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Key figures and benchmarking in the hospital laboratory¹⁾

Abstract: Benchmarking is a systematic and continuous process used to compare products, services, and processes – as regards quantitative and qualitative aspects. Benchmarking in laboratory medicine departments of hospitals is a frequently used but only poorly standardized system. Sophisticated procedures for data collection are necessary due to the large heterogeneity and complexity of activities performed in laboratory medicine with regard to the type of testing, response times, availability and amount of different resources needed for single analysis and reporting. These prerequisites are difficult to fulfill. In internal benchmarking projects – i.e., monitoring of productivity, costs, and revenues within one laboratory over an extended period of time – the current tools for data collection are generally fit for purpose. In external benchmarking, however, several pitfalls may obscure the results. In broad terms, external benchmarking projects compare only partial processes with sufficient validity. Differences in benchmarking have to be controlled for improvements of data collection and for changes in surrounding conditions outside the laboratory. This review lists different approaches for benchmarking projects in laboratory medicine departments and describes their strengths and weaknesses.

Keywords: benchmarking; laboratory information system; lean management; quality management; staff requirements.

Introduction

Clinical laboratory testing is required for almost all patients in hospitals and are, in about 80% of patients, an essential basis for medical diagnosis and treatment decisions [1, 2]. This important diagnostic is provided with a low use of resources, thus, the laboratory costs in the hospital amount, in the finances of the Institute for the Hospital Remuneration System (InEK), to only about 5% of the total cost of hospital care [3]. This is achieved through very extensive flow control processes within the laboratories [4] and through a structure of supplying medical laboratories that is highly adapted to local needs and, thus, very diverse. Quality management processes initiated by medical laboratories, such as Total Quality Management (TQM), provide support which given the general economic pressure further optimize processes within laboratories [5].

The instrument of benchmarking is often used to obtain information or ideas for further process optimization. The word *benchmark* comes from the English *bench* and *mark*, from which *marque* (in French) meaning “ID” or “Trademark” originates. In business “benchmarking” means a systematic and continuous process that compares products, services and processes and their results in one’s own company with those of other companies (or industries) and compares both, qualitatively and quantitatively.

In hospitals, benchmarking is often used to identify factors with which either the success (or failure) of a treatment can be predicted, or with which, by influencing these factors, the medical and economic results of hospital processes can be improved. Typical examples are the comparison of the waiting time in six emergency departments of Swedish university hospitals [6] or infection rates in connection with a defined intervention (cerebral shunt) at 41 children’s hospitals in the USA [7].

A benchmarking of results is especially promising when there exists a strong correlation between the main factor under investigation and the outcome. A major difficulty of each benchmarking of results is that the results

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often depend on very many factors. It can be difficult to recognize the factors methodically and there is an inverse relationship between the quality of data and the number of usable data sets. This, for example, was demonstrated in a study comparing the quality structures of different countries [8]. To assess this question, initially hundreds of variables (factors) had to be identified, which were then quantified by one or more external reviewers. Since, as a result of the high cost, the number of available data to be evaluated was very low, representativeness of the sample was no longer guaranteed.

In many benchmarking projects in the hospital laboratory, the main focus is on cost (“resource use”). The laboratory is seen as a cost center, and it is assumed that the analytical performance can be obtained at a lower cost externally. With its services, the laboratory also represents a service center for other hospital areas and can also generate its own direct contribution margins as a profit center [9]. Benchmarking in the hospital laboratory must, therefore, take into account not only the costs but also always the quantity, quality and availability of the required analytical laboratory services, non-analytical laboratory services provided for the hospital and the revenues (direct contribution margins).

Basically, benchmarking processes and the resulting measures are useful to treat adequately as many patients as possible with the limited resources available. Without such resource control, there is a danger that the attending physician in the pursuit of the goal of an optimal treatment of the individual patient may cause a collapse of medical care: “Surely nobody would quarrel with the proposition that there is a limit to the resources any society can devote to medical care, and few would question the suggestion that we are approaching such a limit” [10].

Below, we describe practices that have been used in benchmarking projects in the hospital laboratory, and discuss the strengths and limitations of these approaches.

Data collection for benchmarking of hospital laboratories

The supposedly transparent and simple structure in hospital laboratories meant that, unlike in any other field of medicine, many benchmarking projects of varying quality have been carried out with published results over a long time period [11]. A distinction is made between “internal” and “external” benchmarking projects. Basically any measurable quantity is suitable for internal

benchmarking, i.e., if a facility wants to study itself over time. If the recording process of this measured quantity does not change over time, this internal comparison can be used to draw meaningful conclusions. However, benchmarking projects that have to compare different facilities (external benchmarking) are much more demanding. A special feature of external benchmarking can be found in large hospitals or hospital associations in which independent laboratories have been integrated into laboratory centers [12] and where the individual laboratories of the center or the hospital association are then “benchmarked” against each other.

Prior to an external benchmark project, appropriate reference sites or partners must be selected and a standardized method for collecting data from all partners must be determined to get the most comparable data sets (Figure 1). In organizing the data collection (questionnaires, telephone interviews or on-site visits), it must be ensured that “information-enabled” contacts are available to all participants and that the data recorded in this way are reliable. This can be of varying complexity, depending on the objective of the benchmarking. The personal circumstances of individuals surveyed can significantly affect the data collection, especially when adverse effects are feared due to the results of the benchmarking, the data transferred may be incomplete or distorted. Differences between the various laboratories outside the analytical work – the availability of efficient stock management, efficient laboratory IT or well-organized activity recording and billing – must also be considered. This not only leads to an optimal use of resources and revenues, but also may affect, via the quality of data collection (and thus independently of the actual consumption of resources), the result of the benchmark project.

While with simple questions, data collection in general can be standardized very well, with more complex issues the quality of the data may be poorer and the quality of data needs to be reworked by further surveys. Often both the respondents and the project managers are unclear about whether optimization potentials are to be predetermined at the time of the data collection, or whether only the status at a historical point in time is to be captured. The comparison will give a wrong impression especially if the reported data were obtained from the laboratories compared through a range of different procedures, or if the comparison partners did not previously agree on a uniform definition of data contents. Typical examples of such errors can be different allocations of personnel and material costs to cost centers at the various hospitals, missing ratings for certain laboratory

Figure 1 Schematic overview of the different components of the benchmarking process. To obtain meaningful results from an external benchmarking project, the type of data collection must be defined prior to the start of the project for all sub-areas listed. Sub-areas may be omitted only for internal benchmarking projects.

services or differences in the statistical recording of laboratory services.

To obtain meaningful results, the standards of metrology must also be met in connection with benchmarking, as they also apply to the analytics at the laboratory (see Table 1). Thus, for example, there can be significant differences between different statistics in connection with statistical evaluations from the laboratory information system (LIS), because statistics rely on a variety of tables that may record alphanumeric events (positive, waived, no material) or incomplete data sets differently. Work with data in archive systems, or after a subsequent re-evaluation of performance, may also yield different results (Table 2). When collecting indicators exclusively through IT systems, generally only systematic deviations must be

considered; when collecting indicators manually, such as recording working hours for non-analytical services, random measurement deviations must also be taken into account. Similar challenges exist for the measurement of inpatient hospital admissions. This parameter, which is used as a key reference in very many benchmarking projects, may be affected by a change in the type of case (outpatient to inpatient), a subsequent rejection of inpatient treatment (primary faulty assignment) and case mergers and deletions. An accurate documentation of the data collection (origin of data and from which IT systems, generally a description of the query syntax and tables, listing of rules applied, description and quantification of the proportion of incomplete data sets) should be in place for benchmarking projects, just as it is with scientific work.

Table 1 Metrological steps in the measurement of key performance indicators as a prerequisite for meaningful benchmarking projects. The metrological requirements of benchmarking are equivalent to those of analytics.

Stepwise procedure in the analysis until a measurement result is obtained
1. Clear definition of the measurement task and the measured variable
2. Establishing a measurement unit for the result
3. Detection of general conditions and influences
4. Selection of a measuring device or a measuring method
5. Performing the measurement and determination of the measured value (comparison/repeat measurements); if necessary, calculation of mean and standard deviation and other statistical measures of variance
6. Correction of systematic measurement errors
7. Representation of the determined measurement result. This consists of the measured value (if applicable, the average of several measurements), supplemented by quantitative assessments of uncertainty and the margins of error

Table 2 Problems when comparing performance numbers that were recorded in various laboratory information systems (LIS) or hospital information systems.

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- The recording of performance for the statistical evaluation in accordance with a rating scale is possible only with prior allocation of performance indicators.
 - A subsequent change of the rating scale or transcoding of individual services (e.g., from microbiology) is not possible with all computer systems and is very complex.
 - There are various performance definitions for the recording of performance (such as requested/invoiced services, net/gross services, etc.).
 - Services are recorded on the basis of different criteria in the daily and archive systems.
 - Duplicates can be generated upon reactivation of orders from the archive, upon repetition of measurements/repeated transmission of measured values or in the case of accidental multiple requests for a service.
 - There are differences in the time-based recording of a service in various IT systems (e.g., counting at the time of material receipt and/or at the time the measured value is created).
 - If the patient is (still) unknown to the hospital information system (HIS), the service may not be recorded, depending on the system.
 - Non-analytical services or rare special analyses (analog rating) are not recorded unless the rating scale used was extended appropriately.
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Measurement and evaluation of laboratory services in the hospital laboratory

In Germany, there are currently 2064 hospitals [13], of which 1208 operate a laboratory on site [14]. The method of service provision or purchase of laboratory services is very different at various hospitals. As no laboratory can maintain all the parameters, each hospital will send laboratory tests, to varying degrees and depending on the urgency, to external laboratories (“outsourcing”). Other tests are done outside the laboratory, as a point-of-care testing (POCT), on the wards and in the outpatient clinics [15]. The share of so-called outsourcing relative to the number of tests can vary from <1% at maximum care facilities to nearly 100% for complete outsourcing; for the proportion of POCT, between 1% and 50% (based on the total number of laboratory tests at the hospital) can be assumed [16].

Performance for benchmarking projects must be recorded in a standardized manner which is binding for all participants. Typically, analytical services are recorded via the statistics of the laboratory information system (LIS). This allows the number of analytical services that were provided in a given period at a laboratory to be determined reliably most of the time. However, in determining the number of in-house laboratory services provided, some rules must also be considered. Thus, only the reported patient results (“reported results”) can be a basis for benchmarking, i.e., control measurements and other approaches must not be included as analytical services, as this would dilute the data. The counting of a singular “reported result” (also “net performance”) is mostly tied

to the completion of the measurement result in the statistics modules of the LIS. This is sent online to the LIS by the IT system. But if subsequently the sample is measured again in one or several “diluted” approaches, and the result is entered manually in consideration of the dilution factor, it may be, depending on the IT system, that the result is captured once again as a service by the LIS statistics module. Such duplication must be removed from the performance statistics prior to any benchmarking.

Measurement profiles in automated analytics, such as urinalysis and blood count, can cause substantial differences in how performance is recorded. Thus, some labs count each event as a single service, while others consider only the complete profile as a service. Especially in laboratories where these measurement profiles constitute a large proportion of the laboratory analysis, apparent differences in performance figures can only be based on differences in how performance is recorded. It must therefore be ensured that profiles that are remunerated under the fee scale for doctors under a service code are entered as one service, not partial services, in the statistics of all participants. The maximum values under the fee scale for specific parameter groups must not be used in the recording of performance.

There is consensus that the unweighted number of laboratory tests is not suitable for meaningful benchmarking. While the recording of the number of services can be standardized with relatively little effort, the resource-related evaluation of the individual services constitutes the actual challenge in benchmarking projects. A typical hospital requests approximately 1400 different test methods [17]. Although approximately half of the methods are rarely needed, each individual service

must be evaluated individually. As the individual services represent different uses of resources, depending on the type and desired availability, they must be evaluated individually in a systematic list or directory. Even if different services are ultimately assigned an identical value, the resource consumption can differ greatly with respect to the individual types of cost (material and personnel costs, maintenance, investment share, etc.). For each testing method, this value is multiplied by the number of services provided within a defined period. The sum of all products is the assessed overall analytical performance of the laboratory in a defined period.

The quantification of the resource consumption of each individual service is based mostly on an assessment model already put in place for other purposes. In Germany, it is typically the 1996 medical fee schedule (GOÄ 1996) that is used for this purpose. Alternatively, the EBM2000 or an internal catalog may be used that is also based on the 1996 fee schedule, but may also contain premiums for emergency services or other special features. The 1996 fee schedule – or EBM2000 – allows for an evaluation of most analytical services, but it is not always a true reflection of the expenses. Thus, for example, a number of rare tests are combined under “collective codes” under the 1996 fee schedule. These services are evaluated equally without any reference to the actual consumption of resources. Other tests may be allocated to different fee codes of varying valuations, particularly in connection with the so-called analogous scoring of innovative services that have not yet been assigned a separate code and in connection with methods-based service evaluations. As a result, different allocations of services in the assessment model can produce distortions in the comparisons of services between different laboratories. Other methods that could improve uniformity in theory at least, such as the use of LOINC (Logical Observation Identifiers Names and Codes) [18], because of their sporadic cover [19], are not widespread.

Technological changes, different specifications regarding remuneration relative to the series length or for the purposes of quantity control in the treatment of outpatients, as well as professional specific interests, have led to significant differences in the assessment of many parameters among the various evaluation criteria, which are not justified economically. The services in chapter 32.2 of EBM2000 are assessed as substantially lower relative to the corresponding chapter MII of the fee schedule. However, the assessment under chapter 32.3 of EBM2000 is not markedly different from the corresponding chapter MIII of the fee schedule. The reason is that in EBM2000, regardless of the medical benefit and expenditure [17], the

number of services that can be procured from laboratory groups in outpatient care is limited.

The share of pathological samples, the processing expenditure of samples and the frequency of emergency samples are much lower in outpatient care than for inpatient care. Many laboratory requests from the outpatient sector, therefore, can be sent to a laboratory group where they can be processed in cost-optimized batch lengths without time pressure (the fixed-cost share per service is greatly dependent on the batch size and can be reduced by larger sample volumes). In hospitals, however, emergency samples regularly have to be processed around the clock, often in single analyses, due to the medical requirements. The provision of emergency diagnostics causes the hospital much higher personnel and material costs than those of a laboratory group. An assessment under EBM2000 would not be appropriate, because this, for example, would not take into account the general conditions of the emergency services provided.

Some of the problems in applying fee schedules could, perhaps, be prevented by way of an in-house catalog. But comparisons with other facilities that use a different assessment scale would no longer be possible. In addition, developing an in-house catalog is very complex and comes at a very high cost. A higher or lower valuation of individual analytical services does not affect the total costs of the lab, which is why all other analytical services would have to be adjusted in a compensatory manner in the opposite direction.

The choice of an assessment model (such as the fee schedule, EBM or in-house catalog) must be taken prior to the start of a project. A subsequent change of the service catalog chosen is problematic, because some areas (especially in microbiology, but also in immunohematology and molecular biology) do not allow for transcoding of the service catalog on a one-to-one basis. A further complication is the fact that some LIS can output a service provided statistically only on the basis of a previously defined service catalog. This means that a subsequent re-assessment of the services is based on a different assessment model for benchmarking, and this increases the expenses considerably. The early assessment of the individual analytical services and/or the early selection and development of an assessment model is, therefore, necessary to obtain a meaningful result from a benchmarking project and to draw conclusions from it.

Even in the case of high-tech services, which ostensibly do not have any patient-related differences, the costs of provision are dependent on patient care (outpatient vs. inpatient) and on concomitant diseases. Particularly in the care of emergency patients and inpatients, one finds a high

percentage of pathological samples, frequent interferences through medication or the necessity of processing samples as quickly as possible so as to be able to take the necessary medical decisions in a timely manner and so as not to put patients at risk. Examples include determining levels of medication with a narrow therapeutic index, special hemostasis and infectious serological tests as well as tests as part of hospital hygiene, such as MRSA-PCR. These factors are especially important in benchmarking when facilities of different care levels or disciplines are compared or if the ratio between inpatients and outpatients varies from facility to facility. Thus, a benchmarking project demonstrated that – even independently of the size of the facility – hospital labs with maximum productivity had a high share of outpatient submissions for non-acute patients [11].

Apart from the analytical services, a hospital lab provides a number of services for the hospital. Acute hospitals deal with a considerable number of transfusion-medical services, including maintenance of a blood bank and the organization of the transfusion system in clinical practice. Other services include the acquisition of blood samples and of internal transportation, consulting and supervision services in hospital hygiene and quality assurance, maintenance and training for POCT in the wards [20, 21]. The expenditure for such non-analytical services cannot be reflected adequately in fee schedules in terms of the actual expenses. This is also true of the expenses for services under certain conditions, e.g., the services of satellite laboratories. For monitoring and evaluating these services, it is often attempted to estimate the use of resources via staff working hours required for the provision of such services [22, 23].

Benchmarking on the basis of fee schedule that takes into account only the costs, therefore, can be assessed only between labs and/or hospitals without further explanations that have similar care structures, a similar service and case spectrum and similar size. A cost-based comparison of the virological diagnostics of a blood bank, therefore, with a virological specialist lab would have only little meaning. While the blood bank needs only few select virological parameters to test stored blood, which can be done in large series in a fully automated way, the virological specialist lab must ensure patient care over a large testing spectrum – often under immense time pressure and in small series – around the clock.

Attention must also be paid to the selection of suitable statistical parameters. Thus, the average series length in a benchmarking project is only suitable as a specification for other facilities to a limited degree. The series length can be optimized through larger sample volumes, but medical requirements may also necessitate (very complex) individual measurements. Specifying an average series length

alone is not a sufficient criterion for efficiency or as a basis for decisions regarding the outsourcing of a method.

If the general conditions of service provision – which vary from hospital to hospital – are not considered, problems occur especially when the external benchmarking is to be used to identify individual efficient and inefficient services. Particularly in the case of major differences in the results of external benchmarking for labs with divergent service spectra, one must always check carefully whether such differences may not be the consequences of unsuitable assessment scales. Further blurring in the assessment of individual services always occurs in areas where estimates or allocations have to be used due to the scarcity of data. Especially at small facilities, an allocation or delimitation of personnel and material costs vis-à-vis other cost centers is necessary if the labs are interlinked with other areas in terms of staff (e.g., on-call service shared with radiology, functional services and, perhaps, pathology).

Recording of POCT services at the hospital

The average share of POCT in the total laboratory testing at hospitals in Europe is on average about 20% [16]. Countries like France, with decentralized lab services, have a smaller POCT share than countries that tend to rely on major commercial laboratories, such as the UK. Similar differences are found in Germany when comparing hospitals in rural areas with those in major urban centers. Benchmarking must take such regional differences into account. When assessing a lab, therefore, it is also essential to know the facility's specific POCT share.

The number of glucose analyses in the clinical departments of a hospital can be determined very precisely in the case of networked equipment. Frequently, however, non-networked glucometers are used. In estimating the performance figures on the basis of the reagents (test strips) consumed, larger deviations from the actual tests carried out are possible. This may be caused by frequent control measurements, the loss of reagents (e.g., glucose test strip packages already started may be given to the patient), and the deterioration of reagents in the event of low analysis frequency in a ward. When a change was made in the blood glucose measurements to systems that are used only in hospitals and in which the measured data are networked, there was a decrease in reagent consumption by up to a third [24]. Here again, it is true that a comparison between facilities can produce reliable findings only if

the data collection is identical (either recording the actual services performed, or the consumption of test strips).

With blood gas measurements, the technical resources needed are highly dependent on the technology used. In the case of single-unit-use instruments, the required test combination can be selected precisely, while with other technologies always and generally a defined spectrum of several parameters is measured, even if only a single parameter was needed. Which technology is the most efficient depends not only on the number of analyses, but also on the general conditions. The costs per test are so high for single-unit-use instruments that the single-unit-use instruments are mostly useful only with very low measurement frequencies.

The recording of the number of tests carried out on blood gas equipment, therefore, is not a suitable parameter to compare different hospitals. The “tests per case” indicator may exhibit substantial differences among facilities, without there being any substantial differences in the costs for POCT services. Especially for equipment that, apart from blood gases, also contain hemoglobin derivatives, electrolytes and lactate as a profile, the recording of performance can produce a multiple of the performance figures compared with single-unit-use devices. Recording the actually necessary tests in connection with conventional technology, however, will not be feasible at a reasonable cost.

Recording of laboratory services for delivery in various departments and outsourcing

Services for patients of a hospital are regularly provided by different laboratories. At teaching hospitals, the spread of laboratory analysis across several independent departments is grounded mainly in science and technology, while for smaller facilities, outsourcing to external labs is primarily an economic consideration or related to inadequate technical equipment or lack of technical skills in case of specialized testing. The rate of outsourcing can be very high particularly for small hospitals. A full record of outsourcing, however, is very difficult and very complex. Cost allocation is not easy at universities either. This is made more difficult not only by the distribution among several internal service providers, but also by the fact that innovative testing very often has to be paid for from research funds, even though they primarily serve the purposes of patient care.

When outsourcing to external labs, especially when it comes to microbiological and serological tests, the service, and thus the cost, is not defined prior to sending out the sample. The client, at the time the order is placed, does not know yet what subsequent services may be needed to process a diagnosis and how this might be assessed by the external lab. For example, an immunoblot or PCR is carried out only in case of a positive hepatitis C screening. In microbiology, the cost is dependent on whether samples are processed with or without bacterial growth. If such growth exists, the pathogen is differentiated, and there is mostly also an antibiogram. Such staged diagnostics is both medically and economically sensible [17, 25].

External labs bill hospitals only for the services provided, which were requested for inpatients covered by health insurance. Elective inpatient services are generally not recorded at all, because they are billed by the external lab to the patient directly, and the requesting hospital does not receive any feedback on the services thus billed. The actual number of tests done, based on the invoices of external labs, therefore, can generally not be assessed by the submitting hospital, which means that the actual expenditure may be severely underestimated. This may result in the calculation of InEK (Institute of Hospital Reimbursement) [26] in lower cost values for the laboratory cost center of the DRGs. A further complication is that the great majority of individual invoice items for external services are in the single-digit Euro range. Consequently, it is so low that the necessary allocation to individual DRG cases is frequently not done (in such cases, the expenditure for recording the cost is higher than the cost to be recorded).

When comparing ratios of different hospitals at the level of different types of costs, one must also consider that according to the InEK calculation rules [3] external laboratory costs must generally be recognized as operating expenses. Depending on the extent of outsourcing, therefore, the ratio between material and personnel costs for lab diagnostics can vary greatly among different hospitals.

Recording of personnel costs in the laboratory

The performance of the laboratory and the quality of patient care are determined by the staff employed there [27]. This usually incurs costs for the Medical Service (AED) and the Medical and Technical Service (MTD).

At labs managed by lab physicians, the costs for the medical service are very transparent. But the share of the cost for producing blood preparations and hospital hygiene must be separated in terms of expenses if lab staff handle tasks in such areas. Labs of smaller hospitals often do not allocate the costs for the medical service to the lab where a chief physician of a clinical department is responsible for the medical management of the lab. The allocation of personnel costs for scientific and non-medical academics, too, varies from hospital to hospital. Depending on the hospital, these are allocated to MTD or AED.

In benchmarking projects, it is often attempted to prepare for a comparison not only the overall lab, but also the services and costs of certain areas (such as microbiology, immunohematology, molecular biology) or service types (on-call service, weekend service, routine service). A correct allocation of personnel costs on the basis of detailed time sheets, however, is very complex and prone to error. The personnel costs per employee are known, but these costs must be allocated to several cost centers in line with the expenses. For example, an employee of the molecular biology lab also provides night-time and weekend services at the emergency lab or works in interlaboratory quality management (QM). If the personnel costs were to be recognized only for one cost center, then the personnel costs of this area would be overestimated with respect to the other areas. This is especially noticeable in small areas where correct cost allocation is especially important to the assessment of efficiency.

In emergency care, the staffing requirements are influenced primarily by the provision of on-call services – and less by the service volume [11]. Because of the very high fixed costs of providing services, the actual number of on-call services performed in relation to efficiency in general is of little relevance [28]. It is, therefore, useful to record these costs of emergency care independently of the number and type of the analytical services rendered.

Differences in personnel costs between different hospitals can also be due to the fact that the costs for release periods as part of partial retirement or pension payments for retired employees are posted to the laboratory cost center. These personnel costs are not offset by services and are, therefore, not suitable as an indicator.

In recognizing the costs of a personnel arrangement (e.g., in connection with a service company associated with the hospital), differences may occur between the participants in an external cost benchmarking project if such costs – fiscally correctly – are recognized as operating expenses, while other hospitals with their own employees in AED and MTD recognize them as personnel costs.

In addition, personnel costs can be allocated for the lab directly to different cost centers and cost types for technicians, IT staff, cleaning staff and administrative staff, even if the DRG calculation [26] records these costs under the cost type “Medical or non-medical infrastructure of the laboratory cost center” and are, therefore, not part of the lab costs in the strictest sense of the word. If activities, such as IT support or cleaning services, are outsourced, these costs are recognized as operating expenses, but when these activities involve own staff, as personnel costs. Staff may also be assigned to a centralized service department that provides the corresponding infrastructure for all hospital departments and the costs of which are allocated in accordance with different codes. Taking these costs into account can make sense in connection with a breakeven analysis – e.g., if the cost recovery (costs and revenues) of an outpatient department is to be examined. Knowing these costs can also be an advantage if the processes of pre- and post-analytics, which are key to the quality and efficiency of the lab, are to be examined. It has, thus, been shown that when the processes are optimized further (“lean management”), it is these very areas that generate the highest return on investment [29]. However, these processes cannot be optimized through a benchmarking project that primarily studies the quantity and costs of lab analyses, but would instead have to be studied further as part of a separate logistics project.

The proper consideration of costs for non-analytical services is still a major problem in benchmarking projects. These are activities that are performed by laboratory personnel outside the laboratory at the hospital and are not part of laboratory analysis. There exist major, often historical, differences between individual facilities, and some of the staff would have to be allocated to several cost centers due to their “mixed” activities. Laboratory management, for example, to varying degrees, may be in charge of POCT or clinical hygiene at the hospital or external facilities; the Medical-Technical Service deals with sample-taking or outsourcing samples, or the lab’s cleaning service is used by many hospitals also for activities in pre- and post-analytics (e.g., sample preparation or transport, etc.).

Benchmarking projects that study primarily the costs of analytical processes and/or analytical lab services of the hospital laboratory should, therefore, take into account only the personnel costs of the medical service and medical-technical service. Only these costs are directly linked to the provision of lab services and are allocated clearly to the lab at all hospitals. Where the lab provides further services for the hospital or external parties beyond analytics, the necessary personnel costs should be

determined and isolated. These personnel costs can then be analyzed separately for other questions, or be considered as overhead expenses.

Recording of material costs of a hospital laboratory

Essentially, these are the costs that are incurred in analytics for reagents and consumables, as well as costs related to the maintenance and repair of laboratory equipment and costs for the operation of the lab's IT, the transmission of reports and the administrative office. These costs can generally be obtained from the cost center reports of the controlling department, where they are available, most of the time very differentiated according to various cost types, such as medical care needs, management requirements and the need for medical-technical maintenance and repairs.

In a cost benchmarking of laboratory analytics, one must be careful to keep in mind that only the material costs should be compared that are necessary to provide the lab services from the receipt of samples to the final report and that can be controlled by the laboratory. But many hospitals also post to the laboratory cost center the costs for stored blood, sample-taking materials, shipping materials, POC tests, etc. These extra-analytical costs do not affect the cost structure of the analytical lab services. They have no direct connection to the provision of lab tests at the hospital laboratory, and the consumption of these items cannot be controlled by the lab. Stored blood and drugs, in terms of both the lab and the hospital, have no relevance for the costs of the individual lab services or lab case costs. Blood collection materials and POC tests are part of the ward's requirements. Statutory changes, such as TRBA250 for the shipping of samples, or the extent of infectious serological diagnostics in the production of stored blood led to a significant increase in these costs. The material costs included in the cost center reports, therefore, may have to be adjusted for these non-analytical costs prior to any laboratory benchmarking. Some laboratory benchmarking projects of consulting firms [22, 23] explicitly exclude these material costs from their data collection, or record them separately, to use them for further – lab-independent – evaluation (e.g., to analyze the costs of diagnostics at the case level).

While the sum of all analytical material costs did not differ so much between facilities with similar levels of care and lab structure, the individual items (medical requirements, maintenance, etc.) can exhibit significant differences, depending on the type of financing and manner in

which they were recognized. As such, many price agreements include the maintenance and investment costs in the prices of reagents and are not stated separately.

Where maintenance agreements exist, the content and type of financing are not always comparable. Besides performance-indicator-dependent maintenance costs (maintenance costs per test), there are also time-dependent maintenance costs (maintenance costs per year). Especially in the case of device lines, integrated systems and pre-analytical systems, an objective allocation of the costs to individual lab services becomes difficult [30]. With a constant premium on all services, regardless of their complexity, the low-rated services are overestimated in terms of resource consumption, and the entire calculation becomes extremely dependent on changes in volume. In a complexity-based overhead calculation, it is hard to justify that the pre-analytical system, for example, uses resources a hundred times more in the processing of a sample for a procalcitonin or BNP analysis than the processing of a sample for a creatinine analysis.

Consideration of capital expenditures and rents

The reported expenditure for investments and rents can differ greatly among laboratories if parts of the expenditure are already included in the material costs for medical requirements. Thus, equipment costs are financed through leasing, hire purchase, rent or reagent leasing to varying degrees. While the maintenance costs contained in reagent agreements or lump-sum budget agreements can often be estimated with reasonable effort, the amount of the investment costs at many hospital labs is unknown unless these costs are stated separately in connection with reagent leasing.

Given the dual financing of hospitals in Germany, no provisions are created for buildings and lab facilities, which means those numbers cannot be used for drawing conclusions either. International laboratory chains state in their published annual reports investment costs for medical technology in the amount of approx. 8% of sales.

As a lab at a hospital usually does not pay any rent, the costs of premises can be estimated only on the basis of comparable rents. Using imputed rental costs for a lab on the premises of a hospital, however, requires that such premises can be used for other purposes or can be rented. But this is rather questionable, given that many labs are located in unattractive areas of a hospital.

For benchmarking projects regarding the costs of laboratory analytics, expenses for investments and rents should be disregarded, as some projects have done as well (see examples: [22, 23]). Proportional investment costs that are included in the material costs for medical requirements should be stated separately and isolated for the purposes of a cost benchmarking of analytics.

Recording and allocation of overhead costs

From cost calculations at outpatient laboratories with a very good recording and delimitation of the individual cost types and centers, a portion of the overheads is reported in the amount ranging from a third to up to half of the overall costs [30]. Due to its integration into the hospital operations, it is significantly more complex for a hospital lab to record and assess the overheads correctly.

A popular method involves an allocation of the overheads of the hospital on the basis of the number of staff or turnover of the individual departments. Given the high added value of the hospital laboratory, the application of this method can produce amounts that are unreasonably excessive and have no relation to the actual costs: Thus, in the case of outsourcing of an average hospital lab with sales of € 3 million a year and assumed overheads of 33%, approx. € 1 million would have to be cut from the hospital administration (outside the lab). This seems unrealistic. Conversely, even with increased insourcing (i.e., the lab provides services for external parties), the hospital's overhead expenses would increase only slightly. The lab space could serve as another allocation formula for overheads. But space-based allocations are problematic too. The space available often cannot be influenced, e.g., if a new building is not possible due to zoning or heritage regulations, or if no funding is available for new or additional lab space.

Often, therefore, overhead costs are left out of the cost benchmarking between hospital labs.

Consideration of the internal and external revenue of a hospital laboratory

In the past, benchmarking projects were often operated only in terms of cost benchmarking, i.e., internal and

external revenues were excluded. This had to do with, among other things, the fact that only the revenue from elective services agreement and from the activities of panel doctors was known. The introduction of the DRG system has now made it possible to also quantify objectively, the predominant part of the internal revenue, i.e., the lab's share of the hospital's revenue from inpatient care. As part of the annual InEK calculation, cost shares are stated for the individual DRGs that can be used as a basis for an internal allocation of the revenue from inpatient care to the individual hospital departments [31, 32].

Apart from this, a growing number of hospital laboratories enter into cooperative arrangements to supply other facilities and outpatients, so that external revenue is gaining in importance. Therefore, benchmarking should not only capture the costs, but also the revenue. The comparison of revenue and costs in terms of a breakeven analysis now allows for a profound assessment of performance and more appropriate budgeting of a laboratory. After all, cooperation cannot only produce additional revenue and cost benefits through improved capacity utilization, but also additional costs in generating such revenue – e.g., for courier services or special services. Costs and revenue are, thus, inseparably linked. More revenue necessitates additional costs, and cost reductions can result in loss of revenue.

Effect of laboratory supply structure on benchmarking results

Even when it comes to supposedly easy-to-determine parameters, such as the frequency of sample transports, the use of averages to assess a hospital laboratory is problematic, because many parameters in a lab are influenced by external factors – that is, factors that the lab cannot control. For example, the courier frequency is dependent on the distance of the wards or departments from the lab, unscheduled blood samples in the wards, and the supply spectrum of the facility. As for external laboratories in close proximity to the hospital, medical care can be ensured at a reasonable cost through several courier transports or even emergency transports, while in rural areas, such courier and emergency transports, e.g., as regards the supply of blood products, can constitute a considerable cost factor. Moreover, especially in rural areas, with a great distance between the lab/blood bank and the hospital, patient care may not be guaranteed. Also the organization of backup solutions or the size of a blood bank can be addressed in a

major city through cooperative arrangements quite differently than in rural areas.

Other popular parameters in the past to assess a hospital laboratory, such as the number of tests per case, the share of follow-up requests or the share of POC tests relative to the lab tests, cannot be interpreted reliably without taking into account the general conditions at one's own facility and the one used for comparison. Benchmarking of the number of tests per request is also of limited significance only. When profiles are used, there is a tendency toward somewhat higher expenditure, but profiles support the standardization of processes and, thus, help accelerate the processes. This is especially true of patients in the emergency room. As a result, high-volume/low-cost tests are useful, for instance, in the emergency room, and a significant reduction in these services produces only marginal (material) cost savings due to the high fixed costs in the emergency lab [33]. On the contrary – a requisition behavior that is too restrictive can result in follow-up requests (sometimes even including new sample collection) and extended emergency room stays. However, with POC tests, lower sensitivity and specificity and higher costs [34] are accepted if this means an improved patient flow at the hospital and intervention earlier in the process [35].

What is ultimately necessary for the patient's well-being, and useful in terms of the efficiency of the respective facility, cannot be determined reliably at all by way of general or sweeping assessments of these parameters.

Assessment of the quality markers in laboratories

Initial indicators of the organizational quality of a laboratory can include parameters like the share of emergency samples, the turnaround time (TAT) in analytics, the number of tests per individual request or the time span between the patient's admission and the request for a lab test and/or communication of the test results. Like economic parameters, the quality parameters, too, cannot be assessed conclusively without knowing the general conditions [36].

Accordingly, depending on the case spectrum of the hospital and the POCT equipment available on the wards, the share of emergency tests can vary greatly among hospitals. A sample transport not adapted to the needs of the clinic can result in increased use of POCT; such requests are then mostly ignored in customary laboratory benchmarking and can lead to the belief that there is a

smaller number of lab tests per patient. But with optimally organized sample transports (e.g., pneumatic tube), the requester has only little reason to conduct POCT.

The assessment of TAT must not be limited to a purely statistical evaluation. When only averages are looked at, patient-critical quality deficiencies – e.g., lack of immunohematological care at night – may be overlooked, because a delay in immunohematological emergency tests might be compensated by a short TAT, for instance, in the automated triglyceride analysis in the daily routine. At the same time, given today's customary processing of emergency and routine samples on a common hardware platform [29], outliers might occur only with non-time-critical samples and would, as such, have no relevance for the success of treatment and the patient flow at the hospital. To obtain reliable information, therefore, the TAT must be stated according to urgency levels (routine, emergency), patient groups (inpatient, outpatient, ER) and also, ideally, individual test methods [37].

Outliers occur regularly if – as is usual for acute care hospitals – follow-up requests are processed for samples already at the lab. When entered into the IT systems, the turnaround time is generally equated with the time difference between collecting the sample on the ward or arrival of the sample at the lab and the communication of the test results, while follow-up requests then result in a massive overestimation of the TAT. A TAT benchmarking should, therefore, omit such follow-up requests.

When POCT services are recorded in the LIS simultaneously, the TAT can be seriously underestimated. In contrast to lab tests, where a request is made first, followed by a specific time span between the request (or receipt of the sample by the lab) and communication of the results, POCT results are released without a prior request. As a result, a TAT (i.e., time from request/sample receipt to results) cannot generally be calculated in connection with POCT.

The recording and assessment of the TAT so far have generally been limited to the analytical portion of the diagnostic process [38], i.e., only to the processing time at the lab, the “analytical TAT” [37]. The time portion of this analytical TAT in the overall diagnostic process, from the doctor ordering the test and collecting the sample, identification, transport, preparation, analysis of the blood sample to the communication of results and the subsequent interpretation by the doctor and, ultimately, the implementation of the resulting therapeutic measures, is only 4% in some cases [39]. The total duration of this process is also known as “brain to brain TAT” or “therapeutic TAT” [40] and cannot be controlled by the lab directly [41].

Similar experiences have also been reported for the error rate, which can also be used for a benchmarking project. Here, too, one finds in analytics the lowest error rate at 0.002% (corresponding to 5.6σ) [4, 42–45]. This extremely low error rate is close to the ideal of a σ -value of 6, which in the Six Sigma assessment corresponds to a zero defect production [46, 47]. It is achieved in the lab by using different strategies and quality management measures to optimize processes, such as standardization, written standard operating procedures, the consistent use of bar codes and lean management. In contrast to this, for pre- and post-analytical process steps, such as test selection, patient identification upon taking a blood sample or upon implementing therapeutic measures, significantly higher error rates have been reported, by comparison, of 3%–4% (corresponding to 3.3σ) [48–50]. Against this background, it is questionable whether the currently customary focus on analytical TAT or the analytical error rate is, indeed, suitable for a benchmarking of the entire diagnostic process. At present, therefore, other quality indicators are being developed with which to open up the pre-analytical phase and post-analytics to benchmarking [50, 51].

As such, the Six Sigma concept is an interesting approach for benchmarking the diagnostic process, because it can be used to compare the error rates in pre- and post-analytics [46, 47] and the quality of different analytical methods in a simple and reproducible manner [52, 53]. The Six Sigma concept also allows for a comparison of the quality of laboratory-medical patient care with the quality of patient care in other areas of the hospital.

An important, but rarely studied, quality criterion would be the proof that the frequency with which certain lab-medical test methods are used affects not only the economic success of the hospital, but also has a positive effect on the patient outcome. A study that examined the use of Hb_{A1c} may serve as an example in this context [54]. However, given the very heterogeneous courses of disease and the large number of factors, only very few lab parameters at the hospital will be this well-suited for clear proof of a correlation between patient outcome and request frequency.

Audit results of accreditation as a benchmark

External quality audits on accreditation, which are common among medical laboratories in outpatient areas, do not show any clear differences in quality management among individual laboratories. At most, large facilities

find it easier to meet the accreditation requirements, because they have greater personnel resources to meet the formal requirements. Despite the effort necessary for accreditation, one must also consider that improvements of processes in terms of “lean management” are also often linked to improvements in efficiency [55], so that accredited labs tend to be more efficient than those that are not accredited.

But the ratio between benefit and expenditure of accreditation can also be unfavorable in some laboratories. As a result, in the benchmarking of laboratories with different accreditation spectra one must consider that the consensus on the type and scope of quality management measures in analytics (and, thus, also lower financial expenditure and/or smaller number of deviations) in the area of high volume/low-cost tests is greater than it is for rare special tests and in-house tests. Consequently, for these tests where commercial tests, control materials and/or interlaboratory testing are not available, the expenditure for alternatively required methodological comparisons can be extremely high, and the scope to be proved can differ as well, depending on the auditor.

Unlike other standards, such as the Joint Commission International or College of American Pathologists (CAP) Laboratory Accreditation Program, the focus of EN/ISO15189:2007, which is widespread in Europe, is primarily on analytical services and those pre- and post-analytical processes for which the laboratory is responsible. In contrast to many other European countries, samples in Germany are taken outside the direct influence of the laboratory by the submitter, and the sample logistics of hospitals, too, are generally not the responsibility of the lab. Therefore, the processes with the highest risk by far to the overall process and the very important parts for the actual level of quality are captured in Germany’s accreditation procedure only on an optional basis [4, 50, 56].

Outlook and summary

Benchmarking in the hospital laboratory is currently an oft-applied instrument, but still hardly standardized. External benchmarking across labs can only compare small sub-processes with satisfactory significance. Given the high level of heterogeneity and complexity of medical lab services with respect to the type of test, the necessary and/or desired availability and the consumption of resources for each service, meaningful benchmarking projects are predicated on complex and structured data collection. These requirements are frequently not taken into

Table 3 Common pitfalls in the collection and analysis of data from external benchmarking projects (see also the specific explanations in the text).

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- No specification of data collection binding on all participants.
 - No binding definition of performance contents of the data to be transmitted (e.g., transmission of gross/net services, recording and assessment of non-analytical services, recording of profiles, etc.).
 - Change in the methodology of data collection during the current survey period.
 - Different practices in the allocation of costs and services to cost centers and cost types among the participants.
 - Different or missing delimitation/consideration of outpatient and inpatient services, costs and revenue.
 - Particularly special tests may be valued differently by individual participants.
 - Collective codes for “similar tests”/analog rating in the common evaluation criteria for different personnel and material costs of services.
 - Different (insufficient) quality of the raw data transmitted by the participants for the purposes of evaluation (missing data from part of the participants or transmission of “estimates”).
 - Lack of plausibility checks for the raw data transmitted and the results of the assessment on the part of the facility responsible for the assessment.
 - Comparison of performance indicators without accounting for the value of performance.
 - Referencing performance indicators and costs to case numbers without accounting for DRG revenue.
 - Lack of consideration/assessment of non-analytical services and the general conditions of service provision; use of an unsuitable assessment formula.
 - Lack of consideration/knowledge of revenue outside of the DRG system.
 - Lack of consideration/knowledge of the extent and costs of POCT on the part of individual participants.
 - Failure to isolate “non-laboratory” costs not directly related to laboratory analytics at the hospital lab (e.g., costs for stored blood, pathology, ward requirements, etc.).
 - Different practices of calculating/accounting for charges, rents, depreciation, etc. attributable to the laboratory.
 - Customary key indicators so far do not take into account the quality of care, or capture only parts of the diagnostic process.
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account sufficiently (Table 3). Unlike other medical disciplines, in which the bulk of medical services is described with only few select diagnoses and/or processes, laboratory medicine, for a meaningful benchmarking, generally actually requires more than looking at the 150 most common tests (analytes) or fewer select indicators.

The existing tools can be useful for internal benchmarking, i.e., comparing a single laboratory or laboratory area over longer periods of time. This is especially so when the supply spectrum of the lab and/or lab area and the other benchmarks do not change significantly over the period under observation. But even with internal benchmarking project, one must always check whether the differences observed were actually caused by changes in the processes or whether they were merely the consequence of improved data collection or changes in the

general conditions outside the laboratory. Particularly in the management instruments very successfully used in laboratory medicine, such as “lean management” or TQM or EFQM, the medical and economic processes are continuously optimized through multi-layered changes. Accordingly, benchmarking parameters may have to be adjusted continuously.

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References

1. Forsman RW. Why is the laboratory an afterthought for managed care organizations? *Clin Chem* 1996;42:813–6.
2. Hallworth MJ. The ‘70% claim’: what is the evidence base? *Ann Clin Biochem* 2011;48:487–8.
3. Institut für das Entgeltsystem im Krankenhaus (INEK). Datenveröffentlichung gem. § 21 KHEntgG. Journal [serial on the Internet]. Date: 2012 Available at: http://www.g-drg.de/cms/Datenveroeffentlichung_gem_21_KHEntgG. Accessed: 22.06.2012
4. Hawkins R. Managing the pre- and post-analytical phases of the total testing process. *Ann Lab Med* 2012;32:5–16.
5. Henker O, Appel S, Hänseler E, Köller U, Neumeier D, Stein W, et al. Organisationsstrukturen zur Verbesserung der Wirtschaftlichkeit medizinischer Laboratorien in Krankenhäusern. *J Lab Med* 2005;29:17–27.
6. van Lent WA, de Beer RD, van Harten WH. International benchmarking of specialty hospitals. A series of case studies

- on comprehensive cancer centres. *BMC Health Serv Res* 2011;10:253.
7. Simon TD, Hall M, Riva-Cambrin J, Albert JE, Jeffries HE, Lafleur B, et al. Infection rates following initial cerebrospinal fluid shunt placement across pediatric hospitals in the United States. *Clinical article. J Neurosurg Pediatr* 2009;4:156–65.
 8. Shaw C, Kutryba B, Crisp H, Vallejo P, Sunol R. Do European hospitals have quality and safety governance systems and structures in place? *Qual Saf Health Care* 2009;18(Suppl 1):i51–6.
 9. Aufenanger J, Schernikau E, Wieland E. Die zukünftige Rolle des Krankenhauslabors. *J Lab Med* 2011;34:271–6.
 10. Hiatt HH. Protecting the medical commons: who is responsible? *N Engl J Med* 1975;293:235–41.
 11. Jones BA, Darcy T, Souers RJ, Meier FA. Staffing benchmarks for clinical laboratories: a college of american pathologists q-probes study of laboratory staffing at 98 institutions. *Arch Pathol Lab Med* 2012;136:140–7.
 12. Patscheke H. Organisation der Laboranalytik in Zentren: sinnvoll oder nicht? *J Lab Med* 2008;32:325–32.
 13. Statistisches Bundesamt. 2012 [updated 2012; cited]; Available at <https://www.destatis.de/DE/ZahlenFakten/GesellschaftStaat/Gesundheit/Krankenhaeuser/Tabellen/KrankenhaeuserJahre.html>. Accessed: 22.06.2012
 14. Zimmermann H, Borges P, Asché P, Leng S. Externe Expertise. f&w führen und wirtschaften im Krankenhaus 2011;28:58–61.
 15. Junker R, Schlebusch H, Luppä PB. Point-of-care testing in hospitals and primary care. *Dtsch Arztebl Int* 2010;107:561–7.
 16. Ehrentreich-Förster E, Andresen D. Marktpotenzial von Point-of-Care-Testing. *J Lab Med* 2009;33:153–7.
 17. Kim JY, Dzik WH, Dighe AS, Lewandowski KB. Utilization management in a large urban academic medical center: a 10-year experience. *Am J Clin Pathol* 2011;135:108–18.
 18. Logical Observation Identifiers Names and Codes (LOINC). Available at: <http://loinc.org>. Accessed: 22.06.2012
 19. Jakob R. LOINC im medizinischen Laboratorium. *J Lab Med* 2005;29:6–10.
 20. Tiran A, Hubmann M, Schweiger C. Qualitätssichernde Maßnahmen im Rahmen des Point-of-Care-Testing (POCT) *J Lab Med* 2004;28:251–5.
 21. Hänecke P, Haeckel R, Koschinsky T, Luppä P, Schlebusch H, Wahl HG. Qualitätssicherung der patientennahen Sofortdiagnostik (Point-of-Care-Testing) im Krankenhaus: Muster für eine hausinterne Richtlinie. *J Lab Med* 2004;28:256–63.
 22. Krankenhausinstitut D. Erhebungsbogen für die Sonderauswertung Labor des DKI-Management-Report 2010. Düsseldorf; 2010.
 23. Roche Diagnostics GmbH C-BfD. Erhebungsbogen_Wirtschaftliche_Qualität_0611.doc. Mannheim; 2011.
 24. Luppä PB, Gässler N, Haeckel R, Hänecke P, Hafner G, Koschinsky T, et al. Stellungnahme der Arbeitsgemeinschaft „Point-of-Care Testing“ der DGKL zum Thema Vernetzung von POCT-Geräten im Krankenhaus mit. *J Lab Med* 2005;29:241–5.
 25. Arnold DF, Timms A, Luqmani R, Misbah SA. Does a gating policy for ANCA overlook patients with ANCA associated vasculitis? An audit of 263 patients. *J Clin Pathol* 2010;63:678–80.
 26. Institut für das Entgeltsystem im Krankenhaus (INEK). Kalkulation von Fallkosten [database on the Internet]. Available at: http://www.g-drg.de/cms/Kalkulation2/DRG-Fallpauschalen_17b_KHG/Kalkulationshandbuch. Accessed: 22.06.2012
 27. Lott JA. Laboratory personnel: the most important aspect of quality control. *Med Instrum* 1974;8:22–5.
 28. Osburg K. Personalbedarf und Kosten im Medizinischen Laboratorium. Anleitungen zur Ermittlung (Instand-Schriftenreihe). Berlin, Heidelberg, New York, Tokyo: Springer; 1987.
 29. Adams J, Graban M. CMCD's lab draws on academics, automakers, and therapists to realize its own vision of excellence. *Global Bus Organiz Excell* 2011;30:12–28.
 30. Früh U, Haarländer S, Platzkötter C. Laborkostenkalkulation. Journal [serial on the Internet]. Available at: http://www.wcg-ag.de/fileadmin/labor/Laborkostenkalkulation_Vortrag_von_Uli_Frueh_und_Deloitte.pdf. Accessed: 22.06.2012.
 31. Thiex-Kreye M, v. Collas T, Blum M, Nicolai D. Ressourcen gerecht verteilen – Aufbau einer erlösorientierten Budgetierung als Vorstufe zum Profit-Center-System. *krankenhaus umschau* 2004;73:863–8.
 32. Plücker W, Wolking F. Personalbestimmung nach DRG. *Arzt und Krankenhaus* 2007;80:9–12.
 33. Winkelmann JW. Less utilization of the clinical laboratory produces disproportionately small true cost reductions. *Hum Pathol* 1984;15:499–501.
 34. Wax DB, Reich DL. Changes in utilization of intraoperative laboratory testing associated with the introduction of point-of-care testing devices in an academic department. *Anesth Analg* 2007;105:1711–3. Table of contents.
 35. Stürenburg E. Editorial: Patientennahe Diagnostik-wie zuverlässig müssen Testsysteme sein? *J Lab Med* 2006;30: 209–10.
 36. van Walraven C, Naylor CD. Do we know what inappropriate laboratory utilization is? A systematic review of laboratory clinical audits. *J Am Med Assoc* 1998;280:550–8.
 37. Mayer H, Brummer J, Brinkmann T. Precise turnaround time measurement of laboratory processes using radiofrequency identification technology. *Clin Lab* 2011;57:75–81.
 38. Hawkins RC. Laboratory turnaround time. *Clin Biochem Rev* 2007;28:179–94.
 39. Manor PG. Turnaround times in the laboratory: a review of the literature. *Clin Lab Sci* 1999;12:85–9.
 40. Lundberg GD. Acting on significant laboratory results. *J Am Med Assoc* 1981;245:1762–3.
 41. Saxena S, Wong ET. Does the emergency department need a dedicated stat laboratory? Continuous quality improvement as a management tool for the clinical laboratory. *Am J Clin Pathol* 1993;100:606–10.
 42. Stroobants AK, Goldschmidt HM, Plebani M. Error budget calculations in laboratory medicine: linking the concepts of biological variation and allowable medical errors. *Clin Chim Acta* 2003;333:169–76.
 43. Shahangian S, Snyder SR. Laboratory medicine quality indicators: a review of the literature. *Am J Clin Pathol* 2009;131:418–31.
 44. Plebani M. Errors in clinical laboratories or errors in laboratory medicine? *Clin Chem Lab Med* 2006;44:750–9.
 45. Ravine D, Suthers G. Quality standards and samples in genetic testing. *J Clin Pathol* 2012;65:389–93.
 46. Nevalainen D, Berte L, Kraft C, Leigh E, Picaso L, Morgan T. Evaluating laboratory performance on quality indicators with the six sigma scale. *Arch Pathol Lab Med* 2000;124:516–9.
 47. Vanker N, van Wyk J, Zemlin AE, Erasmus RT. A Six Sigma approach to the rate and clinical effect of registration errors in a laboratory. *J Clin Pathol* 2010;63:434–7.

48. Howanitz PJ. Errors in laboratory medicine: practical lessons to improve patient safety. *Arch Pathol Lab Med* 2005;129:1252–61.
49. Carraro P, Zago T, Plebani M. Exploring the initial steps of the testing process: frequency and nature of pre-preanalytic errors. *Clin Chem* 2012;58:638–42.
50. Sciacovelli L, O’Kane M, Skaik YA, Caciagli P, Pellegrini C, Da Rin G, et al. Quality indicators in laboratory medicine: from theory to practice. Preliminary data from the IFCC Working Group Project “Laboratory Errors and Patient Safety”. *Clin Chem Lab Med* 2011;49:835–44.
51. Barth JH. Clinical quality indicators in laboratory medicine. *Ann Clin Biochem* 2012;49:9–16.
52. Westgard JO, Westgard SA. The quality of laboratory testing today: an assessment of sigma metrics for analytic quality using performance data from proficiency testing surveys and the CLIA criteria for acceptable performance. *Am J Clin Pathol* 2006;125:343–54.
53. Gras JM, Philippe M. Application of the Six Sigma concept in clinical laboratories: a review. *Clin Chem Lab Med* 2007;45:789–96.
54. Driskell OJ, Holland D, Hanna FW, Jones PW, Pemberton RJ, Tran M, et al. Inappropriate requesting of glycated hemoglobin (Hb A1c) is widespread: assessment of prevalence, impact of national guidance, and practice-to-practice variability. *Clin Chem* 2012;58:906–15.
55. Mayer H, Nordmann S, Plecko T, Wieland E. Prozessorientiertes Labormanagement im Krankenhauslabor: Lean und Six-Sigma. *J Lab Med* 2011;34:277–83.
56. Plebani M, Lippi G. Closing the brain-to-brain loop in laboratory testing. *Clin Chem Lab Med* 2011;49:1131–3.