How to assure the quality of POCT testing

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Medical tests are an important part of the process of healthcare. The first tests were discovered and developed at the bedside as part of the development of clinical observations based on patient signs and symptoms. In the past the taste of urine gave a clue to the understanding of diabetes, while today we approach the possibility of continuous monitoring of continuous blood glucose levels through the use of point-of-care testing (POCT).

The objective of POCT nowadays is to offer a means of **patient-centered care** in a way that brings the use of medical testing to the patient's bedside, home, workplace, the health center and the doctor's office, in order **to fulfill unmet clinical needs**. The opportunity for POCT has been created through technological innovation that has taken the analytical technique, miniaturized it, and packaged it in a way that allow it to be performed quickly and by an operator without a technical background. The miniaturized analytical device can be linked to an information network, including an Electronic Medical Record, so that the results are available to all of those involved in the care of the individual patient.
The benefit for the patient is only derived from its appropriate use, together with disruption of the status quo. The latter demands a hospital-wide development and implementation of ISO-based **POCT-policy with a typical management structure** for the organization and management (including certification and e-learning) of POCT-testing within a healthcare provider organization. Key aspects of successful and justified POCT-implementation are detailed considerations (a) on how POCT can ***improve the process of care*** and solve the clinical problem or unmet need, and (b) on how to ***design efficient and lean POCT-processes***, and informatics including decision support. To deliver adequate patient-centered care we should move POCT-testing from "a rapid testing approach" to a "whole systems approach" **guaranteeing improved patient outcomes**.

Currently, the development of POCT-devices has demonstrated that many of the analytical techniques employed in healthcare can be adapted to this miniaturized, portable format. In some instances the achievable analytical performance is equivalent to that obtained in a central laboratory, and is meeting desirable quality specifications needed in the clinical situation. In our university hospital we aim at POCT test results that are interchangeable and equivalent to central lab test results. To that end we validate POCT-devices using quality performance criteria for ***desirable bias, imprecision and total allowable error*** derived from published biological variation data. During validation, attention is also given to the fact that POCT test results are ***traceable*** to standards of higher order, whenever internationally recognized reference systems are in place. If a POCT-test is considered as a diagnostic replacement test for a central lab test in a specific clinical care pathway, the POCT-test should not only meet the desirable analytical performance criteria but also its clinical performance / diagnostic sensitivity should be similar or better.

Once a POCT-test is implemented, it should be subjected to internal and external quality control. Whereas internal quality control procedures rely on non-commutable control materials, external quality assessment (EQA) is ideally performed using commutable, stable human samples. However, whole blood based, stable EQA-samples are frequently not available necessitating the use of method specific values. Alternatively, accuracy of a whole blood based POCT-test can be assessed by means of a split-sample comparison of the POCT