

The laboratory without walls: point of care service and core lab harmonisation

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Introduction

The medical hospital laboratory acts in a field of tension between medical needs, continually evolving new technologies, increasing financial constraints and last but not least the patients' demand for maximum medical treatment.

Advances in technology led to the development of complex, highly automated instruments for high volume testing on the one side and on the other side small, easy-to-use, portable clinical analysers for low-volume testing. Due to these impressive technological advances point-of-care-testing (POCT) is becoming increasingly popular. These new possibilities enhance the desire for rapid results particularly in critical care units. Widespread introduction of new and ever more sophisticated devices and marketing strategies of the diagnostic industry add to this growing interest.

At first glance point-of-care-testing and centralised, highly automated laboratory testing appear to be opposing poles. However, these two modes of providing laboratory services may not only complement each other but are becoming necessary in hospitals to remain competitive (1).

The clinical laboratory can no longer focus solely on the analytical quality, i.e. accuracy and precision of laboratory investigations. Laboratories are institutions who should provide correct answers to clinical questions in appropriate time at reasonable cost. In order to be successful we must be committed to the customer needs and eliminate barriers between departments by improving communication and teamwork.

In my lecture I will discuss ways how we may harmonise point-of-care-testing and core laboratory testing by trying to bring medical needs, new technologies, economic pressure and the patients' demand into agreement.

First I would like to give you a short impression of the hospital I am working in and to what extent point-of-care-testing takes place. The German Heart Centre in Munich was founded in 1974 as the first specialised heart centre in Germany comprising heart surgery, car-

diology and paediatric cardiology as well as institutes for anaesthesiology, radiology and laboratory medicine. Since 1996 the hospital is located in a new building. About 40% of the 171 beds are in intensive care units. 6 Operating rooms and 5 heart catheter places are installed. Specimen are transported to the laboratory via a dedicated pneumatic tube system. Transport time is regularly below 40 seconds. About 700.000 laboratory results are transmitted electronically into the hospital information system, where they can be viewed in ward workstations or printed on paper or labels.

POCT-systems are established in almost every department of our clinic. Intensive care units use blood gas analysers with ion sensitive electrodes for the determination of electrolytes. In the operating rooms activated clotting times are used for monitoring heparinisation during extracorporeal circulation. Glucose monitors are placed in almost all wards. 55% of all glucose results in our clinic are determined by POCT.

A rather new field of testing nearer the patient is the INR-selfmanagement of patients receiving oral anticoagulant therapy. We instruct patients to determine their INR and to make adjustments of the dosage of oral anticoagulants whenever necessary.

Use of total quality management for the harmonisation of POCT with a centralised laboratory

The process of harmonisation of POCT with a centralised laboratory will be more meaningful if it is integrated into a quality management system, which should maximise organisational performance within a culture of continuous learning, sharing of knowledge, innovation and improvement. In our institution we use the EFQM Excellence Model as a practical tool to measure quality and find out improvement opportunities (2). The EFQM model is a non-prescriptive framework that recognises there are many approaches to achieving sustainable excellence. It is based on nine criteria. Five of these are 'Enablers' (i.e. what an organisation does with regard to leadership, policy and

strategy, people, partnership and processes) and four criteria belong to 'Results' (i.e. what an organisation achieves concerning customer -, people -, society - and key performance results). The main focus of the model is on customer results: 20% of the score points are allocated to this criterion. The technique of self-assessment in combination with an external audit helps to monitor and improve the performance of our and of any organisation, such as a whole clinic or an institute of laboratory medicine, through a regular and systematic review of processes and results. We are sure that proven quality will be prerequisite for reimbursement in the future, because it is already evident that further reductions in health expenses will need to occur.

Finding out the medical and analytical needs and meeting the requirements continually

The first point I will discuss is the question on what are the medical needs. Of course the answer will be highly site specific. To find out what are the true requirements is absolutely necessary, because quality may simply be defined by meeting the customers demands (3).

Even though the term "customer" sounds strange in a clinical context, it is a very helpful and exact term in quality management. Customers are all people receiving something from a supplier. In the view of the laboratory this may be medical staff, administration or patients. Additionally we too can be customers whenever we receive something from the wards, such as blood specimen, or information concerning a patient. In order to find out the customers' requirements as well as the staff satisfaction we make regular visits to the wards and use yearly surveys in form of questionnaires. To establish a focus group, such as a point of care committee, is also helpful. Such a committee has to collect input from all staff, including the people performing the tests, and find solutions to their needs in considering medical, technological and financial aspects. The committee should discuss the aspects:

- Choice of appropriate tests and instruments
- Quality control and validation
- Documentation
- Cost controlling
- Education of staff

The laboratory should keep the oversight in order to guarantee analytical quality and consistency of test results. The expertise of the laboratory is essential because the performance of POCT is not always in the same order of magnitude as compared with a traditionally laboratory analyser, particularly with samples from atypical patients, such as premature neonates, patients in shock and haemodiluted states (4). Another important issue is the concordance of results, not only with the central laboratory method, but also between different POCT units. Moreover, it is necessary to distinguish between results of analytical evaluations of

the system and performance validation of individual units. The reliability of a test result can be influenced by environmental effects on reagent stability, such as temperature and humidity. Nurses or doctors are not always motivated to do regular quality control checks on POCT instruments, because they may think it is not their job, whereas quality control is an integral part of laboratory activities. Useful approaches to identify testing problems are monitoring quality control (QC) results by site and by operator, split sample analysis and participation in proficiency testing programs. Acceptable POCT requires appropriate QC and consequences in response to the results. All that needs continual training and education of staff by experts in QC and analytical instrument handling.

Providing information about patients' condition as main purpose of laboratory tests.

The limiting factor determining the value of a clinical laboratory is often the ability to present a range of information at the correct time in the right place and through an appropriate medium. Of course communication can be verbal, not only via telephone but also in regular visits. Modern information media such as an intranet may be very helpful. Centralised laboratories have implemented diagnostic laboratory database and presentation of information on laboratory tests since several years. This allows highly efficient searching, retrieval and maintenance. Interfaces make it possible to transfer data from and to the laboratory information system (LIS) or hospital information system (HIS).

Simplification of ordering a test and combination with easy access to background information is a beneficial way to increase the acceptance of laboratory medicine. Computerised communication between laboratory and ward allow remote ordering of tests (known as "order entry") and replace paper request cards. The only papers produced are labels for test tubes. A very advanced system developed at the central laboratory of the university clinic in Würzburg uses a two-dimensional barcode containing complete information on patient identification, test requests, clinical question, receiver address. A demonstration version of the system is shown in the internet (<http://www.zentrallabor.uni-wuerzburg.de/>) allowing everyone in the world to enter requests for tests available at the central laboratory in Würzburg and to print a 2-D barcode with which a specimen can be sent to this laboratory where the barcoded information can be read and the analyses performed.

Another way to combine sample and information on patient and test request is the use of radio frequency identification (RFID). This tag technology is an electronic information carrier system not only for sample identification but also for sample tracing, data-collection and data transfer.

Important for immediate decision making at the point of care is to keep information as brief as possible and unambiguous (5). A target of 15s to find the relevant

guidance, and 15s to read it, has been suggested (6) but not always realised. Delays in the availability invalidate the results, no matter whether they are provided from POCT or central laboratory.

Most hospitals, including ours, perform several POC-tests and most of the test results are not integrated into the LIS or HIS. It would be most beneficial to have an easy way to do this. The lack of integration with the LIS and HIS is a big obstacle as is the lack of storage of patient and user data in POCT instruments. Although many POCT instruments provide interfaces for electronic data interchange, to my knowledge today there are only few hospitals beginning with systematic establishment of on-line collecting the POCT-results. The integration of blood gas analysers is today at an advanced stage. Transmission and archiving of data into the LIS/HIS as well as remote control of QC and result validation is already possible. Besides the general problem of connectivity of POCT instruments to a LIS/HIS one rather simple difficulty lies in the large number of interfaces required. In case of glucose monitors a large hospital with more than 1000 beds and outpatient services needs to integrate more than a hundred monitors. The technology to solve this problem exists already. However, the financial problem may complicate the matter even more.

Technology impact on centralised laboratory testing

Advances in technology led to the development of complex, highly automated instruments for high volume sample processing and testing in centralised laboratories. Modular automation contributes to central laboratory consolidation by reducing the number of instruments in the laboratory and eliminating the need to split samples for different workstations. Workflow optimisation simplifies processes, reduces turnaround time (TAT), and enhances efficiency while enabling capacity expansion (7).

Due to technological improvements analytical quality of tests performed by skilled professionals seems to be under control, whereas analytical TAT and cost are not well known in many laboratories. Few laboratories measure TATs as assiduously as they do accuracy and imprecision. In many cases the analytical time is much shorter than the pre-analytical phase and the post-analytical phase comprising validation, reporting and physician accessioning of results. Optimisation of the diagnostic processes in consolidated centralised laboratories leads to fewer but highly automated workstations and requires highest security in sample identification and data transmission.

Technology impact on POCT

The development of POCT-instruments has been facilitated by the technology of miniaturised components

using sensor technology, with increased reliability of performance at reduced maintenance demands and thus eliminating operator-related variances. POCT is particularly attractive because it reduces or eliminates several of the process steps related to central laboratory testing, such as specimen transport to the laboratory and centrifugation and thus clearly reduces TAT. However, an increased use of POCT could mean that clinicians and nurses have to spend more time doing laboratory tests and entering data into patients' charts, with the consequence that they will be spending less time with the care of their patients.

Is faster always better?

Considering harmonisation of POCT and central laboratory testing, it is important to note that laboratory tests can be roughly divided into three groups based on the time frame in which the results are needed: emergent (i.e. within few minutes), urgent (i.e. within one hour) and non-urgent. However, the division into these categories is not absolute. In certain situations, some test results may be required sooner than normal based on the acuity of the patient's situation. Therefore it is necessary to have the possibility of flexible response. This is facilitated by a good laboratory organisation, where a well trained staff is not overworked, uses appropriate instrumentation and a climate of good cooperation between laboratory and clinic, exists.

Increasing specialisation and sub-specialisation of clinicians that may require the development of more specialised tests, leads to a poor understanding of tests outside their skills and therefore requires support from a skilled laboratory doctor.

Therapeutic TAT may be one factor among others in determining the clinical value of a test, this means how the test result influences treatment decisions. Questions remain to what extent and under what circumstances patient outcome is related to test TAT. Published findings back up the impression that many stat tests do not get used for time-urgent clinical decisions. Therefore those fast results cannot impact on clinical outcomes (8). The dialogue between laboratory and clinicians should always keep in mind what consequences a test result would imply.

Again, in order to achieve harmonisation a good cooperation between point-of-care and central laboratory is necessary to define practical response times for test results and confine the number of disposable POCT.

Economic consequences

Considering the economic efficiency of POCT one has to look both on cost and on benefit. Although costs appear as hard figures, it is not clear what the figures really mean, because appropriate, standardised cost accounting methods are not always applied. Moreover the figures depend on the point of view: having a

microeconomic versus macroeconomic perspective, or trying to produce minimum cost at a given benefit in contrast to achieve maximum benefit at a given price. The account of total cost, including direct, indirect and overhead cost, is often believed to be most convincing but it hides more than it reveals causal connections. Direct costing is much more comparable. Consolidation of laboratory services should result in higher economic efficiency. Economic efficiency is not equal to cost savings. Financial savings depend on what the baseline was, i.e., the less efficient the laboratory was before the consolidation, the greater the savings. At present, many POC-tests are expensive. However, their use could reduce resource utilisation – such as coagulation testing during surgery may reduce consumption of blood products – thereby at least partially offsetting the cost of testing. As technology evolves and more POCT products enter the marketplace, costs are expected to drop due to greater competition. The argument that POCT induces savings in central laboratory staff has to be taken with care because this may vary greatly between different types of hospitals. Potential personnel savings in the central laboratory are outweighed by additional labour for the POCT-staff. Whether POCT is economically efficient depends not only on costs but equally on its benefit. The benefit may arise from faster test results, which should expedite diagnosis and the initiation or change of treatment. Thus it might be expected to reduce the length of stay in the hospital. In recent years studies have been performed showing that POCT reduced the time taken to make changes in patient management or that POCT is associated with decreased incidence or earlier detection of adverse clinical events. These outcome-driven and evidence-based aspects should enable economically efficient medical care at a high quality level. In any case – POCT as well as centralised laboratory testing -, the effectiveness of tests (i.e. quality of outcome and value for money) has to be considered and discussed before the service is made available.

The patients' demands

Patients satisfaction may be increased, as POCT offers more convenience due to reduced phlebotomy requirements and may decrease the time spent in a department or clinic. The more rapid therapeutic TAT (this is the time between the decision to test and the initiation of a therapeutic intervention) is of particular interest in emergency departments and outpatient facilities. An unquantifiable benefit of POCT is that it allows the caregiver to use eye contact and other forms of interpersonal communication when providing test results to the patient. Testing near the patient also reduces the problem of misidentified specimen with all its consequences.

Patient (our main customer in health care) satisfaction is indeed a measurable outcome (for instance

using a survey form) and is an essential element in TQM systems.

Conclusion

The laboratory without walls will not remain a fiction – in parts it is already realised:

On condition that the main purpose of laboratory medicine could be defined as “to provide more information to a clinician about a patient's condition than the clinician can derive from his or her own skills” (5) the laboratory system of tomorrow will be highly dependent upon information technology. Important is that the information is reliable and available at the right time and place. It is not so much important in what place this information is created.

There is no question that POCT can markedly reduce TAT of test results. However, the questions remain whether immediate results are always necessary, beneficial and cost effective.

It is unlikely that POCT will replace the centralised clinical laboratories, although the percentage of POCT will increase due to technological development, such as non- or minimal-invasive miniaturised methods. A central laboratory will always be necessary to run complex and esoteric testing, certainly most routine test and some time-sensitive tests. Moreover, apart from performing tests there are several indispensable activities of the laboratory specialist such as giving advice on the choice and appropriate use of tests, performing laboratory-based research, and continuing education of the staff.

Rational use of laboratory tests will lead to harmonisation between central laboratory testing and POCT and will show that they are not opposing but complementary to each other.

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