Celiac disease can manifest itself at any age. It may be clinically silent; some patients may show only vague symptoms or present with extra intestinal manifestations. This also can influence the diagnostic approach and can yield to late diagnosis of the disease.

It is well known that celiac disease runs within families, and first-degree relatives of patients are at much higher risk of developing the disorder. It also holds true for other risk groups such as patients with type 1 diabetes, IgA deficiency, autoimmune thyroiditis, as well as patients with Down, Turner and Williams syndrome.

Even if health care professionals are highly aware of all the above-mentioned facts, active approach in patient finding is not common. General screening with classic serological tests including antibodies against tissue-transglutaminase type 2 (t-TG), deamidated gliadin peptide antibodies (dGP) and antiendomysium antibodies (EMA) is not recommended by current guidelines adopted by European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN).

Active case finding in primary care using sensitive and specific biomarkers of celiac disease might be a solution to shorten diagnostic delays. However, using classic serological tests in centralized laboratories are not available or affordable for medical health care in many parts of the world.

Easy-to-use whole blood self-TG2-based fingertip point-of-care test (POCT) as well as rapid tests based on the detection of dGP antibodies have been developed and were proven in several settings to be effective in celiac disease case finding. These tests are qualitative tests, do not need sophisticated equipment, and can be interpreted by unskilled personnel.

POCT tests for celiac disease proved to be highly sensitive and specific resulting in an accuracy of >95% to detect untreated CD reported by some authors. Their use can be somewhat limited in patients consuming gluten free diet, who must be checked

regularly for possible dietary violations, which limits their home use. Possible misinterpretations can yield to over- or underestimation of the disease.

A better, quantitative POCT test that could simultaneously detect disease specific antibodies and level of total IgA as well as determine HLA status of patients within a visit time, and could communicate with Laboratory information system has been developed within the CD-MEDICS project and needs further validation, but has already shown some initial promising results.

POCT coagulation

Steve Kitchen

UK National External Quality Assessment Scheme (UK NEQAS) for Blood Coagulation

Corresponding author: Steve.kitchen@sth.nhs.uk

POCT in haemostasis and thrombosis is increasingly used in many countries. The main applications are currently as follows: INR for monitoring vitamin K antagonist therapy by healthcare professionals and patient self testing; high dose heparin management using activated clotting time (ACT); assessment of global haemostasis using thromboelastometry (ROTEM) or thromboelkastography (TEG); D-dimer testing for exclusion of venous thromboembolism (VTS); platelet function testing including assessment of anti platelet therapy.

Both internal quality control (IQC) and, where available, external quality assessment (EQA) are required to provide the evidence that results are safe for use in patient management decisions. A number of different POC INR monitors are available, some of which incorporate some form of in-built IQC. There are advantages to having access to IQC materials which mimic patient samples and which can be analysed in a similar way to patient samples, thereby testing the full analytical process including any test strips or cartridges and the functioning of the monitor. IQC can provide important evidence related to the precision and consistency

of testing and to ensure that results are in agreement with those obtained in other centres.

UK NEQAS (blood coagulation) currently offers proficiency testing programmes for the following POC tests and devices: INR – Roche Coaguchek XS/XS/XS PRO; Haemochron junior signature series: INR Abbott – ISTAT: ROTEM: TEG: ACT-Haemochron series.

The most commonly used INR monitor amongst UK NEQAS participants are the Coaguchek XS and XS plus devices. A lyophilized anti-coagulated sample prepared from plasma obtained from patients treated with warfarin is provided together with reconstitution and decalcification solutions so that no local pipettes, diluents or laboratory facilities are required for analysis.

ROTEM (INTEM and EXTEM tests) and TEG results of a NEQAS survey in which a pooled normal plasma sample was used as test material are shown below:

TEG (N = 40 centres)			
	Median result	**CV (%)**	**Range of results**
Rtime (min)	6.3	27	5.2–14.1
Angle (degrees)	76.2	9	54.8–79.8
K time (min)	0.9	52 (9)*	0.8–3.8
MA at 20 min	42	11	39.6–69

* Figure in brackets is the CV after removal of outliers > 5 SD from median.

Rotem (N = 16) INTEM test			
	Median result	**CV (%)**	**Range of results**
CT (sec)	149	12.6	135–196
Angle (degrees)	84	1.2	81–85
CFT (sec)	28	16.4	24–43
MCF (mm)	38.5	9.4	30–46

Rotem (n = 16) EXTEM test			
	Median result	**CV (%)**	**Range of results**
CT (sec)	435	131 (29)*	35–417
Angle (degrees)	85	7 (1)*	12–87
CFT (sec)	26	91/18	19–147

MCF (mm)	41	8	38–50

* Figure in brackets is the CV after removal of outliers >5 SD from median.

Results obtained in 12 months of ULK NEQAS surveys for the CUC XS plus the most commonly used device are shown below.

Sample	N	Median INR	Range	CV%
XS12:03	2165	2.00	1.00–7.10	14.1 (18.3)*
XS12:04	2166	3.60	1.90–8.00	10.3 (13.9)*
XS12:05	2250	3.40	2.00–8.00	9.3 (14.0)*
XS12:06	2245	4.10	2.10–8.00	11.1 (14.7)*
XS12:07	2246	3.30	2.10–8.00	10.1 (14.5)*
XS12:08	2242	4.30	2.40–8.00	7.3 (10.0)*
XS13:01	2384	3.50	1.50–8.00	9.0 (15.5)*
XS13:02	2382	3.90	2.10–8.11	8.2 (12.8)*

*Figure in brackets are the CV after removal of outliers >5sd from median.

POCT blood gases

Ivo Casagranda

General Hospital SS. Antonio e Biagio e Casare Arrigo, Emergency Department, Alessandria, Italy

Corresponding author: icasagranda@ospedale.al.it

Arterial blood gases (ABG's) is a collective term applied to three separate measurements pH, pCO_2, pO_2 generally made together to evaluate acid-base status, ventilation, and arterial oxygenation. With the arrival of more recent ABG's analyzers and the evolution of the concept of point of care testing (POCT), what we meant for BG analysis has been redefined and extended also to meet the needs of critical care and emergency medicine, particularly in managing traumatic and septic patient (1,2). In particular, alongside the traditionally measured parameters, the cations (sodium, potassium, calcium and chlorine) and lactate were added. This allowed us to address more detailed issue related to the acid-base disorders and those related to electrolyte disorders. In the field of oxygenation same measured parameters have been introduced such as haemoglobin and his fractions (FO2Hb, FHHb, FCOHb, FMetHb) and saturation of haemoglobin with oxygen (SaO2). This allowed rapidly discovering some intoxications (e.g. CO and nitrate). Now it is possible to use POCT specific software to help physicians in interpreting the ABG's complex disorders.

In recent years point-of-care testing ABG's analyzers have been increasingly used in the emergency department (ED) because there are times when emergency physicians (EPs) need to have test results readily available. The decision-making process in the ED begins with the main complaint expressed by the patient at triage and then proceeds with the differential diagnosis, risk stratification and early therapy, when necessary. The process ends with the patient admission or discharge.

Within each of the critical nodal points of this decision-making process, the physician may need to receive the results of some tests as quickly as possible in order to make a prompt diagnosis, define risk stratification and establish an early therapy or change it.

What EPs need in the ED is a rapid turnaround time (TAT) or a quite as rapid turnaround time therapy (TATT). The effectiveness of ABG'S POCT in the management of critical patients has been proved by a randomized controlled trial and many other studies have been conducted to assess the usefulness of POCT in the ED, whose availability, fortunately, continue to rise, contributing to improve patient quality of care and outcome (3,4).

References

1. Rivers E, Nguyen B, Havstad S, et al. Early goal-directed therapy collaborative group: Early goal-directed therapy in the treatment of severe sepsis and septic shock. N Engl J Med 2001;345:1368-77. http://dx.doi.org/10.1056/NEJMoa010307.
2. Engineer RS, Peacock F.The use of Blood Gas Analysis in Point-of -care patients monitoring. US Respiratory Disease 2011;7:70-5.
3. Kendall J, Reeves B, Clancy M. Point of care testing: randomized controlled trail of clinical outcome. BMJ 1998;316:1052-7. http://dx.doi.org/10.1136/bmj.316.7137.1052.
4. Ehrmeyer SS, Laessig RH. Point-of-care-testing, medical error, and patient safety: a 2007 assessment. Clin Chem Lab Med 2007;45:766-73. http://dx.doi.org/10.1515/CCLM.2007.164.

POCT cardiac markers

Mario Plebani

Department of Laboratory Medicine, University-Hospital of Padova, Italy

Corresponding author: mario.plebani@unipd.it

Timeliness in diagnosis and therapy represents an essential requirement in the care of patient with chest pain. Cardiac troponins (both troponin I and T, cTn) are the preferred biomarkers for diagnosis of myocardial infarction (MI). Point-of-care (POC) methods can provide cTn results more rapidly than alternative methods, potentially accelerating triage, acute myocardial infarction diagnosis, and improved outcomes. In principle, quality specifications (imprecision, bias and analytical sensitivity) for cTn POCT should be the same as those for centralized laboratory assays. However, currently available POC assays may be less sensitive compared to centralized laboratory assays, namely when compared to the current generation of assays, usually called "high-sensitivity troponin assays" (1). Some papers, in fact, documented the misclassification rate of patients when cTn is measured with poor analytical sensitivity assays. Therefore, (POC) methods represent a viable option for cardiac troponin assay when clinical laboratories: a) cannot deliver results in the time consensually defined with clinicians (usually, within 60 minutes from blood sampling); b) when a 24 hour service is not available (laboratory closed at nights and/or week-ends); c) are poorly connected with wards both for sample transportation and results communication by laboratory/hospital information systems; d) when patients are attended in settings lacking alternative, more sensitive methodologies as those existing in rural, remote sites; and e) if the cost/benefit analysis confirms the value of this option. In addition, it should be emphasized that current recommendations for MI diagnosis stress the need to obtain serial samples for cTn measurement, namely at the presentation (baseline) and after 3 and 6 hours (2). Therefore, both rule-in and rule-out strategies cannot be based on only one blood sample. As results from different assay methods are not interchangeable, for an institution having both POC and central laboratory methods for cTn measurement, it is advisable to use the same analytical method for tracking serial results on any individual patient. Therefore, although timeliness is an essential requirement for cTn assays, an important factor in determining its clinical utility is the diagnostic performance which, in turn, is related to the analytical sensitivity, reproducibility and accuracy. As there is a lack of standardization and harmonization in the measurement for all cTn assays, each laboratory needs to understand the strengths and weaknesses of assays they implement into clinical practice, including POC, with the understanding that different assays often give different clinical results. The measurement and monitoring of the "vein-to-vein" turnaround time (TAT) is a critical quality indicators for cTn assay, but the adoption of a valuable cut-off and an appropriate imprecision value (CV < 10%) at that cut-off are fundamental issues for assuring quality and patient safety in the management of chest pain patients.

References

1. Lippi G, Cervellin G. Identification of troponin determinants for improving its diagnostic performance in the emergency department. J Emerg Med 2012;43:e487-8. http://dx.doi.org/10.1016/j.jemermed.2012.05.016.
2. Keller T, Zeller T, Ojeda F, Tzikas S, Lillpopp L, Sinning C, et al. Serial changes in highly sensitive troponin I assay and early diagnosis of myocardial infarction. JAMA 2011;306:2684-93. http://dx.doi.org/10.1001/jama.2011.1896.

POCT urine drug-of-abuse

Maksimiljan Gorenjak

Department for Laboratory Diagnostics, University Clinical Centre Maribor

Corresponding author: gormax@sb-mb.si

POCT is one of the fastest growing aspects of clinical laboratory testing, with estimated increase of at least 10-12% for year overall and to 30% *per* year in some testing areas. In the area of drugs of abuse (DOA) alone POCT represents a multimillion Euros business. Generally, such testing relies on urine as the sample and targets the more commonly abused substances and/or their metabolites. Information obtained in such a way can be used in dif-

ferent clinical and non-clinical settings, among them some very specific, like visiting nurses, transport vehicles (ambulances), prisons, army etc. POCT devices for DOA are available in different formats, from dipsticks, cards and plastics cassettes or cup devices. A small amount of urine is needed to perform the test and only 3 drops of urine, or approximately 150 µL, is a usual testing volume. Cups are intended as a collection/container device for urine as well. Turnaround times from initial sample application to a result are 15 min or less. Currently, all devices are based on immunoassay principle and final result is read visually and depends upon technological approach. Majority of POCT products in this testing area represents a lateral flow based immunoassay system. The technical basis was derived from the latex agglutination assay, RIA and ELISA, supported with several major patents on this technology. The first lateral flow products were introduced to the market in the late 1980s. Unlike other qualitative POCT devices, most devices for DOA testing give a negative visual sign when the drug of interest is positive. There is some confusion among users, because devices for different POCT application use almost the same design of device housing.

Regarding the intention of use, specific drug or drug group can be the target molecule. When the parent drug is extensively metabolized, the drug metabolite is the preferred target. There is no absolute concordance with comparator method and the highest disagreement can be seen for samples close to a cut-off value. It is generally accepted that POCT device sensitivity is the main test characteristic enabling the test use in specific circumstances.

It needs to be noted that users of POCT for DOA should be aware of the cross-reactivity to related drugs and possible adulteration of urine sample. The cross-reactivity may arise from food, prescribed drug, or other sources. However, samples could also be tampered with added substance, knowing to change the composition of urine, producing negative test result. Sometimes, weakness in specificity of the test can be used in screening purpose, searching a group of drugs, changed regarding the drug origin. Recently, great effort is placed into research for POCT device detecting the

new synthetic products in group of cannabinoids and synthetic amphetamine-like drugs.

POCT is a highly dynamic discipline. With the evolution of technology, the spectrum of POCT for DOA is expected to change over time. The users of POCT for DAU should follow guidelines for POCT, using quality control material and participate in external quality assurance schemes.

POCT in diagnosing and monitoring of diabetes mellitus

Sverre Sandberg

The Norwegian Quality Improvement of Primary Care Laboratories (NOKLUS), University of Bergen, Bergen, Norway

Corresponding author: sverre.sandberg@isf.uib.no

POC HbA1c is commonly used for monitoring of diabetes mellitus. In a monitoring situation more emphasis is usually placed on precision and less on trueness. Concerning HbA1c, however, one can argue that the same quality specifications should be used both for monitoring and diagnosing since many of the recommendations for good practice deal with absolute HbA1c numbers and not only "improvement" or "deterioration" of the diabetic condition. An expert committee officially recommended to use HbA1c for the diagnosis of diabetes in 2009 (1). There are several advantages of using HbA1c compared with glucose such as pre-analytical stability of the sample and low within-subject biological variation of HbA1c (1). Furthermore, HbA1c is stable throughout the day and fasting and dietary restrictions are therefore avoided. World Health Organization (WHO) recommends an HbA1c level of 6.5% (48 mmol/mol) as the cut off point for diabetes, and the assays must be "standardized to criteria aligned to the international reference values" (2). The College of American Pathologist (CAP) recommends that the EQA acceptable limits for accuracy should be 7% in 2012 and 6% in 2013 compared to a target value (6). Furthermore, NACB recommends a within-laboratory CV < 2%

and a single method should have a between-laboratory CV < 3% (3). All CVs are based on the DCCT (Diabetes Control and Complications Trial)/NGSP units (3). NACB recommends using hospital laboratory HbA1c instruments for diagnosis of diabetes since POC HbA1C assays are "currently not sufficiently accurate for this purpose" (3). Results using Afinion and DCA instruments in the hands of trained personal have shown that these instruments have the potential to fulfil the above mentioned quality specifications (4,5). These studies, however, were laboratory experiments following the CLSI EP-5 guidelines and not longitudinal results from clinical practice. In a recent study (6) results from 13 HbA1c external quality assurance surveys (EQAS) during six years in from both GPs offices using POC instruments and from hospital laboratory instruments were compared with the recommended analytical quality specifications for using HbA1c diagnostically for diabetes mellitus. All general practice and hospital laboratories measuring HbA1c in Norway participated in the EQAS. Between 60-90% of Afinion and DCA users and hospital laboratories performed HbA1c measurements within the quality specifications for both trueness (6.0%) and imprecision (CV ≤ 2.0%) in two levels in each EQA survey.

In conclusion, results indicate that Afinion and DCA POC instruments for measurements of HbA1c can fulfil the analytical quality specifications for diagnosing diabetes mellitus, and have an analytical quality comparable to hospital laboratory instruments. A presupposition for using these instruments for diagnosing diabetes mellitus is that a stringent quality assurance program is established to monitor the quality.

References

1. The International Expert Committee. International expert committee report on the role of the A1C assay in the diagnosis of diabetes. Diabetes Care 2009;32:1327–34. http://dx.doi.org/10.2337/dc09-9033.
2. World Health Organization. Use of glycated haemoglobin (HbA1c) in the diagnosis of diabetes mellitus. Abbreviated report of a WHO consultation. WHO/NMH/CHP/CPM/11.1 ed. Geneva, World Health Organization. WHO; 2011.
3. Sacks DB, Arnold M, Bakris GL, Bruns DE, Horvath AR, Kirkman MS, et al. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin Chem 2011;57:e1–e47. http://dx.doi.org/10.1373/clinchem.2010.161596.
4. Lenters-Westra E, Slingerland RJ. Six of eight hemoglobin A1c Point-of-Care instruments do not meet the general accepted analytical performance criteria. Clin Chem 2010;56:44–52. http://dx.doi.org/10.1373/clinchem.2009.130641.
5. Little RR, Lenters-Westra E, Rohlfing CL, Slingerland R. Point-of-care assays for hemoglobin A(1c): is performance adequate? Clin Chem 2011;57:1333–4. http://dx.doi.org/10.1373/clinchem.2011.165019.
6. Solvik UO, Roraas T, Gade-Christensen N, Sandberg S. Diagnosing diabetes mellitus: Performance of HbA1c point-of-care instruments in general practitioners' offices. Clin Chem 2013 (in press). http://dx.doi.org/10.1373/clinchem.2013.210781.

Self monitoring by POCT

Robbert Slingerland

Isala Clinics, Department of Clinical Chemistry, Zwolle, The Netherlands

Corresponding author: R.J.Slingerland@isala.nl

A steep increase in the number of type 2 diabetics and other chronic diseases world-wide is observed (1). Health care is getting yet an overstretched system. Choices will have to be made considering the kind of care that will be provided. What are the pushes in this process? What is the role of POCT in this respect? Who is in charge in this process?

Although the glucose meters used by patients may well be of good quality for patients in general, interfering substances in the patient's blood may infringe on the measurement technique of the patient meter issued (2). Due to this, glucose measurement interfering substances may lead to incorrect glucose values and may result in undertreatment or overtreatment of diabetics, with risk of diabetes associated pathology.

What quality of POC testing is needed from this perspective? Concomitantly with the increase in the number of diabetics the number of inaccurate blood-glucose measurements will also increase, resulting in a decrease in quality of life due to increased diabetes associated pathology and consequently causes an increasing burden on the health-care costs.

Can we achieve the same quality for POC/home-use/lab instruments in the entire health care system? Is this essential? What criteria are relevant? What flow-diagram is optimal in checking the quality of home-use glucose instruments in patients hands and why? What are trends for POC/home-use testing?

References

1. *Baan CA, Schoemaker CG, Jacobs-van der Bruggen MAM, Hamberg-van Reenen HH, Verkleij H, Heus S, Melse JM. Diabetes tot 2025. Preventie en zorg in samenhang. RIVM, Bilthoven 2009;1-121.*
2. *Dungan K, Chapman J, Braithwaite SS, Buse J. Glucose measurement: confounding issues in setting targets for inpatient management. Diabetes Care 2007;30:403-9. http://dx.doi.org/10.2337/dc06-1679.*

Pre-and post analytical errors in POCT: value of POCT

Mario Plebani

Department of Laboratory Medicine, University-Hospital of Padova, Italy

Corresponding author: mario.plebani@unipd.it

According to a recently published article in *New England Journal of Medicine* "traditional testing is usually performed in remote laboratories which increases the cost and inconvenience of accessing health care and leads to a high number of patients who leave the system before a diagnosis is established" (1). Rapid point-of-care testing (POCT) have been advocated to improve accessibility to health care services and timeliness in diagnostic and therapeutic pathways. In fact, POCT devices for blood gas analysis, electrolytes, glucose, and many other tests have long been available and have become common diagnostic tools. New generations of POCT detect more complex and less accessible biomarkers, such as nucleic acids and cell-surface markers taking advantage of advances in microfluidics, microelectronics, optical systems and informatics. However, in spite of major improvements in technology, assuring the quality of POCT re-

mains challenging (2). In addition, most studies have evaluated the analytical performances of POCT devices without taking into consideration pre- and post-analytical issues. However, according to a total quality and patient-centred scenario, there is the need to adopt a framework that allows the evaluation of quality in all steps of the process, as proposed by Kost several years ago.

In the pre-analytical phase major problems arise from: a) patient misidentification/incorrect patient's details; b)test order not documented; c) wrong tube/anticoagulant; d) *in vitro* haemolysis; e) clotting, f) wrong storage condition. For example, in blood gas analysis, major errors documented in the pre-analytical phase are related to: patient and sample identification, patient stabilization, choice and preparation of the collection site, collection device(s), type of anticoagulant, sample treatment after collection, and sample transportation. In the post-analytical phase major problems are related to a) transcription errors (3), b) measurement units and reference ranges; c) lack of documentation; and d) wrong results interpretation.

Connectivity and bidirectional interface with the laboratory information systems represent an indispensable requirement for minimizing the risk of errors and the lack of documentation as there is the need to include POCT results in the patient electronic record. This makes more intriguing the search for harmonizing units of measure, reference ranges and target values. Therefore, despite major advances in device design and informatics, the management of a successful POCT program remains very challenging.

References

1. *Jani IV, Peter TF. How point-of-care testing could drive innovation in global health. N Engl J Med 2013;368:2319-24. http://dx.doi.org/10.1056/NEJMsb1214197.*
2. *Plebani M. Does POCT reduce the risk of error in laboratory testing? Clin Chim Acta 2009;404:59-64. http://dx.doi.org/10.1016/j.cca.2009.03.014.*
3. *Carraro P, Plebani M. Post-analytical errors with portable glucose meters in the hospital setting. Clin Chim Acta 2009;404:65-7. http://dx.doi.org/10.1016/j.cca.2009.03.013.*

Evaluation and selecting of POCT devices

Gunnar Nordin

Equalis - External quality assessment for clinical laboratory investigations Uppsala, Sweden

Corresponding author: gunnar.nordin@equalis.se

The use of point of care devices (POCT) methods varies greatly among different health care settings. For some regions, the use of POCT is controlled through guidelines for its use, or through system for compensating for the cost of use. In Sweden, the use of POCT varies much according to a recent survey, and the variation is not related to e.g. closeness to central laboratory facilities. The frequency of use is probably very much determined by interest shown by local doctors.

The selection process for a POCT device should lie in the hands of a management group, securing that different aspects of use of POCT are covered. The purpose for using POCT should always be considered: Should the POCT measurement improve the decision making in a specific area, e.g. reduce the prescription of antibiotics, or simplify the logistics, e.g. reducing the number of visits or telephone calls for patients, or should it improve the patients confidence, e.g. for patients also using devices for self monitoring.

Point of care methods must be as accurate as „central laboratory methods" in order to be reliable. Even if proven accurate in a once performed evaluation, the POCT method in use must continuously be controlled for accuracy through the participation in a system for EQA, just as central laboratory methods are controlled. Compared to laboratory methods for measurement in venous plasma, it is an extra challenge for the EQA organizers to provide commutable EQA material for the use of POCT devices, made for measurement of capillary whole blood.

The Scandinavian evaluation of laboratory equipment for primary health care (SKUP) project has until now evaluated more than 100 different devices. The evaluations are ordered by the producer of the device or its local distributer, who also covers a part of the cost for the evaluation. For devices on the Scandinavian market, the results of the evaluation are published regardless of the outcome. The reports are freely available at www.skup.nu.

The evaluation of accuracy should ideally be done against primary or secondary reference methods. However, this is almost never possible, but the selected comparison method must be controlled. The comparison method should not be selected to suit the evaluated method.

The accuracy of results found in the evaluation is an important outcome of the evaluation. However, the user friendliness, rated by the evaluators, might also be an important variable to consider when a POCT device is selected. Some POCT devices need specially educated and trained staff for maintenance. The connectivity is important. The device should be able to communicate with the health care record system. This simplifies the process of transferring the results to the patient's medical record.

The cost of the device and its consumables is just one of several variables to consider in the selection process. The cost for staff and maintenance should also be considered when comparing cost between different alternatives. In an ideal world, results from all instruments, POCT and non-POCT, used in a region should be aligned and share the same reference range.

Evidence has been shown for improved primary health care by the introduction of POCT tests for Glucose, Haemoglobin, HbA1c, CRP and (PT) INR. On the other hand the use of POCT tests for Troponin has been questioned, because of the lower accuracy for the Troponin POCT methods compared to the current central hospital laboratory methods.

Benefits and disadvantages of POCT

Elizabeta Topić*[1], Sanja Dobrijević[2]

[1]Professor of Medical Biochemistry, Faculty of Pharmacy and Biochemistry, University of Zagreb, Croatia, EFLM Committee of Education and Training
[2]University Department of Chemistry, University Hospital Center "Sestre Milosrdnice", Zagreb, Croatia

Corresponding author: elizabeta.topic@gmail.com

Point of care testing (POCT) has been used for many years to control diabetic patients either at clinical/general practice settings or as self-control. Blood glucose was the first test analyzed by POC instruments. The number of POC analyses continuously increased and slowly developed into powerful tools to use in management of a number of common diseases such as diabetes, hyperlipidemia, cardiovascular disease or impairment needed anticoagulant therapy (1,2).

POCT is defined as any test that is performed at the time at which the test result enables a clinical decision to be made and an action taken that leads to an improved health outcome. It may be useful adjunct in the management of patients with chronic disease or in emergency.

After a long time of POC instruments on the market many questions related to POCT appeared regarding the analytical performance, clinical effectiveness, costs, satisfaction of the patients and health care professionals both clinicians or laboratory professionals.

Related to analytical performance, the minimum requirement for analytical reliability are preciseness, accuracy and range of measurements. So far, there are many producers of POC instruments on the market, each of them declares satisfactory characteristics; however, the consumer should be very careful in selecting it because many discrepancies related to the above mentioned characteristics can be found in the literature.

Related to the clinical effectiveness there are not so many reports in the literature on satisfaction of health care professionals with POC testing or POC instruments. There are only few articles related to the clinical outcomes, suggesting more rationalized treatment, but changes in prescribing patterns have not occurred or they occur very seldom. Some evidence is available on the role of POCT in improving glycaemia, cholesterol and lipid levels and oral anticoagulant control.

For laboratory professional, it is important that the POCT introduced in certain environment is proven to be accurate and reliable to meet internal quality control and external quality assurance standards. The model for POCT in primary care that incorpo-

rates laboratory training for GP staff with external QA from the central laboratory is suggested. An essentially part of quality management is the adequate training of staff operating the POC instruments including the requirement for understanding of QC and QA processes.

Satisfaction of patients: In the example for acute cough/LRTI, patients were satisfied with quick test results of CRP using POCT what enabled physicians to make an immediate decision about antibiotic therapy. The most common advantage discussed by patients was that POCT is a useful diagnostic tool that gives the clinicians more information to make better decisions about the treatment, which is then administered more quickly, resulting in faster recovery of patients. There are some other reports on satisfaction of patients by POCT (3,4).

Costs effectiveness may be considered from several different aspects, as POCT versus laboratory testing, number of patient visits to physicians, better control, less medication, faster medical decision making and so on.

In the presentation satisfaction of POC instrument producer, laboratory users, satisfaction of physician and of patients and on cost effectiveness using the POC instruments will be discussed.

References

1. Al-Ansary L, Farmer A, Hirst J, Roberts N, Glasziou P, Perera R, Price CP. Point-of-Care testing for HbA1c in the Management of Diabetes: A Systematic Review and Metaanalysis. Clin Chem 2011;57:4:568-76. http://dx.doi.org/10.1373/clinchem.2010.157586.
2. Gialamas A, StJohn A, Laurence CO, Bubner TK, members of the POCT Management Committee. Point-of-Care testing for patients with diabetes, hyperlipidemia or coagulation disorders in the general practice setting a systematic review. Family Practice 2010;27:17-24. http://dx.doi.org/10.1093/fampra/cmp084.
3. Crocker B, Lewandrowski E-L, Lewandrowsli N, Gregory K, Lewandrowski K. Patient satisfaction with point-of-the-care laboratory testing: Report of a quality improvement program in an ambulatory practice of an academic medical center. Clin Chim Acta 2013;424:8-11. http://dx.doi.org/10.1016/j.cca.2013.04.025.
4. Laurence CO, Moss JR, Briggs NE, Beilby JJ. The cost effectiveness of point of care testing in a general practice setting. Results from a randomised controlled trial. BMC Health Service Research 2010;10:165.

P1

Validation of a point-of-care device for monitoring dyslipidemias in adults

Scafoglieri A*[1,2], Bautmans I[3], Clarys JP[1], Provyn S[1,2], Tresignie J[1]

[1]Department of Experimental Anatomy, Vrije Universiteit Brussel, Brussels, Belgium
[2] Department of Human Anatomy, Vrije Universiteit Brussel, Brussels, Belgium
[3] Frailty in Ageing research department (FRIA), Vrije Universiteit Brussel, Brussels, Belgium

*Corresponding author: aldo.scafoglieri@vub.ac.be

Introduction: Point-of-care (POC) devices such as the Accutrend® Plus are helpful in the measurement of lipid levels and have been validated in the laboratory setting, but not in a busy general practitioners office. Since the Accutrend® Plus device has recently been recommended as an additional tool in the personal management of dyslipidemias, it's of the utmost importance to ensure that the precision and accuracy of this POC device is satisfactory.

Materials and methods: The sample consisted of 61 randomly chosen individuals ($\geq$ 18 years) without known history of cardiovascular disease events. Simultaneous capillary and venous blood testing was undertaken on the Accutrend® Plus handheld lipid analyzer and a reference instrument (Vitros® 5.1 FSchemistry system) respectively. To stimulate a true picture of the usual clinical setting all blood samples were taken in the private office of each subject's general practitioner after a fasting period of at least eight hours.

Results: The results show that the Accutrend® Plus system provided significantly lower values ($P < 0.01$) of total cholesterol (TC) but not of triglycerides (TG) ($P > 0.05$) as compared to the values determined in the laboratory. The agreement between methods fell outside clinically acceptable limits for blood lipid measurement (TC $\leq$ 8.9%, TG $\leq$ 15%), as stated by NCEP recommendations. However, a good between-day reproducibility (ICC: TC = 0.85, TG = 0.68, P< 0.001) and significant concordance ($P < 0.001$) with the laboratory method was found.

Conclusion: Accutrend® Plus lacks precision and accuracy compared to a reference chemistry system. However, its reproducibility also suggests that this portable POC device might be useful for the monitoring of metabolic disorders and cardiovascular risk factors. Clinicians should be aware that fluctuations of 0.75 mmol/L (29 mg/dL) for TC and 0.88 mmol/L (78 mg/dL) for TG are to be considered as non-significant under constant diet circumstances.

Key words: reproducibility of results; cholesterol; triglycerides

P2

Inter-lot variation with C-reactive protein (CRP) point of care testing (POCT): The need for external quality assessment.

Albersen A*, Mohrmann K, Souverijn JHM

SHL-Groep, Etten-Leur, The Netherlands

*Corresponding author: a.albersen@shl-groep.nl

Background: Dutch GP's use the CRP value to help differentiate mild lower respiratory tract infection from pneumonia in moderately sick adults. In the latter antibiotics will be prescribed as mentioned by the Dutch practice guideline "acute cough" which advocates the use of CRP-POCT in a primary care setting. Our laboratory provides eighty GP's with CRP-POCT. Recently, discrepancies were found between the CRP-POCT and our laboratory assay with monthly internal quality controls (IQC) with patient serum. This was not observed in the weekly IQC with control levels from the manufacturer.

Materials and methods: The CRP-POCT (Afinion AS 100), with two different lot-numbers, was compared with the Unicel (Beckman-Coulter) and Cobas (Roche Diagnostics) CRP assay using patient sera. Furthermore, retrospective data analyses of IQC results with patient material was performed.

Results: The CRP-POCT results show a positive bias compared to both the Unicel- and Cobas assays. Passing-Bablok regression analyses gave the following results: Afinion = 1.30 x Cobas - 3.01; Afinion = 1.10 x Cobas + 0.75; Afinion = 1.22 x Unicel - 2.64 and Afinion = 1.02 x Unicel + 1.81 with lot number 1 and 2, respectively. Data analyses show a positive shift in our IQC results in the last quarter of 2012 when compared to an earlier period.

Conclusions: Our CRP-POCT showed a lot-dependent positive bias compared to the Unicel- and Cobas assay which can be up to 20% and could lead to unjust use of antibiotics. The IQC serum results shift was attributable to a recalibration of the Afinion CRP-reagents by the manufacturer. Above results justify external quality assessment for POCT devices and if not available, periodical comparison with patient samples should be utilized.

Key words: CRP; POCT; inter-lot variation; primary health care; general practitioner

P3

Participation of laboratory professionals in the public bid for glucose strips for point-of-care testing

Pons AR, Fueyo L, Garcia A, Castanyer B

Hospital Universitari Son Espases, Palma de Mallorca, Spain

*Corresponding author: josepmiquel.bauca@ssib.es

Background: The need for ease and rapidness of laboratory sample testing depends on the patient's particular clinical situation, localization and available therapeutic strategies. In the context of a public bid for glucose reactive strips, the Department of Clinical Analysis participated in the technical evaluation of the commercial pont-of-care systems, together with the Department of Endocrinology and the Department of Management.

Materials and methods: Given the three competing kits (Abbott XceedPro®, Menarini StatStrip®, Roche Accu-Chek Aviva®), we evaluated each of the following characteristics: type of sample, sample volume, range of linearity, correction for haematocrit, duration of analysis, connectivity, information accessibility, user online teaching, data management software, traceability and price. The final decision relied on a common agreement among the three departments, giving higher consideration to price, information accessibility and data management.

Results: All three commercial strips used similar sample volumes and ranges of linearity, whereas the duration of analysis varied considerably, being shortest for Roche's. Menarini presented more informative data management software, thus allowing a better assessment of hospital glucose levels. On the other hand, Roche's offer included tester wireless connection, remote actualizations, user e-learning and total result traceability.

Conclusions: The implantation of point-of-care systems for glucose testing in hospitals represents a great opportunity for laboratory professionals to contribute in the organization, management and accreditation of these processes and therefore warrantee higher patient safety.

Active participation of such specialists in both drafting and evaluation of public bids for point-of-care testing is crucial in order to maximize cost-effectiveness and yield traceable results.

Key words: glucose strips; traceability; data management

P4

Quality Indicators (QIs) in Point of Care Testing (POCT): results of an experience

Aita A*, Babetto E, Carraro P, Sciacovelli L, Plebani M

Department of Laboratory Medicine, University-Hospital of Padova, Italy

*Corresponding author: ada.aita@tiscali.it

Background: The Laboratory Director plays a decisive role in the governance of all POCT aspects. In particular: definition of technical specifications,

management of errors, implementation and monitoring of quality control procedures. QIs can be an efficient quality assurance tool to be used. Aim of this work is to describe the flow chart and the QIs results (2009-2013) collected in our Department.

Materials and methods: Five QIs have been defined concerning instruments maintenance and performances obtained in internal quality control (IQC). Yearly data have been compared from 91 POCT: 54 Glucose meters and 37 Blood gas analyzers.

Results: Glucose meters. The number of unacceptable performances obtained in IQC is significantly decreased, from 8.6% (2009) to 1.5% (2013). The number of suboptimal values of coefficient of variation percentage is decreased from 1.6% (2010), for either concentration levels, to 0.3% and 0% (2013), for level 1 and level 2, respectively. The percentage of incorrect identification of IQC lots or reagent strips is decreased from 5.2% (2011) to 0.4% (2013). Blood gas analyzer: the number of delayed maintenance or electrodes replacement is constant over time (3.68%).

Conclusion: The results demonstrated that the continuous monitoring of POCT performances, using QIs, is a useful tool to check and improve the procedures used by the operators that work outside the laboratory walls. The quality governance by the laboratory is a critical prerequisite to improve the activities of POCT and the use of QIs helps the laboratory staff to monitor the procedures, identify the errors and know the need of the preventive/corrective actions.

Key words: point-of-care-testing; quality indicators; quality assurance

P5

Clinical effectiveness of self-monitoring of blood glucose in improving glycemic control in diabetic patients: A pilot study

Aslan D[1]*, Ergin A[2], Bostancı E[2], Uzun U[2], Akın F[2]

[1] Pamukkale University, Medical Biochemistry Department, Denizli, Turkey
[2] Pamukkale University, Public Health, Internal Medicine Endocrinology Department, Denizli, Turkey

*Corresponding author: daslan@pau.edu.tr

Background: Self-monitoring of blood glucose (SMBG) is considered an important component of diabetic patient management; recently there have been arguments whether all patients should use SMBG, especially type 2 diabetics (T2Ds) not on insulin. Most of the studies have conclusions that use of SMBG for T2Ds may not be beneficial and must be weighed against the expense and inconvenience. The aim of this study was to determine the glycemic control status of T2Ds using SMBG who are admitted to our endocrinology clinic.

Materials and methods: The questionnaires were filled by diabetic patients admitted to our Endocrinology Clinic between the 28th June 2013 and 30th July 2013. The diabetes care quality biomarkers such as HbA1c, lipids (HDL-Chol, LDL-Chol, triglycerides) were measured.

Results: The number of patients whose HbA1c can be measured was 47 [ages: mean (SD): 53.9 (11.3), diabetes duration: 8.7 (6.6)]. 80.9% (N = 38) are T2Ds and 68.1% (N = 32) are using insulin. 57.4% (N = 27), 31.9% (N = 15), and 10.6% (N = 5) patients were found as obese, overweight and normal, respectively. 97.9% (N = 46) have glucose meters; but 74.5% (N = 35) and 93.6% (N = 44) don't know about accuracy control and calibration, respectively. The percentages of patients that are out of the targets recommended by the ADA were found as 48.9% (N = 23), 35% (N = 6), 61% (N = 17), 40.4% (N = 19), 40.4% (N = 19) for HbA1c, HDL-C for males, HDL-C for females, LDL-C and TG, respectively. The previous glucose values obtained from glucose

meters didn't show good correlation with HbA1c values (r = 0.39, P = 0.02).

Conclusion: Although this study has limited number of patients, it may be concluded that the SMBG is limited clinical effectiveness in improving glycemic control.

Key words: self monitoring blood glucose; clinical effectiveness

P6

Comparison of measured and calculated LDL-C in HIV-positive patients

Dorotić A*, Marević S, Laškaj R, Sokolić B, Begovac J

University Hospital for Infectious Diseases Dr. Fran Mihaljević, Zagreb, Croatia

*Corresponding author: adrijanadorotic@yahoo.co.uk

Background: Dyslipidemia has been described in treated HIV-patients as a side effect of antiretroviral therapy and therefore lipid status is an essential part of monitoring HIV-positive patients. In the present study we compared measured with calculated low density lipoprotein cholesterol (LDL-C) (Friedewald's formula and a recently new Anandaraja's formula) in HIV-positive patients.

Materials and methods: Determination of triglycerides and cholesterol (Thermo Fisher Scientific, USA), direct LDL-C (D-LDL-C) and HDL-C (Dijagnostika d.o.o., Croatia) was done on Beckman Coulter AU400 analyzer in sera of HIV-positive patients (N = 98). Calculation of LDL-C with Friedewald's and Anandaraja's formulas was performed. Measured D-LDL-C was compared with calculated LDL-C. Statistical analysis was done with MedCalc software (version 12.7.0).

Results: Mean and standard deviation for LDL-C concentrations were as follows: 2.53 ± 0.79 mmol/L (D-LDL-C), 3.15 ± 1.13 mmol/L calculated by Friedewald's formula (F-LDL-C) and 3.46 ± 1.14 mmol/L calculated by Anandaraja's formula (A-LDL-C).

Passing-Bablok regression analysis showed a constant difference between D-LDL-C and F-LDL-C, but not between D-LDL-C and A-LDL-C and a proportional difference for measured D-LDL-C and both equations (D-LDL-C $vs.$ F-LDL-C: y=-0.259 + 1.353 x; D-LDL-C $vs.$ A-LDL-C: y = -0.425 + 1.500 x). Bland-Altman plot showed a mean difference between methods: D-LDL-C $vs.$ F-LDL-C -0.62 mmol/L (95% CI: -1.50 to 0.27) and D-LDL-C $vs.$ A-LDL-C -0.93 mmol/L (95% CI: -2.07 to 0.21).

Conclusion: According to our results, measured and calculated LDL-C should not be used interchangeably in HIV-postive patients. Friedewald's and Anandaraja's equation generally overestimate LDL-C in HIV patients.

Key words: low density lipoprotein cholesterol; Friedewald's formula; Anandaraja's formula

P7

How well are patients with diabetes mellitus educated to measure glucose levels at home using a glucometer?

Dobša L*, Crnković M

Laboratory of Medical Biochemistry, Health Institution Varaždin County, Varaždin, Croatia

*Corresponding author: lidijadobsa@gmail.com

Background: Daily monitoring of glucose levels in patients with diabetes mellitus is performed by diabetic patients themselves using a glucometer at home. For accurate results of measurements, it is paramount that patients are educated on the correct preparation and methods of using a glucometer.

Aim: To examine how well patients with diabetes mellitus are educated regarding the correct methods for accurate glucose measurements using a glucometer at home.

Materials and methods: An anonymous questionnaire was given to patients who were diagnosed with diabetes mellitus and were also re-

ferred for blood tests at the Medical Biochemistry Laboratory of Health Institution Varaždin County. The questionnaire was filled by 76 patients, with an average age of 61, ranging between ages 25-93 years and of which 50% were women. The questionnaire contained 14 questions about their treatment, the method of obtaining instructions, clarity of received instructions, the preparation of patients and the measurement of glucose.

Results: In the observed group, 86% of the patients use glucometers at home. Of these, 85% of them obtained a glucometer and 15% bought one. The patients received a glucometer mostly from doctors (67%) and pharmacists (14%). Instructions about the method of glucose level measurements were mostly given by doctors (66%) and nurses (22%). Those instructions were clear to 97% of patients. Instructions about the use and calibration obtained with the device were read by 91% of patients. The majority of patients measure glucose once a day (37%), 19% measure it twice a day and 23% measure it three times a day. 45% of patients measure glucose levels before their meal, 23% of patients measure glucose levels after their meal while 32% of them measure it before and after their meal. 82% of patients who measure glucose levels after their meal, measure it exactly two hours after.

Conclusion: Patients are well informed about the measurement of glucose levels using a glucometer at home and subsequently perform the measurements mostly in the correct way. However, a larger number of Diabetic patients should be involved in monitoring of glucose levels by using glucometer at home.

Key words: diabetes mellitus; glucometer; measurement

P8

POCT practise in the Institute of Oncology Ljubljana

Lenart K*, Grošel A, Možina B

Institute of Oncology Ljubljana, Slovenia

*Corresponding author: klenart@onko-i.si

Background: Our hospital conducts programs of comprehensive management of cancer diseases in terms of prevention, early detection, diagnostics and treatment. We follow all professional and technical requirements laid down by the Rule on medical laboratories in Slovenia (2004), which stipulates particular requirements for ensuring competent and high quality POCT.

Materials and methods: POCT analyses are carried out on 18 glucose POCT devices in different hospital units and on two blood gas analyzers in the Intensive Care Unit, where blood gas, pH, electrolytes, metabolites and haemoglobin are tested. All glucometers in our hospital are made by the same manufacturer (Hemocue), which helps to ensure a uniformity of patient results. Since June 2010 an analysis of two control samples, which are prepared in the laboratory, has been performed on all glucometers. During each control cycle, the results are statistically evaluated and compared within the group of glucometers. From this year on we are also participating in an international external control scheme for POCT. Blood gas analysis is performed on two Rapidlab 1265 (Siemens). Analysis and everyday maintenance of the analyzers is performed by hospital nurses. More complex maintenance of the analyzers and an evaluation of the internal quality control results are performed by our laboratory. For both blood gas analyzers, the internal quality control samples are taken by using the Automatic Quality Control Cartridges three times a day, and the international external quality control samples are taken once a month.

Our ambition for the future is to introduce identification codes for POCT operators and patients' samples and to ensure a transfer of POCT results into the hospital information system.

Key words: POCT; legal basis; quality control

P9

Comparison of haemoglobin and haematocrit levels on point of care blood gas analyzer and automated haematology analyzer

Grzunov A*, Lenicek Krleza J

Children's Hospital Zagreb, Department of laboratory diagnostics, Zagreb, Croatia

*Corresponding author: anagrzunov@gmail.com

Background: The aim of this study was to compare haemoglobin and haematocrit levels measured as point of care testing and measurements done by automated haematology analyzer.

Materials and methods: In this prospective study, haemoglobin and haematocrit levels were measured in 126 consecutive paired arterial or capillary samples using a point of care blood gas analyzer and automated haematology analyzer. Pearson correlation coefficient and Passing-Bablok regression were calculated for the data comparison.

Results: Mean (SD) level of haemoglobin measured on blood gas analyzer was 135.59 g/L (26.48) and measured on automated haematology analyzer 118.84 g/L (25.59). The mean difference between the blood gas analyzer and automated haematology analyzer was -16.75 g/L (P < 0.001). Mean (SD) level of haematocrit measured on blood gas analyzer was 0.399 L/L (0.078) and measured on automated haematology analyzer 0.356 L/L (0.071), respectively. The mean difference between the blood gas analyzer and automated haematology analyzer was -0.043 L/L (P < 0.001). Comparison of the results of two devices yielded correlation coefficients r = 0.98 (P < 0.001) for haemoglobin and r = 0.75 (P < 0.001) for haematocrit.

Conclusions: Although the correlations between the measurements were significant, blood gas analyzer has shown unacceptable agreement with automated haematology analyzer. It overestimates haemoglobin and haematocrit values, which is not clinically acceptable.

Key words: point–of-care; blood gas analyzer; haematology analyzer; haemoglobin; haematocrit