Review

Wolfgang Vogt*

About quality of management – hospital laboratory medicine: results from the working group “Laboratory Management” of the DGKL^{1), 2)}

Abstract: Balancing the partly different needs and expectations of stakeholders is one of the most fundamental tasks of a manager. Therefore, successful managing means identifying and prioritizing the relevant stakeholders, balancing out their needs and interests, and achieving outstanding results. Professional methods have to be used to overcome these challenging tasks. The extensive results of the working group “Laboratory Management” are presented in short. The article focusses on topics such as outcome measures, benchmarking, cost accounting, and business excellence that have been well-known subjects in other sectors for a long time.

Keywords: benchmarking; cost accounting; EFQM; inter-factory comparative study; management; marketing; model of excellence; outcome measures; performance indicators; TQM; working time estimation.

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***Correspondence:** Prof. Dr. Wolfgang Vogt, German Heart Center Munich, Institute for Laboratory Medicine, Gailkircherstr. 6, 81247 Munich, Germany, Tel.: +49-89-8119873, E-Mail: prof.vogt@dhm.mhn.de

Introduction

The essential task of a manager (or, simply, that of a responsible leader of an organization) is to balance the

sometimes conflicting needs and expectations of stakeholders, such as customers, investors, employees, communities, partners, management, or supervisory offices. Successful management, then, means identifying first and prioritizing the relevant stakeholders, balancing their interests and, of course, achieving outstanding results. In other words, it is about the quality of management.

In a free market, the very existence of an organization is based on customer demand. It is about the satisfaction of their needs – about customers’ benefits. In relation to laboratory-based medical examinations, this means, fortunately, that the doctor at the bedside, as a customer, has, and will continue to have, an uncontested need for laboratory tests (currently: about 3 billion tests in Germany per year) as to diagnosis, treatment monitoring, prognosis and prevention. Therefore, the diagnostics industry will not have to worry about a decline in medically indicated laboratory investigations and therefore in equipment and tests sold in the foreseeable future. The outlook is similar for the people that conduct such tests: Germany’s medical technical assistants (MTLA). However, the situation is different when it comes to the question of whether the customer is convinced that, in order to solve his problems, he needs local, easily accessible, always-available competence of a medical specialist for laboratory medicine – which is how laboratory services are organized in hospitals. It must be stressed in express terms that this does not involve the question of whether this is *objectively* necessary, but only whether stakeholders *subjectively* perceive it as such and therefore present a clear case to the outside world.

In a buyer’s market with excess supply, as is known, the rules of the game are defined by customers. The customer mostly assumes that the services on offer are largely interchangeable and of the same quality; that is, they are “vendor-independent”. In addition, there is a clear competitive situation that exerts pressure on the management of suppliers constantly to be looking for real or perceived competitive advantages, without the market, however, explicitly demanding this. This is the situation in which

laboratory medicine finds itself, and for years, this also affected many laboratories installed at hospitals. An example of this is the “voluntary coercion” for accreditation. Since this is how the market behaves, unfortunately, the objective must be to identify one or several *actual unique features* of one’s own organization, and to convey these to the customer in a persuasive manner.

The successful response to these challenges requires courage, creativity and flexibility – in short, the characteristics of professional management.

The following article is to present a few aspects of excellent management. As such, it relies on the work done by the “Laboratory Management” working group over twenty years.

Vision – mission [1, 2]

Vision is the long-term objective (five to ten years) of the organization. The objective must be set high, challenging, but still attainable. As well, the vision must be scrutinized for its validity on a regular basis.

The general supply mandate (mission) of a medical laboratory in a hospital consists of the timely provision of the professional, high-quality laboratory results necessary for patient care, as well as of analysis and consultation if the medical laboratory is headed by a specialist doctor.

Critical success factors [2]

Critical success factors describe for the organization typical and specific characteristics that must be in place to achieve the global objectives defined in the vision and the mandate. Examples of this are medical quality, speed, economic quality and marketing. They must be defined by each organization. Although laboratories are similar to each other, there are still no two laboratories that are completely identical. Each laboratory is faced with a different environment and conditions.

Strategy

Strategy is derived from the vision, mission and critical success factors. It, too, has a long-term horizon (around five years), and must be reviewed regularly to determine whether it is still sufficient to achieve the global objectives. The strategy, and the reasoning for it, must be

communicated to all members of the organization. A very useful tool for strategic control is the Balanced Scorecard (BSC) [2, 3].

Objectives

The strategy is broken down into main objectives, sub-objectives and tasks, that is, it is operationalized. The time horizon is short-term. The degree to which objectives are achieved must be measured and monitored by means of appropriate indicators.

Ways and means

Quality management

The quality of results played a role in laboratory medicine early on. From 1969 to 1970, quality control in laboratory medicine was mandatorily laid down in the German Weights and Measures Act [4, 5]; since 2002, they have been subject to the Medical Devices Operator Ordinance (MPBetreibV) [6]. Thus, laboratory medicine was by far the first medical discipline to have institutionalized quality assurance.

Having a quality management system (QMS) has not only been the law in medicine for many years [7], but it is also the basis of professional management. The implementation of Part A of RiliBÄK 2008 [8], the quality control guidelines of the German Medical Association, meets the requirements. Additional guidance is provided by the ISO 9000 norm that is in effect from time to time.

Cycle of continuous improvement

The principle of continuous improvement is based on the Deming cycle. Each activity is seen as a process, and is thus capable of gradual improvement. The approach is based on this sequence: Plan – Do – Check – Act – utilizing knowledge and findings gained for the purpose of improvement. This procedure is repeated continuously, which makes it cyclical.

The PDCA cycle is the driving force of continuous improvement. All processes and activities in the entire medical laboratory must be captured. This involves the optimization, initially, of functionally limited processes and, subsequently, cross-functional processes. After a plan has been prepared for a change or improvement

(Step 1), the plan is implemented (Step 2). The measures and changes are checked for successful improvement (Step 3). Persisting or emerging weaknesses of the process are identified, and proposed solutions are worked out (Step 4). These considerations again result in a plan for realizing further improvement measures (Step 1 of the next level), and so on. The continuous application of the PDCA cycle is the basis for a learning (from reviews and the resulting experience) organization.

Key figures [2]

An essential prerequisite for the review step within the cycle of continuous improvement is the availability of meaningful indicators. Indicators are used to measure the state of different aspects of an organization. So far, only few indicators have been used regularly in laboratory medicine. For example, imprecision and inaccuracy constitute key aspects of the analytical process. Another key process indicator is the turnaround time, although it is measured and applied to the control of the laboratory much less frequently than the other two key figures. Other common key figures in laboratory medicine are the number of tests performed, the total costs and turnover.

Economic efficiency and quality [2, 9, 10]

In preparing its findings, the medical laboratory has to meet clearly defined quality standards. This main objective must be reconciled with the secondary objective, that is, meeting the quality standards as efficiently as possible. From this it can be concluded that economic efficiency, too, is a quality feature of the medical laboratory. It must be monitored and controlled internally on a continuous basis (Controlling [11]). But this is possible only if the costs are analyzed as the main factor influencing efficiency, and thus rendered controllable [12].

The financial results are key results of an organization. Aside from the medically-based quality of structure, process and results, economic efficiency is of equal importance and must be optimized. The business tools of cost and performance accounting as well as controlling must be used in this context. For detailed information, refer to the “efficient hospital laboratory – performance and costs” [9, 11, 13]. The procedure described there can be taken as a recommendation of the specialist bodies and associations.

The medical laboratory is mainly subject to the minimum principle (achieving a defined benefit with the

least possible effort). The objective is to cope with the volume of laboratory tests while meeting all medical and organizational requirements. Thus, a reasonable level of economic efficiency can be achieved only if the efforts move steadily toward the least possible expenditure, that is, the minimization of the costs while maintaining or continuously improving the quality of performance (buyer's market).

Cost and performance accounting

In business administration, costs are defined as the “rated consumption of goods and services to create outcome”.

Cost and performance accounting (CPA) serves primarily to analyze, plan, control and manage economic efficiency. This is driven by the ultimate goal of profitability optimization. It serves mainly to identify and scrutinize deviations and failures. Particularly suitable for this purpose are the more modern cost accounting practices, such as direct or marginal costing.

The second purpose of CPA is the price calculation for a specific product or service via unit-cost calculation, or calculation of prime costs. This is generally done by means of full-cost accounting. More frequently, however, prices are defined by the market.

Furthermore, the three-stage cost and performance accounting is a necessary requirement for obtaining a meaningful comparison of operating costs [14].

The introduction of CPA that is accurate from a business point of view is expensive, but worth the effort. This is the only way for decisions to be based, for example, on contribution margins. That the institutes of laboratory medicine are still reluctant to introduce accurate CPA from a business point of view, an urgent necessity, is understandable, but highly regrettable. Every larger trade company uses CPA [15]. In terms of their size and turnover, medical laboratories in hospitals are mostly comparable to medium-sized enterprises, under company law, some of them are limited liability companies.

Performance recording

Costs must be allocated to quantifiable, well-defined and appropriate performance parameters, that is, put in relation to costing objects. The Laboratory Management working group has dealt intensively with the topic of capturing the *volumes of analytical and non-analytical services*, and has published the result, with many examples for a clearer understanding [16]. The starting point

was a DIN draft [17]. Fee schedule positions, such as the GOÄ fee schedule for doctors, are not suitable for these purposes [18], because they do not apply in some cases from the point of view of cost accounting. LOINC [19] is not suitable for these purposes either. It is set up for the electronic transmission of test results, and well-suited for this purpose, but it does not lend itself to cost accounting, because it does not include any methodological breakdown. But the methodology applied in the laboratory does determine the costs. A proposed set of specifications suitable for cost accounting can be found in Vogt and Stein [20], which was also incorporated into the methodological and testing structure of the “Medical Laboratories” sector committee of the central authority of German states for health protection regarding medicinal products and medical devices (ZLG).

The *measurement “unit”* is the applicable costing object for medical laboratory tests during regular service, that is, the number of tests communicated (net statistics) or carried out (gross statistics). The situation is different for services such as standby or shift services of the medical laboratory. Since fixed costs account for the lion’s share of the total costs, and the capacities must be ensured independent of the number of tests, a better reference parameter to choose is the *hour per employee*.

The *gross statistics* are essential to personnel, organizational and capacity planning as well as to benchmarking. This cannot be derived from the laboratory information systems, which means it takes effort to compile such information and also comes with a higher error rate. But the ratio between gross and net statistics produces the *expenditure ratio* [21]. This is where hidden services are found (multiple analyses, repetitions, controls, calibrations – that is, necessary or also undesired “waste”). The comparison of this indicator with other laboratories is highly revealing and also includes cost reduction potential.

Net statistics are collected via performance statistics accessible from the laboratory information systems. But some of that information has to be corrected first to be used for cost accounting.

Cost accounting

Cost accounting is the easier and the more precise, the better the costs can be allocated directly to the performance (individual costs) according to their causation. But when it comes to medical laboratories, this constitutes one of the special problems, because a large part of the total costs pertains to indirect costs, which means they cannot be readily allocated to cost units.

Only part of the material costs, that is, the reagent costs, can be allocated directly to specific analyses. With the remaining material costs (e.g., plastic, glass products), personnel costs (salaries, social security contributions) and equipment costs (depreciation, lease payments), at best an indirect, approximate allocation is possible. The other costs (office space, phone, etc.) that have virtually no direct link to any individual test can only be allocated as imprecise assessments.

Hospitals must apply commercial accounting. The balance sheet is an *external* account. In addition, hospitals must maintain an *internal* accounting system. The first and most crucial step, which also determines the accuracy of all further evaluations, is account allocation, i.e., the proper allocation in terms of subject matter and time to the amounts to be posted to the specified accounts. This applies to financial accounting and, to a much greater extent, cost accounting.

Material costs

The rough cost type allocation done at the hospital, that is, a breakdown for personnel and material costs [22], with the latter especially being problematic due to being a combination of direct and indirect costs, must generally be rejected for accurate cost and performance accounting and benchmarking purposes resulting therefrom [23]. The cost type allocation of cost and performance accounting must be used (cost types according to production factors: materials, personnel, equipment, external tests, etc.).

The deeper the cost type and cost center structure, the harder it is for an external person (e.g., in administration) to carry out the account allocation function alone, because the proper allocation depends on laboratory-specific issues and often has to be decided on a case-by-case basis. This means that part of the account allocation work has to be done by a laboratory staff member, or at least has to be coordinated with a staff member. Here, too, it is necessary that the persons in charge of that at the laboratory be familiar with the commercial implications.

Personnel costs

Correct cost and performance accounting requires a detailed determination of the staff time and costs [24]. What does not matter in this context is the staff time and costs for each individual employee, but rather those of the different occupational groups that work in the laboratory areas (it is common for staff to switch workstations). The total costs of the respective staff groups are allocated to the corresponding cost centers in relation to the staff

time, which can be correctly estimated without much effort. This naturally includes also non-analytical tasks. For rarely conducted tests, however, one has to rely on methods for determining staff time similar to the REFA work analysis, because estimates fail in this context.

Documentation and allocation of overhead costs

Overhead costs have to be broken down, at a minimum, into laboratory-internal overheads and overheads attributed to the laboratory by the hospital administration. Again, comparisons can often prove useful and provide arguments to be taken towards management. If these costs are stated clearly, they will not interfere with benchmarking, because benchmarking takes place *at the different levels of cost accounting*. The consideration of the full costs of cost units is not meaningful, as already mentioned, due to the high proportion of apportionments.

Unsuitable methods for determining costs

Fee schedules, such as GOÄ and others, are price lists and appropriate for the calculation of notional revenue. But they are completely useless for the cost assessment of services, even though they are still being invoked today [22]. A case cannot be made by referring to an internal fee point or arguing that this is how things are done: The result thus calculated has nothing to do with the actual costs of the cost units of a specific laboratory. Moreover, fee schedules are also known to be used to pursue political objectives. The point allocation to individual laboratory tests is based on cost calculation in the case of GOÄ 1996, but the point relation is significantly biased, among other things, in favor of “mass parameters”.

Intercompany comparison versus benchmarking [14, 25]

Intercompany comparisons are important sources of information for management, and have been conducted in many industries for a long time. They are usually based on key figures or indicators. This requires, of course, reliable indicators with respect to the type, substance and scope of services [26].

This has evolved further into the core of “business excellence”, that is benchmarking (=determining one’s own position), with the objective of “learning from the best” [27, 28]. It is a process of comparing oneself with other, preferably excellent organizations with respect to

results and/or approaches. Used as a tool of competition analysis, it can be carried out within a company or industry or across industries [2]. The maturity of one’s own company can be determined reliably only by comparison. This concerns primarily the quality of processes whose performance is measured on the basis of indicators. A benchmark is, originally, a height mark or reference point and, in the context of management, represents a “best in class” model that one emulates or, if possible, exceeds, thus setting a new benchmark. The benefit (value of knowledge gained) of such methods is significantly higher than the expenditure.

The first, business-based benchmarking project on costs and performance in a laboratory was initiated by Institut für Qualitätsmanagement in medizinischen Laboratorien e.V. (INQUAM) in 2005 and continues to this day. INQUAM is a quality association of laboratory physicians in management positions [29] (Institut für Qualitätsmanagement in medizinischen Laboratorien e.V., associate member of EFQM; URL: www.inquam.de).

Intercompany comparisons on the basis of GOÄ relations are tantamount to reading tea leaves and must thus be rejected (see “Unsuitable Methods for Determining Costs”).

But even a comparison of laboratories solely on the basis of *full costs* determined correctly from a business administration point of view is of little value unless the individual *partial costs* of a cost unit are available and can be compared as well. This has to do with the allocations that are added higher up in the cost hierarchy, which can be allocated by causation only to a limited or very limited extent. This, too, is a reason for the introduction of *detailed cost and performance accounting* (the main reason being, of course, the continuous use for decentralized controlling).

Marketing

What matters is whether the customer is convinced that he has obtained an optimal benefit from the product or service. In other words, it is the customer’s perception that determines the future of a supplier of a service, in this case, a medical laboratory (Figure 1) [30].

We *think* to know the customer expectation. But without a professional marketing survey, it is hardly possible to actually know it. The analysis of complaints provides a good approximation. Every complaint, every demand should be interpreted as (not-yet-met) customer expectation. Complaints are therefore desirable. A very small number of complaints, therefore, must be deemed rather unfavorable.

Figure 1 GAP model according to Parasuraman A, Zeithaml V and Berry L [30].

The specification of the service in the next step of the GAP model, however, is relatively easy.

Of importance is also the information on the service addressed to the customer, i.e., one should not raise customer expectations that cannot be met.

Other subsystems

Other key management subsystems should be mentioned by way of examples:

Knowledge management [31, 32], vendor management [33], change management, risk management, environmental management.

Business excellence – model of the European Foundation for Quality Management

Laboratory medicine, like medicine overall, must remain affordable despite continuous progress and rising quality. To ensure this, the “European Model for Organizational Excellence” of the European Foundation for Quality Management (EFQM), which has stood the test of time for almost 25 years in non-medical fields, should be used [34, 35]. Founded in 1988, the EFQM comprises over 500 leading European companies, consulting firms and organizations. Since 1995, it has had guidelines in place

for the public sector. The guidelines have been continuously developed further over the past 20 years. The EFQM Excellence Model acts as the enterprise-wide generalized PDCA cycle.

The Institute for Quality Management in Medical Laboratories (Institut für Qualitätsmanagement in medizinischen Laboratorien e.V., INQUAM) and the “Laboratory Management” working group have been committed to this for 17 years [1, 36, 37].

The model

The processes operate within structures and lead to results. From the results, it can be seen whether the structures and processes have accomplished the intended objective. The structures and processes (criteria 1–5) allow for outcome or results (criteria 6–9) to be delivered as intended. The results are in relation to the customers, employees, the company and core processes, with the latter also including the financial results. The qualifying criteria are leadership, strategy, employees, the key resource, other resources and partnerships as well as processes, products and services. Accordingly, the model uses five qualifying and four result criteria with a total of 32 subcriteria.

Assessment

The qualifying criteria are assessed according to the RADAR logic, broken down into the approach, that is, the processes, deployment, or extent to which the concept of the approach was realized – at all hierarchy levels and horizontally – as well as the assessment and improvement of the procedure. The PDCA cycle corresponds to the RADAR logic (**R**esults, **A**pproach, **D**eployment, **A**ssessment, **R**eview) of the EFQM model.

In contrast to norms and standards, the question is not about “What” or “If at all”, but rather about “How” – the reasoning and clear derivation from the vision, mission and strategy as well as effectiveness and efficiency of the procedure or approach.

The results obtained – typically time-delayed – can be traced back to the thorough, systematic, sustainability-oriented and strategy-driven approach. They are assessed, according to the degree of quality of the outcome, in terms of relevance and benefit, as well as performance (long-term trends, targets, comparisons with other organizations, strategy as the cause of success) in relation to all relevant activities and areas.

Determining maturity of an organization through self-assessment

EFQM defines self-assessment as a “comprehensive, systematic and regular review of the activities and results of an organization on the basis of a model for business excellence” [38]. The term “self-assessment” suggests a rather subjective approach, implying a temptation to gloss over and trim the results. But instead it serves to identify strengths and weaknesses (improvement potential) and to develop from this improvement measures whose success is monitored and controlled by the continuous repetition of this process. Any manipulation of the actual situation would, therefore, be counterproductive.

Depending on the assessment process, the organization can review its position at varying depth and expenditure. EFQM recommends five self-assessment models [questionnaire, matrix diagram, workshop, standard forms, simulated application for the European Excellence Award (EEA)]. All of them have advantages and disadvantages. Therefore, the most appropriate model for the given situation must be selected. The highest expenditure is involved in the simulated application for the European Excellence Award, but it also yields the most accurate results.

Levels of excellence

EFQM introduced “levels of excellence” about ten years ago in order to pave the way for the application for one of the excellence awards.

Committed to Excellence (C2E): the applying organization does an initial and simple self-assessment according to the EFQM model of excellence, prioritizes the resulting improvement potential, and implements three potential improvement areas with project plans. This is followed by an on-site visit from an experienced validator, who will provide verbal and written feedback. Successful applicants receive a certificate from EFQM.

Recognized for Excellence (R4E): intended for organizations that have already achieved a high level in terms of self-assessment and implementation of the EFQM model. The award is handed out in three levels: 3, 4 and 5 stars. The application is based on the full EFQM model. A team of two or three assessors makes the assessment and issues a feedback report on the criteria. Recognition requires an assessment of at least 300 points by the assessors (>400=4 stars; >500=5 stars). Organizations at this level of recognition are very well managed and have progressed far on their way toward excellence.

Experience with the EFQM model at the medical laboratory

The Department of Laboratory Medicine at the German Heart Center in Munich was the first institution of its kind to subject itself in February 1999 to an external assessment according to the EFQM model by way of a simulated application for the European Excellence Award, and then published the results [1]. The department achieved the European “Recognized for Excellence” in 2006.

That same year, two other institutes, the Center of Laboratory Medicine, Microbiology and Transfusion Medicine at the Municipal Hospital of Karlsruhe and Medilys – Labormedizin, Mikrobiologie und Krankenhaushygiene LBK Hamburg GmbH, Clinical Chemistry (area of competence), received the “Committed to Excellence”. In 2012, the recognition was given to the Institute of Laboratory Medicine, hospitals of the Göppingen district. The Greifswald Medical School has received “Committed to Excellence” three times so far. Other institutes are on the road.

Further reading

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