Congress Report

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Congress report: 5th Munich POCT Symposium, September 27–29, 2022, Klinikum rechts der Isar der TU München

https://doi.org/10.1515/labmed-2023-0025
Received February 27, 2023; accepted March 6, 2023;
published online March 22, 2023

Introduction

The POCT section of the German Society for Clinical Chemistry and Laboratory Medicine (DGKL) has organized the 5th Munich POCT Symposium on the subject of "*New Horizons for Cross-Sectional Technologies and Extended Application Areas*". The international symposium had been postponed several times due to the corona pandemic and could finally be held in presence in September 2022 (Figure 1). The Congress president Peter B. Luppa, TU Munich, organized a total of nine sessions which were mostly chaired by the members of the POCT section. The Scientific Committee was formed by Francesco Baldini (Florenz/IT), Roman Fried (Zürich/CH), Maria Luisa Hortas (Marbella/ES), Ralf Junker (Kiel/DE), James Nichols (Nashville, TN/US), Robbert Slingerland (Zwolle/NL), Antonio Buño Soto (Madrid/ES), William Clarke (Baltimore, MD/US), Leslie Donato (Rochester, MN/US), Markus Herrmann (Graz/AT), Oswald Sonntag (Munich, DE), Andrei Tintu (Rotterdam/NL), and Michel Vaubourdolle (Paris/FR). The local Munich committee was composed of Kathrin Tinnefeld and Susanne Weber.

The total number of attendees reached 350. The congress languages were mostly English, but also German. A special session on the first congress day, organized by DVTA and DIW-MTA and dedicated to actual aspects of POCT management attracted 55 participants. A connected industrial exhibition with 34 IVD companies showed the latest POCT analysis devices.

Besides the 48 oral presentations, there were also two poster sessions where 32 poster presentations were exhibited. Selected authors gave also short presentations of their results. As it was the case in 2019, four best posters and oral talks were awarded. A new format for the conference was created by four lunch symposia, organized by various IVD companies on the congress days 1 and 2.

The event was again a great success, especially since it could be held entirely in presence again after the pandemic. The participants obviously enjoyed this very much, even though they all had to pass a rapid SARS-CoV2-antigen test every day. Single presentations and photos of the event and the industrial exhibition can be downloaded from the internet at www.poct-symposium.de.

Congress president Peter B. Luppa (Munich) explained that the theme of the conference: *New Horizons for Cross-Sectional Technologies and Extended Application Areas* can be seen as a kaleidoscope focusing on the rapidly emerging new analytical techniques as well as on the fast-growing novel applications of POCT methods on a global scale. The COVID pandemic has explicitly demonstrated to everyone the outstanding importance and performance of near-patient laboratory diagnostics [1]. Also, themes, such as health economics, medical care, and patient safety were on the agenda of the POCT symposium.

The oral presentations within the nine sessions

The session numbering is not consistent due to a last-minute relocation. The enumeration of the individual sessions in this report reflects the course of the conference from day 1 to day 3. Sessions 1 to nine took place in lecture hall A.

Session 1 "IT concepts for POCT", chaired by Andreas Bietenbeck (Munich) and Thomas Streichert (Cologne), depicted IT aspects important for the important for the routine handling of stationary, but also ambulatory POCT services.

Thomas Streichert started the session with the presentation "*eLearning for POCT with respect to the IT landscape*". Essential prerequisites for establishing eLearning are

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Figure 1: The symposium's icon.

service agreements with the staff councils, comprehensive user administration and identification also at device level which meet the requirements of the DSGVO, compliance with the RiliBÄK, the MPG and the MPBetreibV (in future: IVDR, MPDG, MPAMIV) with regard to training and continuous education, particularly with regard to initial and follow-up instruction. In addition to the technical requirements, such as a suitable eLearning platform and availability of suitable training rooms and terminals, there are content-related requirements for an eLearning offering. These include the device-specific content, but must also include the conceptual aspects of POCT in the respective clinic. This complicates the use of commercially available products, as location-specific adaptations are usually difficult to achieve. The second presentation by Andreas Bietenbeck was dedicated to "*Patient-Based Real-Time Quality Control for Point-of-Care-Testing*". He described the concept of the Patient-Based Real-Time Quality Control (PBRQTC) [2] and pointed out that this concept can be seen as an effective method for the quality control strategy of POCT devices. If only a few patients are measured repeatedly (e.g. using a personal glucometer), PBRTQC cannot distinguish between a change in these patients and a measurement error. For often-repeated analytes (e.g. blood-gas analysis), the average of patient deltas will enhance error detection. A low robust normalized spread of patient results indicates that PBRTQC algorithms such as Moving Medians, Moving Averages or Exponentially Weighted Moving Averages might be appropriate. Computer simulation can select optimal parameters to quality control a POCT device in a specific setting. Jennifer Meinl (Berlin) entitled her talk with "*Outpatients – a problem for POCT blood glucose monitoring systems? Establishing a new IT concept as an innovative solution approach*". Unlike inpatients, outpatients are not discharged in the HL7-ADT system and are therefore not automatically deleted from the BG devices. Large amounts of data are generated within a short period of time, exceeding the storage capacity of the POCT devices. She described as a consequence, how POCT BG measurements were administrated by use of a specialized IT middleware in accordance with the structural division of the clinics into three campuses. Crucially for the operation is that all outpatient data records older than 48 h are removed from the database and thus deleted from the devices the next time the glucometers are docked.

Session 4 "POCT methods for the identification of infectious agents – NAT" was chaired by Daniela Huzly (Freiburg) and Norbert Gässler (Hildesheim) and gave with

seven presentations an insight into this very vibrating topic.

First, Frank Hufert (Potsdam) gave insights in the topic "*Rapid detection of SARS-CoV-2 by RPA using a reusable handheld device and cloud-based analysis for diagnostic at home*". He presented a novel and simple to use single tube real-time RT-RPA assay for the rapid detection of SARS-CoV-2 RNA for use in an affordable, digitally linked handheld device for home testing. A suitable set of RPA oligonucleotides were generated for the virus N-, E- and RpRP genes. The excellent clinical sensitivity and specificity data in comparison to real-time RT-PCR were 94 and 100% for the RdRP RT-RPA assay [3]. The assay was implemented in a low-cost fluorescence spectrometer assembled from off the shelf electronics parts available in the mobile phone industry. The minoo device runs independently after connecting to a mobile phone App which identifies the device and the sample. The App acts as transmitter to a backend where the raw data generated on the minoo device are analysed and transmitted back to the App which provides the result to the user. Usability is at the core of the concept and the recently CE (IVDD) marked product and its performance parameters were presented. Chen Liu on behalf of Dana Cialla-May (Jena) explained the audience about "*Sensitive detection of drugs and metabolites in complex biological matrices employing surface-enhanced Raman spectroscopy (SERS)*". The SERS method is based on an exceptional Raman signal enhancement of molecules attached to nanostructured metallic sensing surfaces. In label-free or direct SERS approaches, the analytes that have high affinity to the metallic surface dominate the spectral response. This makes SERS-based detection feasible for TDM in body fluids. To illustrate the potential of SERS in personalized medicine, the antibiotic sulfamethoxazole is detected spiked into urine matrix after liquid-liquid extraction within a concentration range of 10–200 µg/mL. Moreover, the group of Cialla-May developed a Raman- and SERS-based detection scheme to quantify ciprofloxacin in four different pharmaceutical formulations within the context of quality control.

Hereafter four short communications were given: Anna Lena Maisch (Mainz) reported about "*15-min SARS-CoV-2 detection with oscillating-flow microfluidic PCR*"; Markus Riester (Berlin) presented "*A mobile SARS-CoV-2 nucleic acid amplification assay for efficient decentralized testing of throat swabs*"; Rainer Wittig (Ulm) talked about "*PhotoDynaLysis: Photoswitchable sample preparation for single cell analysis in automated digital assay workflows*"; Andrea Kulik (Neuried) reported about "*Multiparametric point-of-care (RT-)PCR*", and finally Holger Wurm (Ulm) gave an insight into "*Multispectral light source for parallel frequency-modulated fluorescence analysis*".

Session 3 "POCT in the emergency room and the intensive care unit" was conducted by Dirk Peetz (Berlin) and portrayed important clinical aspects of POCT methods in the ED.

The first presentation of Evangelos Giannitsis (Heidelberg) was one of the highlights of the symposium: "*POCT with high sensitivity cardiac troponins in the evaluation of patients with suspected acute coronary syndromes*". The number of new POC cTn assays, developed to meet the high sensitivity criteria is increasing, thus allowing implementation of faster diagnosis, e.g. the ESC 0/1 h algorithm, in the ED. Implementation of hs-cTn POCT methods is likely in settings where hs-cTn is not available or where central laboratory based hs-cTn assays cannot be measured 24/7. An overview on the landscape of POCT with hs-cTn was provided, discussing potential strengths and potential caveats. The second speaker, Antonio Buño Soto (Madrid), dedicated his talk to "*POCT in the emergency room and the intensive care unit*". POCT coordinators must be aware that near-patient testing is not an error free process and that the quality of these tests must be equivalent to those at the central laboratory. The economic benefits of POCT are more likely to be realized through improving the efficiency of the ED and the ICUs. Multidisciplinary approaches involving the laboratory medicine professionals is the best strategy to mitigate errors and to improve patient care. The third presentation was given by Dirk Peetz (Berlin), dealing with "*Evidence for POCT in ED and ICU*". POCT diagnostics for blood gas analysis, cardiac markers and other parameters are regularly used in the ED and the ICU. Reasons for using POCT are speed of results for diagnosis and initiation of therapy in life-threatening diseases as well as process optimization with shorter stay of patients, especially in the emergency room. The lecture examined which tests/settings show evidence – based on randomizes controlled trial, systematic reviews and meta-analyses – that POCT is advantageous compared to measurement in the central laboratory.

In parallel to the sessions 4 and 3, the professional associations of the medical technicians in Germany (DVTA and DIW-MTA) organized a **Seminar on organizational aspects of POCT management** which was chaired by Christiane Maschek (Berlin) and Marco Kachler (Klagenfurt/AT). This seminar was held in German in order to allow non-English speaking technicians the full understanding of the presented contents. The multifaceted subjects ranged from the effectiveness of POCT in the Covid pandemic, the new IVDR to the new German reform act on medical technologists.

The first day was finalized by the poster session "*Analytical innovations*" and a series of oral short presentations, given by: Dieter Haberzettl (Allmersbach i.T.), Bettina Sailer (Munich), Christian Klenk (Munich), Christoph Dillitzer

(Munich), Martin Brischwein (Munich), Henning Sabersky-Müssigbrodt (Munich), Edoardo Farnesi (Jena), Chen Liu (Jena), Fabio Aldo Kraft (Kiel), Ghulam Destgeer (Munich), Anni Matthes (Jena), Leopold Daum (Munich), Isabella Tavernaro (Berlin), and Andreas Schreiber (Freiburg).

The second conference day started with **Session 2: "Innovative clinical applications of POCT in different settings"** which was dedicated to new applications fields for the near-patient diagnostics. The session was chaired by Ralf Junker (Kiel) und Peter B. Luppa.

Lea Elsner (Lüdenscheid) reported about "*Establishment of herpes simplex virus (HSV1/2) and varicella zoster virus (VZV): Direct detection from vesicle contents by POCT multiplex PCR*". In addition to meningitis/encephalitis diagnostics, the identification of HSV1/2 and VZV is also desirable for ulcerated lesions with suspected HSV or VZV. A previously used direct immunofluorescence test is no longer available. Therefore, the multiplex PCR system BioFire® with the Meningitis/Encephalitis Panel (ME) was evaluated for POCT applications. The sensitivity/specificity for the determination in CSF are found with 100%/99.9% for HSV1/2 and 100%/99.8% for VZV. Robbert Slingerland (Zwolle/NL) turned his gaze to the future with the presentation "*Shrinking labor force and clinical chemistry laboratories: A role for POCT, drones, interstitial fluid sensors etc.?*". Among the different facets of his presentation about innovations in the Zwolle region were the description of a self-guided radar-driven drone transportation service equipped with a decentralized pilot in case of emergency, but also interstitial fluid sensors which have been introduced to monitor glucose in patients with diabetes at home and in the perioperative period for elective surgery patients. Finally, an electronic nose with an AI network connection was evaluated in combination with a questionnaire to detect instantaneously Covid-19 infected employees and prevent an unnecessary temporary quarantine for those employees with unconfirmed infection and a negative final result. An additional short presentations was finally given by Dominik Gray (Bad Langensalza): "*Innovative POCT applications in outpatient and inpatient settings RESISTOVAC – Rapid and economical POC tests for the determination of immune status and bacterial resistance factors*".

Session 5: "Continuous monitoring of biomarkers and TDM using POCT" was conducted by Guido Freckmann (Ulm) and Hans G. Wahl (Lüdenscheid) and was dedicated to the important new technology of continuous monitoring, highly impacting clinical treatment.

Guido Freckmann (Ulm) started the session with "*Continuous Glucose Monitoring (CGM) systems: Patient use vs. professional use*". Subcutaneous continuous glucose monitoring (CGM) has become an important method to monitor glucose levels in insulin-treated patients with diabetes. While usually being used by patients at home, CGM might also be useful in hospitalized patients. Studies indicate benefits of professional use CGM for patients and also for working processes, as it reduces patient contacts. However, currently CGM systems are intended to be used only for self-measurement. In Germany, the use of CGM data by health care professionals (HCPs) might therefore currently be off-label-use, which means that responsibility for proper function of the system and possible harms shifts completely to the HCPs. In case of use of CGM by HCPs, this would need to be included in the intended use. Standards to define accuracy and traceability as well as quality control procedures need therefore to be established. Then Maurice O´Cane (Londonderry, UK) reported about "*The value proposition for point-of-care testing*". POCT is a key innovation that allows tests to be performed close to the patient with the rapid availability of a result which provides an opportunity to expedite clinical decision making and impact on patient outcomes. As such it transforms and disrupts traditional models of care. Both the adoption and implementation of POCT is hampered by barriers which include incomplete recognition of unmet clinical need, the complexity of healthcare pathways with multiple stakeholders, challenges in change management in the implementation of new care pathways and silo-ed healthcare budgets. The IFCC-WASPalM Committee on the Value Proposition for Laboratory Medicine has developed a framework for stating the Value Proposition for laboratory tests which includes defining the unmet clinical need, the patient population and care pathway under consideration, stakeholders, and other issues. There are also outcome measures to be monitored to assess effectiveness of implementation. The framework has particular relevance to POCT since the successful adoption/implementation of POCT is complex and generally requires the redesign of care pathways and involves multiple stakeholders in delivering care if implementation is to be effective. The third speaker was also from the UK: Mark O'Connell (Bath, UK), talking about "*Propofol Monitoring at the Point-of-Care*". Despite increasing evidence of benefits to patients and the environment of using Total Intravenous Anaesthesia such as propofol rather than volatile or gaseous anaesthesia, adoption by clinicians is limited partly by the lack of a real-time blood propofol concentration monitor. There is mounting evidence that patients given sedation (for instance in ICUs) are frequently over-sedated. Somnus Scientific developed a near patient real-time propofol measurement system. The developed sensor system demonstrates good linearity over the clinically relevant range, and good specificity. A short presentation was finally given by Monika Conrad (Tübingen) dealing with "*Functionalization of gold nanoparticles with antibodies for*

lateral flow assay for quantitative detection of amitriptyline". The antidepressant amitriptyline is one of the drugs for which TDM is strongly recommended. Therefore, a quantitative lateral flow test was developed for this drug. For the sensitivity of lateral flow tests, the recognition element is of great importance, which is why strategies for binding antibodies to gold nanoparticles were compared and optimized.

Session 6: "New horizons for cross-sectional technologies" was under the conduct of Oliver Hayden and Peter B. Luppa (both Munich) and performed a memorable sequence of eight outstanding presentations.

Antje Baeumner (Regensburg) opened the round with "*Development of nanomaterials for the POCT*". The future of POCT depends on the ability to further improve test performance characteristics. While maintaining key features of robustness, low-costs, simplicity of use, and accuracy, of utmost importance are the development of strategies that significantly lower the limits of detection and increase sensitivity of a POCT. The author approached this challenge with the development of nanomaterials specifically targeting key features of POCTs. Liposomes are lipid nanovesicles that provide instantaneous signal amplification through large quantities of entrapped signaling molecules. Their outer surface is tagged with biorecognition elements or ligands and can thus partake in hybridization and binding events with high avidity. The group developed formulations that can be dehydrated on membrane materials of lateral-flow-assays (LFA) or can be lyophilized and used as dry reagent. Colorimetric liposomes were shown to lower the limit of detection of IL-6 in serum in comparison to commercial LFAs based on gold nanoparticles by one order of magnitude [4]. Furthermore, novel nanofibers as highly functional separators or immobilization matrix within the test line of LFAs were investigated. Then Francesco Baldini (Florence/IT) presented "*New horizons in optical biosensing for POCT*". In recent years, new perspectives for optical biosensing in POCT are emerging due to, on one side, the advent of novel and very promising optical fibre platforms based on a label-free approach capable to assure very low-limit of detections and, on the other side, the possibility of a continuous access to the vascular system by means of intravascular microdialysis. If intravascular microdialysis represents a novel body interface that can be connected to any platforms, whatever the sensing approach used, new label-free approaches can constitute an important feature capable of strengthening the role of optical sensing POCT. In this context, a fluorescence-based optical platform for the detection of immunosuppressants in the dialysate of transplanted patients was described [5] and the label-free biosensing potentialities of optical fibres with inscribed gratings or exhibiting lossy mode resonance shown. Günther Proll (Tuebingen) continued with the topic "*How cross-sectional technologies can be used to improve therapeutic drug monitoring and evaluate the individual immune/vaccination status*". He presented two examples demonstrating how POCT solutions were only made possible through the use of cross-sectional technologies: 1. Laser structuring meets LFT: Lateral flow tests (LFTs) are highly relevant for POCT. However, LFTs suffer from many limitations due to their limited analytical quality. In particular, to address the limited reproducibility of LFTs for quantitative readouts, nitrocellulose membranes can be patterned using laser techniques to create parallel flow channels. 2. Label-free detection for serology: A novel diagnostic system was presented that allows a detailed serological diagnosis of a SARS-CoV-2 infection. The results should not only allow the reliable detection of the specific antibodies but also the differentiation from other coronaviruses. Via further characterization of patient antibodies, also a statement about the patient-specific immune or vaccination can be given as well. This novel POCT approach utilizes antigen microarrays, being read out by a PON-reader employing the direct optical transduction technology "single color reflectometry".

Oliver Hayden (Munich) portrayed novel "*Platform technologies for cell function diagnostics*". Despite major advancements in the fields of fluorescence, flow cytometry or mass spectrometry, cell function information for infectious disease diagnostics and immune system information is still often hidden for the clinical routine and for decentralized testing. He discussed strategies to develop point-of-care compatible imaging and magnetic flow cytometers, which allow single cell and cell aggregate diagnostics in complex matrices of biomarkers with low logistical stability. For sample preparation the author has been exploring acoustophoresis for label-free manipulation of single target cells and micro cell aggregates in microfluidic systems, which could support cell-cell interaction diagnostics of rare cells without the need for large target cells numbers as required for flow cytometry. Second, the group of O. Hayden started an *in vivo* theranostics project with orthopedics, where they integrated optoelectronic sensors and imagers in transparent knee spacer (short term implants), to support antimicrobial therapy and clinical decision making for surgical interventions. In his key-note presentation, Roland Zengerle (Freiburg) brought up the topic "*Molecular Diagnostics at the Point-of-Need enabled by centrifugal microfluidics*". Centrifugal microfluidics enable efficient miniaturization, integration, parallelization and automation of biochemical assays on portable desktop sized instruments. This talk presented some of the key building blocks for fully integrated sample-to-answer assays as well as application

examples such as PCR based SARS-CoV-2 testing at the Point-of-Need or assays employing digital PCR for antibiotic resistance screening. As an outlook he introduced the innovative emulsion coupling technology which allows to detect proteins and/or protein-protein interactions in a multiplexed manner at the point of care. Christian Karnutsch (Karlsruhe) presented a new technology: "*BANSAI: A novel analytical system for clinical chemistry analyses at the point of care*". With the BANSAI (Biomedical ANalysis System with lAser lIght), a novel potential analysis system is introduced that should make it possible in the future to perform clinical chemical analyses directly at the POC in central laboratory quality. In doing so, most of the common clinical chemistry assays will be measured with one and the same instrument. For measurements for renal diagnostics the author already demonstrated the functionality of this system. The BANSAI uses organic semiconductor lasers as light source. Very short light pulses (duration 3 ns) allow a highly dynamic and precise measurement of absorbance. A method comparison with clinically samples between the BANSAI system and a standard method on the Siemens Dimension Vista instrument showed a good correlation over the entire measurement range. For this purpose, human albumin was measured using the BCG method and compared to an immunonephelometric assay on the Dimension Vista. This demonstrates that the BANSAI is a novel analytical system for point-of-care clinical chemistry measurements. The use of organic laser light sources shows unique potential for miniaturization and cost reduction. Philip Tinnefeld (Munich) dedicated his talk to the topic "*Technology push for POCT by DNA nanotechnology*". DNA nanotechnology and in particular the DNA origami technique allow the construction of complex self-assembled devices with a variety of functions that are modularly incorporated. He presented biosensing approaches based on DNA origami nanostructures that enable sensing of molecules such as nucleic acids, antibodies and enzymes as well as physical parameters such as forces, membrane potentials or nanoparticle curvature. Unique features of the sensors include amplification mechanisms that enable single-molecule detection on a portable smartphone microscope as well as the tuning of molecular interaction strengths without directly changing the target and bait [6]. The last talk was given by Maximilian Urban (Munich) on "*Signal amplification for highly sensitive Point-of-Care immunoassays*". Advances in lateral flow testing rely on the ability to detect smallest amounts of biomarkers with high sensitivity. State of the art tests often suffer from sensitivity issues. Troponin I lateral flow assays are an example, where state-of-the art technologies cannot meet the medical need. The author applied a novel DNA nanotechnology to amplify signals in lateral flow immunoassays. The technology is based on precisely configurable nanostructures [7], to prevent amplification of off-target signals and does not rely on enzymes or time-consuming nucleic acid amplification steps. The latest results show robust troponin detection in 10 min on lateral flow assays based on well-controlled 10× signal amplification in human serum.

The second congress day was continued by the **Session 7: "POCT concepts of the IVD industry and of clinical users",** chaired by Christine Rode-Schubert (Heidelberg) and Christian Karnutsch (Karlsruhe) and presenting a plethora of different POCT activities of various developers.

Authors and titles of the presentations were as follows: Hans Eberhardt (Heidenheim), Cepheid GmbH – *Strategic diagnostics and management of patients with suspicion or detection of MRE, non-MRE, & Co. – the Heidenheim way*. Peter Beck (Graz/AT), Roche Diagnostics Deutschland GmbH – *Clinical decision support at the point-of-care in inpatient diabetes therapy*. Holger Gundelach (Kornwestheim), Quidel Germany GmbH – *Savanna – Insights in a new generation of multiplex RT-PCR for the point-of-care*. Ivana Baršić Lapić (Zagreb/HRV), Hemcheck Sweden – *Improving the pre-analytical phase – measuring hemolysis in blood gas samples*. Andrea Kulik (Neuried), FRIZ Biochem GmbH – *CYCLE® Dx – PCR diagnostic at the Point-of-Care*. Mirko Brummer (Espoo/FI), AIDIAN – *SIBA – an isothermal amplification technology enabling infectious disease POCT*.

This last session of the day was followed by the poster session **"Innovative applications"** and a series of oral short presentations, given by: Robby Markwart (Jena), Christian Döring (Jena), Dirk Kuhlmeier (Leipzig), Janina Treffon (Münster), Anna Kremer (Berlin), Benedikt Simon (Mistelbach/AT), and Kerris Klug (Mannheim).

The last day of the conference presented two additional sessions. **Session 8: "Regulations for POCT – New challenges caused by the European IVDR"** was chaired by Oswald Sonntag (Munich) and depicted the role of regulations for the application of POCT methods.

The first presentation was given by Oswald Sonntag: "*Sustainability – an important topic of the future also for the POCT*". The topic of sustainability has now also arrived in the medical laboratory and in the field of POCT. Due to a plethora of new guidelines and regulations, as well as actions of the professional societies, we have to meet the requirements and develop solutions. Especially in POCT, many consumables are discarded, the disposal of which is not unproblematic. The author also discussed the new situation and the requirements for a better sustainability. Proposals for solutions were presented. Then, Marta Carnielli (Munich) showed the "*Impact of the IVDR on POC Testing-Point of view of Notified Body*". Starting from 26th May 2022, regulation EU 2017/746 (IVDR) gradually replaced the existing *In Vitro* Diagnostic Medical Devices Directive (98/79/EC) (IVDD). The

IVDR now significantly strengthens the regulatory requirements for POC Testing, including an increased involvement of notified bodies in the conformity assessments of all class B, C and D POCT devices. The presentation reviewed the IVDR key requirements impacting POCT devices with a specific focus on the role of the notified body (here: TÜV Süd, Munich) in the conformity assessment process of these devices. Pascal Pernet (Paris/FR) continued then with "*Regulations for POCT and new challenges*". According to ISO, POCT is performed near or at the site of a patient with the result leading to possible change in the care of the patient. This covers 3 situations: 1 – tests under lab responsibility in hospital settings, used by clinicians with immediate therapeutic decision, 2 – guidance or screening tests, done by health professionals with a possible confirmation of results by lab, 3 – self-tests used by patient for their own care management. In Europe, 2 surveys (EFLM-EA) showed that, for case 1, quality management is often based on the 22870 accreditation norm. However, a great heterogeneity in the world for the management of these 3 situations can be observed. The practices of POCT inside hospital setting are generally well-managed in terms of risk management, with an adapted lab-controlled quality management system. However, the use of POCT outside the hospital environment remains unregulated and heterogeneous in European countries. The IFCC C-POCT group is working on new recommendations to help health authorities and professionals to progress on a lighter quality management system. A position paper is currently under revision and addresses the following areas: oversight and regulatory compliance, justification for using POCT, device selection and method verification, QMS including key performance indicators, assessment and maintenance of operator competency and connectivity. Subsequently, Folker Spitzenberger (Luebeck) was connected online from home to give his talk "*impact of the EU IVDR on in-house products: Requirements and implementation concepts*". Whereas requirements for "in-house laboratory-developed tests" (LDTs) have so far been regulated in Germany on the basis of the Medical Devices Act (MPG) and the subordinate Medical Devices Ordinance (MPV), the introduction of Regulation (EU) 2017/746 (IVDR) in May 2022 is the first time that regulatory EU-wide harmonization of regulatory requirements in this area. LDTs, which in academic medical laboratories account for up to approximately 50% of the analyses, will remain exempt from IVDR from the obligation to CE mark (in-house privilege). However, they must fulfill various requirements, including the establishment of a QM system, the implementation of a comprehensive risk management process over the entire life cycle of the LDT and a documentation of the validation. It must be able to demonstrate that the applicable safety and performance requirements of safety and performance requirements of Annex I of the IVDR for the LDTs in question are met. New is the obligation to perform a risk classification and to document a rationale for the in-house use. The individual requirements for LDTs have so far remained without further interpretation by European authorities and are discussed differently by the individual stakeholders. The German AWMF has developed recommendations that provide guidance on the implementation of the IVDR requirements for LDTs both horizontally, i.e. across the individual disciplines, and vertically, i.e. on specific topics and areas of investigation. While not legally binding, these are intended to provide guidance from a medical science perspective and in accordance with the IVDR.

The final **Session 9: "Ensuring quality of POCT – General legal and IT issues"** was conducted by Alexander von Meyer (Munich) und Ulrich Gassner (Augsburg) and dedicated to legal aspects which must be taken into account for developers and users of POCT.

Ulrich Gassner (Augsburg) described the "*European and national regulations for the quality assurance of POCT processes*". The quality assurance (QA) of POCT is specified by guidelines and directives as well as sub-legislative standards. The MPBetreibV contains special regulations for QA during use and operation. In particular, it prescribes the implementation of a QMS. In addition to general requirements for operation, maintenance obligations are also regulated. The MPBetreibV, in turn, incorporates the RiliBÄK, which defines the quality standards for laboratory measurements. POCT and central laboratory services are basically treated equally. Special rules exist for unit-use reagents, for example. Further information on quality and competence for POCT can be found in DIN EN ISO 22870, still referring to DIN EN ISO 15189. DIN 58964 deals with assuring the quality of POCT results. For supervisors and operators of POCT there is a guideline in ISO/TS 22583. In addition, occupational health and safety regulations and the MTAG may apply. Connecting POCT devices to a central information system can facilitate compliance with QA. As for cybersecurity issues, MDCG Guidance 2019-16 should be considered. For data obtained through POCT, different sets of regulations provide for storage and deletion periods that must be observed and documented. In addition to the ensuring data security, a comprehensive deletion concept is required. With regard to the liability of the operator and user, the ProdHaftG, tort law, and claims arising from (treatment) contracts. In this context organizational and selection fault, traffic safety obligations, and the attribution of third-party fault – such as that of the nursing staff deployed – become important. In the event of violations against the RiliBÄK guideline on quality assurance, organizational fault is obvious. An insufficiently established QMS and violations of data protection law can impose fines. The

"golden rule" is: QA measures must always be adapted to the specific circumstances, since POCT as such – as well as its area of application – might be very heterogeneous. In this respect, the legal framework is only an external boundary, but one that must always be observed. Carolin Schächerle (Berlin) reported then on "*Requirements for IVD manufacturers due to European environmental laws*". In addition to the European IVD Regulation (EU) 2017/746, manufacturers of IVD products must also comply with numerous environmental laws at the European and German levels. One significant environmental law is the European Regulation No. 1907/2006 on the registration, evaluation, authorization and restriction of chemicals, known as the REACH regulation. The aim is to regulate the use of certain substances and minimize the use of hazardous chemicals, thus protecting human health and the environment. Reagents and articles in IVD products contain many chemicals to enable medical analysis of the patient sample. Safe handling of all necessary reagents required for the assay is ensured by all IVD manufacturers. Maria Luisa Hortas (Marnella/ES) continued with "*Use of analytical quality indicators for blood glucose meters to study the effectiveness on the equipment and user performance*". Quality assurance in POC testing is an important issue for organizing POCT structures within the healthcare sector. Strategies for monitoring analytical quality control for glucose blood meters have been proposed in different guidelines. Traditional QC for clinical chemistry recommends the use of different levels control materials every analytical series and there is a guideline specific for unit-use testing based on the CLSI guideline (EP18-P). The author evaluated the results of the glucose meter internal control programs in POCT with several strategies: i. Daily electronic QC; ii. Use of control material, daily measurement of a control level; iii. Use of control material upon receipt of new equipment and new batches of strips, and six-monthly evaluation of glucometers with 1 level; iv. Evaluation of results after application of an error matrix and identification for critical points. No analytical errors was detected in the different control strategies. However, errors related to the user have been detected, consisting of depositing less amount of control material than necessary to carry out the measurement. The audits have revealed non-conformities with the recommended protocol. POCT coordinators must reflect on control strategies and a combination of evaluation of performance of every new equipment, new deliveries of test strips. Audits can result as more useful than conventional quality control strategies.

The next presentation was from Anetta Leue (Walldorf) on "*Committment to global and local responsabilities*". When talking about sustainability, we first think of careful use of the scarce and finite resources available to us. We think of environmental protection and the associated issues such as energy management, waste minimization, recycling, local sourcing, more environmentally friendly products and their handling, and the optimization of packaging and logistics. However, sustainability goes much further and includes a company's responsibility towards society, its employees. Companies that want to live up to this responsibility must implement a clear vision and consider the entire value chain, i.e. from product development to application in the laboratory. In the decision-making process for a product, the sustainability factor has long played an increasingly important role, also for users in the laboratory. The example of Promega shows how far the topic of sustainability and responsibility has already been implemented. The final oral presentation was given by Ivana Baršić Lapić (Zagreb/HRV) dealing with "*Detection of hemolysis in samples collected for blood gas analysis*". The sample for blood gas analysis is whole blood, therefore the operator cannot see potential hemolysis that can produce unreliable results. Testing for hemolysis in whole blood before the sample is analyzed on a blood gas analyzer can reduce errors and help in making right clinical decision based on blood gas analysis. Helge H10 is a photometric system intended for use as a point-of-care device to detect hemolysis in whole blood [8]. In a clinical study with a total of 570 arterial and venous whole blood samples, the Helge H10 system identified hemolyzed blood gas samples (using a cut-off value of 0.7 g/L of free hemoglobin in plasma) with a sensitivity of 100.0% (95% CI: 63.1–100.0%) and a specificity of 100.0% (95% CI: 99.4–100.0%) compared to the reference method in the central laboratory. Kappa value of 1.00 (95% CI: 1.00–1.00) indicated an almost perfect level of agreement with the reference method. The device is easy to use, fast and mobile. After proper education of the operator it can be used as a POCT device for fast detection of hemolysis.

Poster awards

Final action of the congress president was the award ceremony. Four poster awards were given to:

Chen Liu (Jena) for his presentation "*Raman-based detection of antibiotics in pharmaceutical formulations and biological matrices*"; Dirk Kuhlmeier (Leipzig) and his working group for "*In vitro differentiation of various bacteria and antibiotic resistant E. coli strains by ion mobility spectrometry as a basis for POC applications*"; Anna Kremer (Berlin) "*Train-the-trainer concept – a small adjustment – a big effect*", and Benedikt Simon (Mistelbach/AT) "*Comparison of a laboratory method with a POCT for the determination of CRP*". Two awards for best oral presentations were given to

Evangelos Giannitsis (Heidelberg) for his presentation at session 3 "*POCT with high sensitivity cardiac troponins in the evaluation of patients with suspected acute coronary syndromes*" and Maximilian Urban (Munich) for the presentation at session 6 "*Signal amplification for highly sensitive point-of-care immunoassays*".

Final remarks

At the end of the conference, which offered the participants many new impressions and valuable information, Peter B. Luppa and the local organizing team thanked all speakers, discussion speakers and participants for their commitment and perseverance. Special thanks were also due for the patrons DGKL, DVTA, DIW-MTA, VDGH, RfB, and INSTAND e.V., the sponsors for their generous support and the congress organizing company Conventus, Jena, for the excellent organizational realization of the event.

This was the last POCT symposium hosted by Peter B. Luppa as congress organizer in Munich. In two years from now, he will be retired from his position and therefore no longer be able to organize the congress in the Klinikum rechts der Isar venue. However, the DGKL POCT section hopes to continue the symposium in the future in the biennial rhythm somewhere else. There is no detailed planning for this yet, but all members from the POCT section are confident that the 6th POCT symposium will be continued successfully.

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