European Association for Professions in Biomedical Science

Point of Care Testing

The Patient is the Point

Zagreb 8th October 2015

European Association for Professions in Biomedical Science
EPBS is an International Non-Profit Association (AISBL) registered under the Belgian law.
Place Jean Jacobs, 3
1000 Bruxelles (Belgium)

Biomedical Scientists are passionate about diagnosis and monitoring of disease. They are committed to ensuring that the result which forms the basis for diagnostic decisions is the best quality possible.

Point of Care Testing is an addition to the armoury of diagnostic testing. The fact that this takes place outside the traditional laboratory, and is performed by those not trained in analysis, is a challenge for us.

Point of Care Testing has revolutionised many patient's own ability to be involved in, and in control of their disease. Its use in critical care settings where time is of the essence is well documented.

The patient is at the point where the test is done and is the point of the test.
As Biomedical Scientists we must ensure that this innovation and agent for change remains a good force in healthcare. It must enhance and not harm patients. We can do this by ensuring quality products are brought to market that are fit for purpose, to be used by those for whom they are designed. We must provide good governance, ensuring training and competence of users, quality control and assurance. And we must work with researchers to develop the capacity of this innovation.

I welcome you to come to our 2nd Conference in Zagreb, Croatia, on 8th October to explore with colleagues, manufacturers, regulators and patients how we can endure that in Point of care Testing we never forget that the Patient is the Point.

I look forward to hearing the presentations and to the fruitful discussions

Marie Culliton. MSc, MBA, FAMLS

President EPBS

08:30	**Registration**
	Session 1: Point of Care Testing in 2015
	Chair: Anneke Geurts, EPBS, Netherlands.
09:00	Point of Care Testing *Marie Culliton, President EPBS, Ireland*
09:15	POCT in Hospital *Catharina Gottschall, DVTA, Germany*
09:45	Quality assurance of POCT in primary health care *Kari Nerhus, NOKLUS, Norway*
10:15	POCT in Croatia: Where are we today? *Ivana Baršić MSc, Mirjana Fučekn MSc, Specialists in Clinical Chemistry and Laboratory Medicine, Croatia*
10:45	Coffee – Poster Walk
	Session 2: Standardization and Regulation of POCT
	Chair: Sonia Daadoucha-Perroud, EPBS, Switzerland
11:15	International Standardization of POCT *Lena Morgan, Swedish Standards Institute (Sweden)*
11:45	Lab in a Bag' - The UK Military Solution *Mr Gary Fitchett FIBMS, Defence Special Advisor in Pathology*
12:30	Lunch
	Session 3: POCT Impact on The Health Care System
	Chair: Anne Berndt EPBS, Sweden.
14:00	POCT a Multidisciplinary Approach to Improve Patient Care and Safety *Andrea Schiefthaler, Klinikum Klagenfurt am Wörthersee, Austria*
14:20	The Role of POCT Coordinator/Administrator *Anne Dorthe Møller, Denmark,*
14:40	Training and Re-training of the Users: How, When, Why. A web-control solution *Fabio Como, SiPMEL, Italy*
15:00	Patient Experience *TBC*
15:30	Coffee – Poster Walk
	Session 4: Development and Research of New POCT Devices
	Chair: Fernando Mendes, General Secretary EPBS, Portugal
16:00	New applications on POCT *Winnie Edith Svendsen, Denmark,*
16:30	The role of POCT in future *Prof. dr Veronique Stove, Ghent, Belgium*
17:00	**Session 7: Round Table Discussion**
	Chair: Marie Culliton, President EPBS, Ireland

Oral Presentations

Session 1: Point of Care Testing in 2015

Chair: Anneke Geurts, EPBS, Netherlands.

Point of Care Testing
Marie Culliton, President EPBS, Ireland
POCT in Hospital
Catharina Gottschall, DVTA, Germany
Quality assurance of POCT in primary health care
Kari Nerhus, NOKLUS, Norway
POCT in Croatia: Where are we today?
Ivana Baršić MSc, Mirjana Fučekn MSc, Specialists in Clinical Chemistry and Laboratory Medicine, Croatia

Anneke Geurts, The Netherlands

Anneke Geurts has been a delegate to EPBS since 2005 and has been treasurer of EPBS since October 2011. She works as Biomedical Laboratory Scientist at the Department of Laboratory Medicine of the Radboud University Medical Centre in Nijmegen, the Netherlands. The laboratory supports patient care with routinely and specialized based laboratory activities and comprehends the field of Clinical Chemistry, Haematology, Immunology, Genetics, Endocrinology and Metabolism. One day per week she is busy with work for the Works Council of Radboudumc.
Besides her scientific work (coauthor of more than 70 publications, member of the executive committee as treasurer of the PathoBiology Group of the European Organisation for Research and Treatment of Cancer (EORTC)), Anneke is involved in education of (bio)medical (laboratory) students and retraining and continuous professional development (CPD) of (bio)medical laboratory scientists and technologists in order to keep abreast with research and development within the specialties of laboratory medicine. Her topic on which she stakes is the recognition and registration of (bio) medical scientists in the Netherlands and in Europe in order to maintain the profession of laboratory scientist as dynamic, challenging and fascinating.

Marie Culliton. M.Sc., M.B.A., F.A.M.L.S., President E.P.B.S. (Ireland)

Marie Culliton has been a delegate to the EPBS since 2001. She has been President of EPBS since 2004.

Marie Culliton entered the profession of Medical Science in 1973. She was awarded the Diploma in Medical Laboratory Science (Microbiology) in 1978 and Fellowship of the Institute of Biomedical Science in 1980 specialising in Clinical Chemistry. Further professional development resulted in the award of MSc in Clinical Biochemistry from Trinity College in 1990 and the MBA in Health Services Management in from UCD and RCSI in 2001

Marie worked in the Endocrinology Laboratory at St Vincent's University Hospital for many years where she had research interests in Congenital Adrenal Hyperplasia and Polycystic Ovarian Disease. In 2004 Marie was appointed Chief Medical Scientist/Laboratory Manager at the National Maternity Hospital, the largest maternity hospital in Europe. Current research interests are in the field of 1st trimester screening and fetal wellbeing. Marie has been a member of the Council of The Academy of Medical Laboratory Science since 1985 and has completed 2 terms as its President.

Marie has worked with the Management Body in the production of Statutes and Internal Regulations, registration of EPBS in Belgium and in the production of the position paper on education standards. She has appeared before a committee of the European Parliament outlining the objectives of EPBS and seeking the establishment of a common platform.

Marie is committed to working with member associations to ensure that Biomedical Scientists are recognised as key contributors to healthcare and to ensuring that they have the education and experience necessary to be leaders in Laboratory Medicine.

Marie has been appointed by the Minister for Health and Children to the Council of CORU, the Registration Council for Allied Health Professionals.

Point of Care Testing

Marie Culliton EPBS

In this presentation Marie will set the scene of Point of Care Testing; the challenges it poses for the laboratory and Biomedical Scientists and the potential benefits it brings to patients and their disease monitoring and management. We need to build on the theme of last year's conference and consider ourselves as Diagnostic Partners in this emerging field.

Catharina Gottschall, Germany

Catharina has been working for over 30 years in the University Hospital Rostock. For the last 12 years she has been in the role of Quality Manager and POCT Coordinator

Management POCT Point-of-Care Diagnostics - the function and role of POCT

Catharina Gottschall, Germany

Point-of-Care Diagnostics (POC) include medical laboratory single-sample measurements performed outside of the central laboratory, typically by ward staff without specialized trained. A key criterion of POC the direct derivation of therapeutic decisions and consequences.

If Point-of-Care Testing (POCT) within a hospital is supervised by the central laboratory, this laboratory is responsible for monitoring the implementation of internal quality assurance measures in the individual organizational units of the facility, in accordance with the legal requirements set by the "Guideline of the German Medical Association for quality assurance of quantitative medical laboratory tests ".
Consequently, overlapping processes and responsibilities arise between the central laboratory and the hospital departments implementing POC diagnostics.

POCT-managers are responsible for the coordination of all activities related to the implementation and operation of POCT systems. These managers communicate and monitor the quality assurance measures set by the German Medical Association.

They mediate between the central laboratory, the POCT-Commission, POCT users and other service areas, and function as their advisers.
Additionally, they are the primary contact for industry representatives.
POCT managers develop training concepts and monitor their implementation.
Furthermore, they provide guidance and assistance in the development, implementation, documentation, and maintenance of the processes required for POCT quality assurance.
These tasks can only be carried out if the POCT officers' responsibilities and authority are defined relating to their specific institution.

Kari Nerhus NOKLUS, Norway

Education:
Bachelor of Science (Medical laboratory Scientist), Bergen University College, 1981
Master of Science, University of Bergen, 2010

Professional Experience:
Medical Laboratory Scientist for 14 years in hospital laboratories (Førde and Bergen, Norway), Laboratory consultant for 4 years (Noklus), Head of the professional area “Self-Monitoring Blood Glucose” for 15 years (Noklus) and Quality manager for 3 years (Noklus).

Professional interests:
Laboratory analyses performed outside hospitals in general and by patients in particular, especially Self-Monitoring Blood Glucose. Analytical quality of laboratory analyses (main focus in Master degree).

Quality Assurance of POCT in Primary Health Care

Kari Nerhus, Noklus

Key issues for POCT in primary health care are choosing appropriate POCT assays, adequate analytical quality of the POCT-instruments, having systems for quality assurance of POCT in place, ensure proper use of POCT-instruments and correct interpreting of the results from POCT.

Regarding appropriate assays, relevant factors that must be considered are the patient's need, analytical quality, ease of use, frequency of the use of the test and response time. Norwegian Quality Improvement of Primary Health Care Laboratories (Noklus) provides lists on www.noklus.no of laboratory assays recommended for general practitioners offices and nursing homes in Norway.

Analytical quality and ease of use can be determined by testing the instruments. Scandinavian Evaluation of laboratory equipment in primary health care (SKUP) performs instrument evaluations according to a standardised protocol (www.skup.nu).

External quality assessment scheme is an important part of a quality assurance system for POCT and Noklus provides such a scheme including pre-analytical and analytical programs to smaller laboratories using POCT-instruments outside hospitals.

To ensure proper use of POCT-instruments, the staff using the instruments needs proper training. Laboratory consultants (medical laboratory scientists) engaged in Noklus provide guidance in laboratory work to 3000 participants. The consultants organize training courses and visit them regularly. The consultants guide the laboratories in choosing POCT-instruments and internal control routines. Noklus has also drawn up procedures for all laboratory work conducted outside of hospital and offers e-learning courses in laboratory work.

Correct interpretation of the results from POCT-instruments is important for the patients and Noklus provide guidance to the physicians. As a part of this service, Noklus compile practice profiles and case reports that focus on the use of the laboratory tests and the post-analytical phase.

Ivana Baršić MSc, Croatia

Education:

Master of Medical Biochemistry, Faculty of Pharmacy and Biochemistry, University of Zagreb, Laboratory Medicine Residency Program, Clinical Department for Laboratory Diagnostics, University Hospital Center Zagreb, Croatia

Professional Experience:

Medical Biochemist since 2006 and from 2014 Specialist in Laboratory Medicine, POCT Coordinator

Clinical Department for Laboratory Diagnostics, University Hospital Centre Zagreb

Professional interests:

Member of Croatian Society of Medical Biochemistry and Laboratory Medicine, chair working group for POCT and member of working group for acid-base. Member of IFCC POCT Working Group - "How should Glucose Meters be Evaluated for Critical Care"

Mirjana Fučekn PhD, Croatia

Education:

PhD of Medical Biochemistry, Faculty of Pharmacy and Biochemistry, University of Zagreb,

Professional Experience:

Medical Biochemist since 1991 and from 2014 Specialist in Laboratory Medicine, POCT Coordinator

Clinical Department for Laboratory Diagnostics, University Hospital Centre Zagreb.

Lecturer in professional study at University of Applied Health Sciences

Professional Interests and Activities:

General and emergency laboratory diagnostics - optimization of different methods on automatic analyzers, improvement of workflow. Urinalysis - automated microscopy. Atomic absorption spectrophotometry - work with flame and graphite furnace technique. Optimal

use of laboratory tests. Application of preanalytical professional standards in the laboratory. Laboratory accreditation. Medical Informatics - IT Coordinator for Department of Laboratory Diagnostics. Informatization of laboratories, active participation in the project of informatization in University Hospital Centre Zagreb. Implementation of barcoding laboratory samples on clinical departments. Continuous education of clinical and laboratory staff.

POCT in Croatia: where are we today?

Ivana Baršić, Mirjana Fuček, Department of Laboratory Diagnostics, University Hospital Centre Zagreb, Croatia

Today there is a growing awareness that the majority of problems that arise with point of care testing (POCT) are due to incorrect implementation of POCT devices, incorrect sampling technique, poor operator experience and training, inappropriate interpretation of results and absence of appropriate quality control which can lead to unreliable results that may have serious implications for patients.

Even though there are international standards for point of care testing (ISO 22870 Point-of-care testing (POCT) – Requirements for quality and competence) and point of care testing guidelines published by Clinical and Laboratory Standards Institute (CLSI) we still don't have a system that provides proper use of POCT in Croatia. According to the regulations of Croatian Chamber of Medical Biochemists from 2005 (*Regulations for performing laboratory testing near patient's bedside* and *Regulations for supervision on performing laboratory testing near patient's bedside and in the doctors' offices*) POCT must be carried out under the supervision of central laboratory. In spite of this the most of laboratories in Croatia are not included in implementation of POCT and they don't have information about POCT devices that are used in their hospital environment.

In 2015 the Croatian Society of Medical Biochemistry and Laboratory Medicine created Working group for POCT. The aim of this working group is to investigate the current situation of POCT in Croatia and to provide national guidelines for the implementation and management of POCT with a specific focus on the safe use of POC tests. It is intended to provide guidelines for best practice in POCT to ensure accurate and reliable patient result. We truly hope that with this national guidelines the current status of POCT in Croatia will be greatly improved towards better quality and patient safety.

Session 2: Standardization and Regulation of POCT

Chair: Sonia Daadoucha-Perroud, EPBS, Switzerland

International Standardization of POCT

Lena Morgan, Swedish Standards Institute (Sweden)

Lab in a Bag' - The UK Military Solution

Mr Gary Fitchett FIBMS, Defence Special Advisor in Pathology

Sonia Daadoucha-Perroud, EPBS, Switzerland

Sonia entered the profession of Biomedical Laboratory Scientist in 1990 at the District Hospital of the Glâne in the canton of Fribourg. She got her diploma of laboratory management in 2000 and became more active in her professional association (labmed), first as member (2001 to 2005), then as president of the French speaking section (2005 to 2009). Sonia has always been concerned with continuing professional development (CPD). Beside her collaboration on a survey regarding CPD during her management training, Sonia organised several French CPD courses. She is also concerned with quality which formed the topic of her dissertation while undertaking her laboratory management diploma. As member of the editorial board of labmed journal, she is in charge of French and English scientific articles.

Sonia has collaborated as French speaking delegate in the production of the new Swiss BLS professional framework curriculum. Beside her work in the laboratory, she is now acting as a professional expert for the federal recognition of teaching programmes in French speaking Swiss BLS schools.

She has represented Switzerland as delegate to IFBLS from 2005 to 2008 and EPBS since 2005. Since her election at the position of director of the management body of EPBS in 2010, she is in charge of recruitment and worked closely with her colleagues on different issues such as finances.

She is delighted to continue serving EPBS to contribute to the recognition of Biomedical Scientists as full part of healthcare professionals and ensuring that they get the means to develop their competences.

Personal Interest:

Sonia enjoys travelling and discovering new cultures and customs. She also likes music and sports such as running, swimming and walking.

Lena Morgan, Registered Biomedical Laboratory Scientist and Project Manager, Swedish Standards Institute

Professional Interests; Laboratory medicine, Standardization, External Quality Assessment, Professional development I have worked in all these areas during my work life. Currently working with both national and international standardization within the health care sector

Professional affiliations: Previously president of IFBLS and part of the board for 10 years, vice president of IBL (Swedish Institute of Biomedical science)

International standardization of POCT

Lena Morgan, Registered Biomedical Laboratory Scientist and Project Manager, Swedish Standards Institute

To work in a standardized way with POCT is essential for safe analytical results and correct treatment for the patients. Standardization concerns all aspects of POCT, from manufacturing the IVD devices, evaluation of the IVD kit, procurement, EQA and the processes when the patient samples are performed and how to interpret results and recommend medical action.

This presentation will describe the structure of international standardization both in Europe (CEN) and globally (ISO). This includes the organizations work and collaboration and also how to become a part of the standardization community as an individual. There will also be a short presentation of the Swedish mirror committee and their work to describe how you can work with standardization issues within a country.

The main part of the presentation will focus on the existing standard for POCT ISO 22870: 2006 Point-of-care testing (POCT) — Requirements for quality and competence and the New work item Guidance for Clinical and Non-Clinical Testing independent of Medical Laboratories.

Some parts with in the documents will be highlighted and discussed. The presentation will also show how a Swedish hospital have been working with ISO 22870:2006 and now are accredited

Lab in a Bag – The UK military concept to provide a fast efficient and high quality POCT service

Gary Fitchett FIBMS, Defence Specialist Advisor in Pathology

The laboratory support to deployed troops follows NATO medical doctrine and traditionally operates towards the rear of the battlespace. With the development and introduction of small, robust analysers and following their successful use in Sierra Leone during the Ebola crisis, an opportunity has arisen to provide a highly mobile, reactive laboratory capability closer to the military patient.

Contained in a suitable bag and coupled with the expertise of a multi-disciplined military biomedical scientist (BMS) the capability provided will exceed the prescribed medical doctrine in STANAG 2571 and provide better outcomes for the non-trauma patient.

Session 3: POCT Impact on The Health Care System

Chair: Anne Berndt EPBS, Sweden.

POCT a Multidisciplinary Approach to Improve Patient Care and Safety
Andrea Schiefthaler, Klinikum Klagenfurt am Wörthersee, Austria
The Role of POCT Coordinator/Administrator
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Training and Re-training of the Users: How, When, Why. A web-control solution
Fabio Como, SiPMEL, Italy
Patient Experience
TBC

Anne Berndt, EPBS, Sweden.

Anne Berndt is an advisor for biomedical scientists at Vårdförbundet (the Swedish Association of Health Professionals) located in Stockholm. She received her training as a biomedical scientist with a specialty in histopathology and cytology. Anne has worked as a cytotechnologist and biomedical scientist for about 11 years at different labs in Sweden and for 4 years abroad as a research technologist (Chicago and Zürich). In 2007, Anne received her Master's Degree in Quality Management and Leadership and the same year was given the opportunity to combine her interest in the profession and in people and work at the Swedish Institute for Biomedical Laboratory Science (IBL, the professional organization for biomedical scientists). Here Anne became involved in promoting the profession, both nationally and internationally. At Vårdförbundet she continue this work and is currently focused on the organization and awareness of continuous professional development and professional ethics.

POCT – a Multidisciplinary Approach to Improve Patient Care and Safety

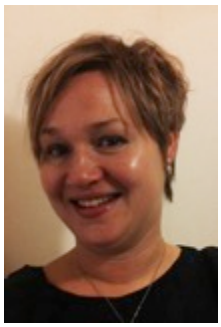
Andrea Schiefthaler, Klinikum Klagenfurt am Wörthersee, Austria

POCT can be found at nearly every place in our healthcare systems. In the Hospitals it is used especially in acute care for example in the emergency departments, in the intensive care units, in the operation theatres and is further applied in outpatient clinics, ambulances, helicopters by visiting nurses and while patient self-testing. Because the testing takes place close to the site of the patient care, the results can be obtained at higher speed (TAT) , the decisions for the further patient management can be taken faster and the suitable patient care can begin earlier.
This is one of the reasons, why manufactures provide tests and devices for many medical disciplines, and the market will increase.

Concerning the patients' safety we have to consider, that the tests are typically performed by clinical personnel, whose main competencies are not in the clinical laboratory sciences. Although the devices appear to be simple, so that anyone could perform the test, in reality POCT is as complex as any other laboratory based analytical instrument.

Especially in Austria the very big hospitals, in order to get quality insurance and patient safety under control, have established systems for the organisation of POCT based on Önorm K 1950 or Önörm EN ISO 22870. These systems consist of an Advisory multidisciplinary body, the POCT commission, the POCT coordinator and POCT commissioned persons for every department. The members of the POCT commission, all experts in their discipline, have to take decisions regarding lots of aspects such as patient orientation, patient safety, usability and acceptance by the staff, achievement of evidence based quality and economy. The professions of the laboratory act as consultants and can support with their expertise. A Quality management system can ensure process-related procedures and effective communication.

Anne Dorthe Møller, Denmark



In January of 2001 I finished my education as Biomedical Laboratory Scientist and since then I have worked at Aarhus University Hospital, Department of Clinical Biochemistry in several different jobs.

September of 2003 I was fortunate to get the first job at the hospital as a POC-specialist. As a POC-specialist my main interest where to initialize and fulfill POC glucose testing at the hospital with the new highly improved glucose meters which were able to transfer results electronically to the LIS. Later on acid-base was included in our POC-program.

In June of 2009 I joined a position as a combination of Teacher Biomedical Laboratory Scientist and a laboratory consultant for the primary sector.

February of 2012 I started my current job as a Department Biomedical Laboratory Scientist where my main area of responsibility is to be a POC-coordinator. I lead a team of 5 POC-specialists, each are specialized in several POC-instruments and/or IT-middleware. I'm part of a management team with a senior doctor and a biochemist and together we've the responsibility for all POC at the hospital.

Besides POC I also have the responsibility for our activities towards the primary sector and the overall responsibility for preanalytical procedures.

The Role of POCT Coordinator/Administrator

Anne Dorthe Møller, Denmark

In Aarhus, which is the second largest city in Denmark, five hospitals have merged into what's going to be Denmark's largest hospital. A brand new university hospital creates new conditions for both Out-patient and emergency visits as for hospitalized patients. The basic strategy is to get the patients quickly in and out - and that increases the need for a POC-Coordinator!

As a POC-Coordinator I engage in dialogue with the physicians about their need for fast results which can either lead to implementing a POC-instrument or somehow facilitate a

faster result from the main laboratory. I'm a member of the hospital's POC-multidisciplinary management team where I present POC issues to be discussed and decided. Besides that my main responsibility areas as a POC-Coordinator are to ensure that:

- the ISO 22870 is complied
- there as far as possible is uniformity between the different types of POC-instruments and IT-middleware for the benefit of the users
- the education of the users has a good quality with as low time spent as possible
- the suppliers solve any long term problems which may be
- the monthly overview of the QC's is satisfying, including determining frequency for each type of instrument

Every six months I join a specialists group with other POC-Coordinators in Central Region Denmark. Here we share knowledge, develop ideas and facilitate solutions for the benefit of users who move to another hospital in the region.

Fabio Como SiPMEL, Italy

I work in the Italian Public Health System since 1996 in different Laboratory Segments and today in Novi Ligure.

1992/93 Alessandria USSL 70
Certificate of qualification as Medical Laboratory Technologist.

2004/2005 Pescara University “G. D`Annunzio di Chieti”
Degree in "Biomedical laboratory techniques” (SNT 3)

2006-2007 Rome University "Unitelma"
Master “Management and coordination functions of the health professions”. Title: “The importance of training in the light of the national program of Continuing Medical Education. Experience within an inter-department: problems and solutions”.

2010-2011 University Piemonte Orientale A. Avogadro di Novara
Master “coordination and management activities for decentralized diagnostic and

laboratory” Title: “the importance of education and communication in the management of a point of care by a multidisciplinary team of professionals".

I'm Regional First Counselor for SIPMeL Piemonte and “Trainer Manager” for this society.
Member of the Permanent National Commission on Education for the SIPMeL and in 2013 Deputy Chief Delegate at the EPBS, at the GGB held in Berlin on 18 and 19 October 2013.

Since June 2014 Italian Chief Delegate for EPBS.

Training and Re-training of the Users: how, when, why. A web-control solution

Fabio. Como SIPMeL – Italy

WHY: Errors are more often associated with lack of understanding, inadequate training and miscommunication rather than the analytical systems. Appropriate training of both the trainer and the user is therefore essential for a first-class POCT service.

In US since 2006 there are the guidelines of the National Academy of Clinical Biochemistry (NACB): guidelines 3:“We strongly recommend training programs to improve the quality of POCT.”
International Standards 15189/2007-2012: The manager shall develop, implement, and maintain an appropriate training program for all POCT personnel.

Italy: The POCT system must be operated by fully trained and regularly updated personnel (SIMeL 2010)

"Lab is responsible for users' training, their certification and re-certification" - Piedmont Region 2010.
The University Master's Degree in COORDINATION AND MANAGEMENT IN DECENTRALISING DIAGNOSTIC LABORATORY gave a boost to the professional development of the BLS in Italy.

HOW: Operators' competence should be objectively and independently established through a combination of knowledge, understanding and practical skill-based assessments.

WHEN: It is absolutely subjective, every six months or every year, but all together, without considering that each operator, each situation, is different from each other.

A software has been developed to generate a registry of the operators involved and the instruments; rules for training and re-training, list courses for CPD; POCT data registry, list of errors occurred in POCT.

Cost savings, decrease errors, increase trained users, more safety, protection for the staff involved, better operator visibility through growing curriculum.

Conclusions

POCT governance is absolutely ours and if we are not careful, there will be other professionals that will take advantage of the vacuum WE left.

The project "POCT Web Control" could manage to standardize time for training and re-training of staff.

The Patient Experience

A live video link interview with a young active woman planning life and family with the added complication of Type 1 Diabetes. This interview will explore the contribution that use of Point of Care Testing makes to her management of this chronic disease.

Session 4: Development and Research of New POCT Devices

Chair: Fernando Mendes, General Secretary EPBS, Portugal

New applications on POCT

Winnie Edith Svendsen, Denmark,

The role of POCT in future

Prof. dr Veronique Stove, Ghent, Belgium

Fernando Mendes, General Secretary EPBS, Portugal

Fernando Mendes started as Biomedical Scientist in 1994. He was awarded the Bachelor Degree in Clinical Analysis and Public Health in 1994 and with honour's degree in 2002. Further professional development resulted in the award of MSc in Molecular and Cellular Biology, at the present he is a PhD student at Faculty of Medicine of University Coimbra.

As Biomedical Scientist Fernando worked in the Transfusion Science for 14 years, changed career in 2008 when he became a Associate Professor at the College of Health Technology of Coimbra. He is also the Academic Coordinator of ERASMUS for Biomedical Science, Coordinator of the Entrepreneurship and Innovation Club and one of the coordinators of the Health Tec Working Group. He has already been a visiting lecturer in Austria, Belgium and Finland. He represents the College at Eucolabs project, financed by the EU.

His main areas of research are: immunology, cancer, radiation, cell culture, transfusion medicine and blood bank having several papers published at national and international level. He presented numerous posters and has been a lecturer at several congresses of national and international level.

Has been a member of the Board of Sciences and Health Technologies Union since 1999 and is currently serving as member for fourth term at office, being the coordinator of the International Relations of the Union.

Since 2001 he has been working actively within EPBS where he was the founder of the Student Forum in 2002, being Director from 2005 until 2010, and from this date on he is the General Secretary of the European Association.

Being involved in the development of Biomedical Science Education, undergraduate and master level (coordinating the European group for a European Master degree in Biomedical Science), setting up the European Academic Network for Biomedical Science, working in a Vision for the profession, European Directives, POCT and CPD.

Winnie Edith Svendsen, Denmark

Associate Professor W. E. Svendsen completed her master degree with honors in 1993 from the University College Dublin. She received her doctorate in atomic physics in 1996 from Copenhagen University, Denmark. Thereafter she was a postdoctoral position at the Max Planck Institute for Plasma physics, Garching, Germany. She returned to Denmark in 1998 and was appointed Associate Professor at Copenhagen University in 1999. Since 2001 she has been at the Danish Technical University. In 2006 she established her own research group Nano Bio Integrated Systems (NaBIS) applying micro and nanotechnology within biomedical applications. Winnie has more than 80 publications in international journals, several patents and participated in 4 start-up companies.

New applications on POCT

Winnie Edith Svendsen, Denmark

The technologies developed for current Point-Of-Care Technology (POCT) devices have enabled mankind to monitor health related problems at home, such as blood pressure or glucose, hemoglobin and cholesterol levels in blood. Efforts are now being made to develop a POCT that can detect other biomarkers for e.g cancer at an earlier and potentially more treatable stage. To fulfill this requirement a highly sensitive sensing technology is needed, that can detect very small amounts of cancer markers in the blood.

The Nano Bio Integrated Systems (NaBIS) group at DTU integrates micro- and nanoscience in lab-on-chip systems for biological analyses. NaBIS uses nano- and microtechnology to build lab on a chip systems for personalised diagnosis, monitoring and treatment of different diseases.

Part of the research focuses on identifying the right disease biomarkers in bodily fluids to diagnose a disease. The big challenge is to design the surface chemistry of the sensor in order to make it sensitive to these specific biomarkers. The resulting biosensor is able to find signs of disease in just a drop of blood, saliva or mucus. Examples which will be addressed are detection of biomarkers for cancer and virus infections, monitoring personal cancer treatment. Finally, an example of integrating the sensors into a true point of care system is given: Detect-A-Pill – a novel initiative to develop a pill swallowed by patients to detect colon cancer while traveling through the intestine.

Prof. dr Veronique Stove, Ghent University Hospital, Belgium

Veronique Stove holds a PharmD and a PhD in medical sciences from the University of Ghent. She specialized in laboratory medicine and since 2007, she is head of the core lab at Ghent University Hospital. She has built up expertise in high-throughput analyses and urgent chemistry/hematology/TDM/POCT analyses. During the course of years, Prof dr V. Stove has received several invitations for lectures on automation and accreditation in the clinical laboratory at both national and international symposia. Besides her PhD work, covering fundamental research on the role of the HIV protein Nef on T cell development, Dr Stove has published a number of original papers on chemistry, hematology and therapeutic drug monitoring topics. Her current research work is focusing on therapeutic drug monitoring of antibiotics and protein binding.

The role of POCT in future

Prof. dr Veronique Stove, Ghent University Hospital, Belgium

Like all other technologies, point of care (POC) testing is continually evolving and it can be expected that in future years, its use will further increase. This growth is likely to continue with focus on delivering less costly care closer to the patient's home in developed countries. In the developing world, more effective care for infectious diseases is needed and POCT may also play here a major role to achieve this goal in the future. Here, we will focus on new technologies and the future roles of POCT.

Whereas the GeneXpert system can be seen as a system to automate PCR-based

infectious disease assays, real POC devices for molecular testing are currently being commercialized. The POCT concept Lab-on-a-chip is including small devices that perform analysis at microscopic scales and incorporate microfilters, microchannels, microarrays, micropumps, microvalves and bioelectronics chips.

Glucose finger-stick testing is commonly known as a self-testing assay for diabetes patients. The new trend in this area, is real-time continuous glucose monitoring and is currently implemented in critical and non-critical care, for in- and outpatients. Besides new glucose testing solutions, diverse other home testing kits are appearing on the (internet) market, such as kits for HIV, cholesterol testing kits. In the future, most routine hematology, coagulation and chemistry test kits will become available. The research center Imec, headquarterd in Belgium, is developing the next generation of “lab on a chip” concepts. Theranos is another example of a company that is revolutionizing the POCT market.

Although primary care practitioners are quite eager to use a variety of POC tests, future research is warranted to investigate whether these POC tests can really improve patient outcomes in a cost-effective way.

Session 7: Round Table Discussion

Chair: Marie Culliton, President EPBS, Ireland

Integrated Laboratory and POCT Testing: Adding Real Value to Patient Care

Participation by speakers and the delegates

Poster Presentations

Estonia

Point-of-care testing (POCT) in Estonian

Remm, M.[1], Orav, A.[1,2] Pille Mee [2]

1) Tartu Health Care College;
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Introduction

Point-of-care testing (POCT) is an expanding area of diagnostics where the testing is carried out by persons without lab-related education and without knowledge from quality of lab-studies. Arrangement of POCT is differently organised in labs of Estonian hospitals, there is no national regulation, but suggestions by professional association is currently worked out. In general: managing POCT, training and maintenance is led by laboratories in the main hospitals.

Three researches about POCT have been conducted in Tartu Health Care College (THCC) and one is in the process. As in Estonia most of the POCT related problems occur in family medicine centres, we will present the results of the THCC research about family medicine centres, conducted by Remm, M., Orav A., Jädal, K. and Otsmaa, K.

The evidential-based information on using POCT in family medicine in Estonia is incomplete. The aim of this study was to find out which POCT methods and means to ensure quality are used in Estonian family medicine centres. This is the first study of POCT devices in Estonia, providing facts concerning devices, their maintenance and quality assurance.

Materials and methods

The study was conducted as a joint effort by Tartu Health Care College and Estonian Association of Laboratory Medicine. A convenience sampling from family medicine centres was studied with the questionnaire-based survey in the summer 2012. The 173 family medicine centres provided information about 442 devices which are used.

Results

POCT are in use nearly in 95% of family medicine centres. The most widely used POCT devices are different instruments which measure glucose levels (30%) and also urine analysers (19%). The staffs have completed user trainings provided by the sellers regarding 88% of the devices. The family medicine centres possess certificates related to only 12% of the devices. POCT device maintenance is done only on 53% of the instruments, and maintenance on only 13% of the

instruments is documented. Internal quality control (IQ) procedure is carried out for 47% of devices, comparative testing is conducted with 62% of devices, whereas there are devices on which quality control is never performed.

Discussion

The study enables to initiate the unification of POCT quality and lab quality standards. Family doctors, nurses and also other POCT users have to understand and follow the rules of instrument maintaining and accept quality control necessity as the POCT expands in future. The remarkably low application of IQ is a current disadvantage.

Conclusion

POCT devices are in use nearly in all family medicine centres, the mean number of devices is 2–3 per centre. The maintenance of instruments is insufficient; also the maintenance and usage trainings are often not recorded in documents.

The quality control implemented in POC testing is in many ways deficient.

The laboratory staff assistance is needed for family doctors centres in the application of quality assurance and trainings.

Italy

POCT in Italy: present situation and a project to standardize training.

F. Como, A. Musella, P. Dal Checco, A. Esposito, A. Ferrari, M.R. Finardi, M. Morandini, A. Villani

introduction

SIMeL position paper on POCT (2010)

The POCT system must be operated ... only and exclusively by fully trained and regularly updated personnel

Lab must provide training for all staff authorized to the use of POCT instruments.

In 2010, the Piedmont Region published D.D. 199: "Lab is responsible for users' training, their certification and re-certification"

Aim

govern education standardizing the system.

facts

The University Master's Degree in COORDINATION AND MANAGEMENT IN DECENTRALISING DIAGNOSTIC LABORATORY gave a boost to the professional development of the BLS in Italy.

A software has been developed to generate a registry of the operators involved and the instruments n use; rules for training and re-training, list of courses for CPD; POCT data registry, list of errors occurred in POCT.

results

Cost savings, decrease errors, increase trained users, more safety, protection for the staff involved, better operator visibility through growing curriculum.

Conclusions

POCT governance is absolutely ours and if we are not careful, there will be other professionals that will take advantage of the vacuum WE left.

The project "POCT Web Control" could manage to standardize time for training and re-training of staff.

Norway

Policy for organising Point Of Care Testing in Norway

Marie Nora Roald[1]
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Introduction: Point of care testing requires a multidisciplinary approach, and involves taking samples and carrying out biomedical laboratory analyses close to the patient outside medical laboratories.

Description: During the last fifteen to twenty years, the quality assurance and quality improvement of the point of care testing (POCT) has become the responsibility for the biomedical laboratory scientists (BLS), both within and outside of hospitals.

In Norway, the biomedical laboratories have an overall responsibility for POCT carried out in hospitals. Outside hospitals, Noklus (The Norwegian Centre for Quality Assurance of Laboratory Activities outside Hospitals) is established to ensure good analytical quality of these tests.

The Norwegian Institute of Biomedical Science has made a policy document with definitions and principles for point of care testing. The document is written by a BFI advisory board, a group of BLSs who are working with POCT in hospitals and in Noklus.

With this document we share the knowledge and experience of biomedical laboratory scientists and set up a common platform for organising and quality assurance of POCT in the health care system.

Portugal

POCT: quality control and patient safety - a cause for concern?

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The request for examination has undergone several changes over the past few years. The trend toward decentralization of health in the areas of diagnosis in laboratory medicine has undoubtedly contributed to the conversion of traditional laboratory tests to point-of-care testing (POCT) (1, 2). As Medicine today requires, laboratory test results need to be available in real time in order to meet the clinical needs of the patient in its present condition. Many POCT devices have been developed in response to immediate clinical needs. (3, 4). POCT, near patient test, is likely to occur at users home, emergency and operating rooms, outpatient or accident sites and became popular on the assumption of availability of a rapid delivery result. However, when incorrectly performed, POCT presents a risk to the patient and a potential increased of cost (5,6). Therefore, it is important to keep in mind that POCT is more than a quick and intuitive test that just needs to follow the operating manual instructions. An accurate result is unlikely to be obtained without a well-trained operator, whose competence is essential for optimal performance POCT (7). With disadvantage of an incorrect result expose the user to safety risk, the scientific community in the health sector is working to evaluate and improve procedures that ensures analytical quality and safety. To achieve this goal, it is essential to create a multidisciplinary management working group, to ensure and delegate responsibilities, training, monitoring, maintenance and quality control. In line with this, the International Standard Organization (ISO) reinforces the importance of POCT coordinator, so that the quality and competence can be reached and includes the following statement,"…risk to the patient and to the facility can be managed by a well-designed, fully implemented quality management system…" (8). In Portugal, there are no known studies on the operational impact of POCT. However, through the results of the survey presented in a master's thesis, it should be noted that the vast majority of respondents professionals (88.4%), used POCT, especially for therapeutic monitoring, and the most widely used test was glycosylated haemoglobin. (4) Regarding the respondents, 63.2% were nurses and 36.8% were doctors. Only 54.2% of the professionals, received practical training on the equipment. In 61.4% of cases the training was given by nurses, 27.3% of manufacturer technicians and 11.4% by doctors. 49.3% of respondents highlighted not knowing who performs the quality control (QC). Those who knew said, that 41.1% was carried out by nurses, 6.8% for manufacturer technicians, 1.4% biomedical scientist and 1.4% by doctors. However 84.5% said not knowing how often takes place (4). The

general assessment of POCT is good. This feeling may be based on quick achieving result and easy accessibility to the test, eluding the opinion of the operator that the test is safe and not vulnerable to error. However, the degree to which the error affects the result can have strong clinical and economic implications. The great challenge of POCT regards training and assessment competences. Leadership, management and planning, in a chain of responsibility that needs to be implemented by qualified professionals, to ensure analytical quality. Quality is not automatic. The ISO procedures don't apply themselves just because they exist.

! The Portuguese reality, based on only a few available reports, rises the hypothesizes of quality errors to be considerably higher than expected. There are external quality control programs implemented in Portugal but, most POCT operators are not aware that quality control is being done, and by whom. Against this background it is imperative to allocate responsibility to a multidisciplinary team in which biomedical scientists have a major role. Greater adherence to the Guidelines can be improved through mandatory training courses and a annual training component with continued support by biomedical scientists, based on a POCT program education, education certification, internal programs and external QC Internal, QC results and patient registration, supervision and periodic reviews of a team.

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Sweden

Point of Care Testing in Sweden:Biomedical scientists are key to ensuring quality, patient safety and ethics

Anne Berndt[1,2], Agneta Colliander[3,4], Gabriella Lillsunde Larsson[3,4],Lena Morgan[5], Michelle Dobos Sandell[1], Susi Nilsson[1], & Tanja Wijkmark[3]
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A health care revolution is underway around the globe causing us to rethink the relationships between people and the services that provide their care in order to ensure quality, ethics and sustainability. Person-centered care (PCC) addresses these challenges - encouraging and

supporting the individual to more effectively participate in the management and decision making about their own health and health care. As much as 60-70% of health care decisions are based on diagnostics which comprise less than 5% of hospital costs[a]. Shifting diagnostics closer to the point of care has led to point-of-care tests (POCT) that facilitate more rapid decision-making. POCT now has a significant share of the diagnostic market reaching €15 billion globally in 2014 and is expected to grow at an annual rate of over 4.5% for years to come[b]. A major challenge is to assure the quality of POCT and ensure communication and collaboration between the clinical laboratories and test performers. Some examples of efforts to assure quality control and patient safety when implementing POCT in Sweden are presented.

The accompanying poster will detail selected efforts in Sweden to assure quality control and patient safety when implementing POCT. Equalis AB[c] is a Swedish not-for-profit company providing external quality assessment of clinical laboratory investigations. Equalis is a partner in the Scandinavian cooperation SKUP (Scandinavian evaluation of laboratory equipment for primary health care)[d]. SKUP is spearheading an effort to improve the quality of POCT by providing objective and supplier-independent evaluation of analytical quality and user-friendliness of laboratory equipment. Three regions, Örebro, Västra Götaland, and Skåne have been working with accreditation of POCT implementation. In Örebro[e], the primary care clinics have been co-accredited with the university hospital clinical laboratories using ISO 15189. As coordinators, biomedical scientists oversee education, procedures, and documentation resulting in increased confidence and competence among the health care workers implementing POCT. Sahlgrenska University hospitals (Västra Götaland)[f] were the first in Sweden to receive accreditation for POCT. ISO 22870 was chosen to give wards and clinics a standard suitable for their point-of-care activities. Utilizing the knowledge and competence within the clinical laboratories and promoting education and certification of end users has been key to their progress. The clinical laboratories in region Skåne[g] have received a mandate to organize and coordinate all POCT activities into a single functioning unit, overseeing and managing methods, instruments, and quality control according to ISO 15189. Here, nurses and nurses' assistants staff laboratories at primary health care centers. In the arena of POCT, the biomedical scientists in the role of diagnostic partner share their knowledge with the extended health care team and are positioned to act as stewards of quality, patient safety and ethics.

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The Netherlands

Point-of-care testing in Dutch hospitals A highly regulated process

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Point-of-care diagnostic medical devices are in vitro diagnostics, used by health care professionals to obtain (on the spot) results rapidly, near or at site of a patient. The devices are used by a variety of users in various clinical and non-clinical settings. The majority of POC tests in the Netherlands are performed to test biochemistry parameters. A minority of POC tests are used in clinical microbiology, immunology and cyto-histopathology laboratories.

Introduction of point-of-care testing is often presented as easy and quick. POC tests do reduce the TAT (Turn Around Time), regarding the duration between test and obtaining results. However, introduction and use of POC tests also means bringing instrumentation into a non-clinical laboratory environment. Eliminating the risks of using POC tests in an environment in which staff is less experienced as it is in clinical laboratories, quality management including training and retraining become an important issue.

In the Netherlands > 90% of the clinical laboratories are CCK[3)] / ISO accredited and implemented (in case using POCT) ISO 22870[1)] in conjunction with ISO 15189[2)].

With regard of the aging population, an increase in chronic diseases, e.g. diabetes, heart and vascular diseases an increase in use of POCT can be expected. This means that clinical laboratories need a well managed POCT quality management program. The poster will show how POCT is embedded in patient care in Dutch hospitals. Self – or home – test are excluded in the presentation.

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