Point-of-Care Testing **Redaktion: P. Luppa**

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Application guide: training of professional users of devices for near-patient testing

Anwendungsregel: Schulung professioneller Anwender von patientennahen Tests

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Abstract: Insufficient operator training has been identified as an underlying root cause for many errors of point-of-care testing. However, while the need for operator training is beyond doubt, the practical solutions on how to train operators remain challenging. Therefore a multidisciplinary team of experts created the application guide VDE-AR-E 2411-2-101 "Schulung professioneller Anwender von patientennahen Tests" (Training of professional users of devices for near-patient testing). This work is based on the talk of Nicola Barabas during the POCT-Symposium in Munich 2017 and presents selected aspects of the application guide such as the role of the manufacturer, the learning path, the selection of training topics, the train-the-trainer concept and e-learning.

Keywords: conference report; e-learning; operator training; point-of-care testing.

Zusammenfassung: Eine ungenügende Ausbildung der Anwender liegt vielen Fehlern bei Point-of-Care Tests (POCT) ursächlich zu Grunde. Obwohl der Bedarf nach Anwenderschulung zweifelsfrei besteht, bleibt es schwierig, diese Schulungen praktisch umzusetzen. Deshalb hat ein multidisziplinäres Expertenteam die Anwendungsregel „Schulung professioneller Anwender von patientennahen Tests" verfasst. Die vorliegende Arbeit basiert auf dem Vortrag von Nicola Barabas im Rahmen des 3. Münchner Point-of-Care Testing Symposium und stellt ausgewählte Aspekte dieser Anwendungsregel vor. Dazu zählen die Rolle des Herstellers, der Lernpfad, die Auswahl der Unterrichtsthemen, das Train-the-Trainer-Konzept sowie E-Learning.

Schlüsselwörter: Anwenderschulung; e-learning; Konferenzbericht; Point-of-Care Testing.

Introduction

Point-of-care testing (POCT) has advanced considerably in recent years. Analytical problems, like the susceptibility to interfering factors, have not been solved completely but have been reduced to a great extent. The analytical quality of many tests is now sufficient for a broad range of clinical applications. Because no sample transport is needed, overall turn-around-time of POCT is usually shorter than in central laboratories. Instable samples, e.g. for blood gas analysis, cannot be affected during transport. Therefore POCT can supplement the analytical spectrum of many central laboratories [1].

Error frequencies vary widely by point-of-care test type, but approximately two-thirds of all errors occur in the analytical phase [2]. Frequently cited problems include failure to perform minor maintenance procedures, failure to follow testing protocols and failure to correctly identify operators and patients [2–4]. Warnings given by the POCT device were simply ignored [5]. For many of these errors, a lack of operator training has been identified as an underlying root cause [6–8].

Many standards and regulatory requirements demand a sufficient level of operator competence for point-of-care tests. The German Rili-BÄK – anchored within the German Medizinproduktebetreiberverordnung (MPBetreibV) – makes no distinction between central laboratory and point-of-care testing and calls for qualified personnel for all analysis. Likewise, the closely related ISO 15189 states that operators need to be qualified for laboratory tests. ISO 22870 is specially designed for POCT and explicitly

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calls for certifications of operator training. The standard recommends appointing a manager responsible for training and competence assessment of operators.

While the need for operator training is beyond doubt, the practical solutions on how to train operators remain challenging [9, 10]. The POCT operators usually outnumber laboratory personnel responsible for POCT management manifold. A high staff turn-over common in some medical institutes aggravates this problem. Moreover, POCT devices are operated by people with very diverse backgrounds. Physicians, other academics, as well as nursing personnel, all use POCT devices.

This work is based on and expands the talk of Nicola Barabas during the POCT-Symposium in Munich 2017. The presented application guide provides best practice examples as published under VDE-AR-E 2411-2-101 "Schulung professioneller Anwender von patientennahen Tests" (Training of professional users of devices for near-patient testing). Unlike a standard, this documents is not indented to be understood in a normative way. It aims to be a starting point that can be used to design training for a specific institution.

Materials and methods

The application guide was created in a roundtable format under the guidance and with the support of VDE e.V. Procedures followed the rules laid down in the DIN 820 series for standardization. Great emphasis was placed on an as wide as possible public participation. Participants included experts from academic and private laboratories. Representatives of POCT device manufacturers and of a publisher of e-learning software contributed as well.

The first meeting has been on June 29th, 2015. Since then regular meeting in person or web conferences followed. The wording was chosen to fit in the existing framework of standards and regulations. In particular, the regulations of the European Union on in vitro diagnostic medical devices define important concepts within the application guide.

Before publication, the application guide underwent a public comment phase from December, 9th 2016 until February 9th, 2017. All comments were incorporated into the final document.

Results

The application guide addresses all important points in the context of training of POCT devices. It starts with the regulatory demands for the responsible operator as well as the manufacturer. The training need arises next to the before mentioned Rili-BÄK, DIN EN ISO 15189 and DIN EN ISO 22870 also indirectly from the European IVD Directive. Suitable instructions and maintenance of expertise are a prerequisite for an appropriate operation of POCT devices. Non-compliance can lead amongst others to liability for damages of the responsible operator. The manufacturer is obligated to provide all information in an adequate form to give a good basis for subsequent training. A close cooperation between responsible operator and manufacturer is therefore recommended for best training results. One working model can be the provision of training material through the manufacturer and modification or extension through the operator with organization-specific information.

It is important to define responsibilities, e.g. within the framework of a POCT committee. Here the basic conditions like training scope and type, success monitoring or all organizational points are defined. Additionally, training frequency has to be addressed. It is amongst others dependent on the potential risk, complexity, and observed errors. Accordingly, the training frequency has to be adapted as required.

The operator is free to choose between plenty of different training methods and structures. The application guide suggests using a modular form, e.g. as a learning path. In this way, different related aspects like e.g. quality management, hygiene and POCT performance can be imparted together. The learning path and training content should be customized to the user's competence and risk profile and oriented on the needs of the target group. Often it is helpful to explain special topics in a scenario- or case-based manner.

The training's topics are manifold. The complete list with explanations can be found in the application guide itself. The aim is to inform the user as extensively as necessary about the system he or she is supposed to use. This includes general topics like contact persons, consumables or hygiene as well as the description of the test device itself. Here the pre-analytics can be as important as the analytics itself. Additionally, interpretation of the result, documentation and the handling of quality controls should be addressed. This short summary already shows that the explanation of the device itself is not enough to guarantee an accurate measurement. A complete understanding of the techniques, the analytical steps but also the other related procedures is assumed to be essential by the application guide.

Different techniques and combinations of them can be chosen to impart the necessary knowledge about the used

device. This can range from instruction through the manufacturer or a POCT manager over training of big groups or individual persons to theoretical or practical courses. The most commonly used training method is the train-the-trainer concept. Here e.g. the manufacturer or the POCT manager trains a small defined group of responsible persons (e.g. POCT representatives), who then spread the knowledge to the end users. Thus the trainers get an especially deep understanding of the device and they have a visible exemplary function. The knowledge transfer happens through personnel familiar with the local structures and the user has a defined contact person. Another model, which is not as common yet, but gains more and more importance, is the e-learning concept. Through the use of electronic or digital media, the knowledge transfer is possible in a very short time and can be distributed flexibly to all employees. It can be considered as especially useful for refresher training. The user can do the training at any time and autonomously. The application guide introduces some potential platforms for e-learning. The challenge will be to provide the training contents in a suitable format (e.g. the *Sharable Content Object Reference Model format – SCORM*), to organize the needed IT equipment and consider the necessary working time.

Discussion

This application guide is based on experience. It lacks the scientific rigor of an interventional study to analyze the effects of operator training [11]. However, this weakness is mitigated by the very diverse fields of expertise of the participants who wrote the application guide. It has been suggested, that face-to-face training has the highest impact on POCT performance, but is also very time-consuming [3]. In the present work, several ways to distribute knowledge were suggested trying to balance impact and costs for training. The application guide emphasizes the need to adjust training to individual needs. In their study, Lehto et al. [10] tailored their training to the individual need of each health care unit.

Although some recommendations might be transferable, this application guide is limited to the professional users employing a POCT device to analyze another person. Other guidelines exist to train patients for self-testing [12, 13]. Also, the training for medical devices, in general, is not covered by this application guide. Despite some overlapping themes, POCT has unique problems that warrant special attention. Finally, this application guide describes the situation in Germany. Especially the legal requirements and the central position of the Rili-BÄK for laboratory medicine differ in other countries. Nevertheless, the application guide was written with the existing framework of standard and regulations in mind. Therefore many suggestions will be readily transferable to situations in other countries.

This application guide emphasizes the importance of a close relationship between the supplier and the institution deploying the POCT test for successful training and application. Quality frameworks like EFQM and ISO 15189 call for a dependable partnership not only for POCT but the whole laboratory well [14]. For POCT the responsibility of suppliers is even greater as the laboratory can influence a point-of-care test much less than a regular analysis in the central laboratory. For training of operators, the supplier should act as a specialist for its test. The institution where the POCT is performed should act as a specialist for its individual environment. A close cooperation can ensure patient reliable POCT.

Due to copyright restrictions and space constraints, this work provides only an overview of the application guide VDE-AR-E 2411-2-101 "Schulung professioneller Anwender von patientennahen Tests" (Training of professional users of devices for near-patient testing). A complete German version can be obtained from VDE Verlag, Berlin. An English translation is not yet available but can be produced on sufficient demand.

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