Clin Chem Lab Med 2008;46(8):1189–1194 © 2008 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2008.225

Quality indicators and specifications for strategic and support processes in laboratory medicine

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Abstract

Background: This work is the second part of a study regarding indicators and quality specifications for the non-analytical processes in laboratory medicine. Five primary care and five hospital laboratories agreed on the indicators for two strategic processes (quality planning and project development) and various support processes (client relationships, instrument and infrastructure maintenance, safety and risk prevention, purchases and storage, personnel training).
Methods: In the majority of cases, the median values recorded over 1 year is considered to be the state-of-the-art in our setting and proposed as the quality specification for the indicators stated. Values have been stratified according to primary care and hospital laboratory for referred tests and group of personnel for training. In some cases, the specifications have been set equal to zero events, such as serious incidents in the infrastructure maintenance process and number of work accidents in the safety and risk prevention process.
Results and conclusions: In light of this study, an effort is needed to optimize decisions regarding corrective actions and to move from a subjective individual criterion to systematic and comparative management. This preliminary study provides a comprehensive vision of a subject that could motivate further research and advances in the quality of laboratory services.
Clin Chem Lab Med 2008;46:1189–94.

Keywords: laboratory processes; quality indicator; quality management; quality specification.

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Received February 29, 2008; accepted April 10, 2008; previously published online June 20, 2008

Introduction

In the first part of the present study, a working group including 10 clinical laboratories from the Institut Català de la Salut (ICS, Catalonian Health Institute) established the indicators for key laboratory processes in their setting, as well as the quality specifications for each of the indicators (1). All the participating laboratories are certified according to the EN ISO 9001 norm, which requires the following conditions:

- Identification of all processes involved in their activity.
- Recording of all incidents occurring in daily practice.
- Quality activity under the supervision of a laboratory staff coordinator.

For the purposes of the first part and this second part of the study, laboratory processes were defined as follows:

- Key processes are the core of laboratory activity and include pre-analytic, analytic, and post-analytic processes.
- Strategic processes refer to activity that defines the laboratory's reason for existence in terms of what it is trying to accomplish.
- Support processes refer to activity that makes possible the efficiency and effectiveness of the strategic and key processes.

The aim of the second part of this study is to define the most appropriate performance indicators for the strategic and support processes of our laboratories and determine the quality specifications for these indicators.

Materials and methods

The working group consisted of quality directors from five primary care and five third-level hospital clinical laboratories within the public health setting. The quality system and the basic philosophy of laboratory service is similar in all these laboratories, but the volume of activity differs considerably between those located in cities and those in rural areas (250–1000 patients per day).

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The following preliminary steps were taken in each laboratory:

- Processes used were identified and given a standardized description.
- The indicators for each process were described.
- The formulas used for the calculations were determined.
- The frequency of the analysis was determined.
- The specifications for the indicators were defined, so that activity to reduce errors could be initiated when the limits were not reached.

Quality indicators were defined based on the indicators each center had implemented to obtain certification. In general, the laboratories comprising this working group use the same indicators; hence, it was only necessary to unify their designation and the units in which they were expressed. Most of the indicators were established as relative measures and are expressed as a percentage of the attributes or incidents of the processes examined relative to the total activity. The remaining indicators are presented simply as the number of events.

Every 2 months, the members of the working group met to present their data for the quality indicators of strategic and support processes. The values collected were from 2005 and 2006. The median of these values was considered the desirable quality specification for the indicator, according to the state-of-the-art concept, with a few exceptions that are described in the Discussion section.

Results

Based on consensus, the strategic processes included quality planning and project development, and the support processes were client relationship, instrument maintenance, infrastructure maintenance, risk prevention, purchases and storage, and personnel training.

Strategic processes

The three indicators established for the strategic processes were:

Quality planning:

1) Goals reached
2) Referred tests for

Project development:

3) Projects carried out.

Support processes

In total, 12 indicators were defined for support processes:

Client relationship:

1) Physician satisfaction
2) Patient satisfaction
3) Written complaints
4) Verbal complaints
5) Consultations and suggestions

Instrument maintenance:

6) Corrective maintenance of instruments

Infrastructure maintenance:

7) Serious incidents (information system crash, energy breakdown)

Risk prevention:

8) Workplace safety and risk prevention

Purchases and storage:

9) Non-conformities to providers
10) Incidents in referred tests

Personnel training:

11) Evaluation of training
12) Training for each professional group.

The designation of each indicator, the median of values presented by the laboratories, maximum and minimum values, desirable specification, and the formula for the calculation and units are shown in Tables 1 and 2. Calculations were performed annually.

Discussion

Over the years, a series of efforts have been made to assure the quality of the analytical phase of laboratory medicine (internal quality control and external quality assurance). Laboratories have seen that comparison of their analytical performance with that of peer groups improves the health service they provide. However, to accomplish their analytical task, laboratories require a large number of support and strategic processes, and up to now, these activities have not received systematic and comparative management.

Table 1 Indicators and specifications for strategic processes.

Indicator	Median	Maximum	Minimum	Specifications	Formula	Units
Quality planning						
Goals reached	83.8	100	52	75–80	100×sum of percentage reached for each goal/no. goals	%
Referred tests						
Primary care	0.9	2.0	0.3	0.9	100×no. referred tests/no. tests done	%
Hospital	0.1	0.12	0.07	0.1		
Project development						
Projects carried out	100	100	52	75–80	100×no. projects made/no. projects planned	%

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Table 2 Indicators and specifications for support processes.

Indicator		Median	Maximum	Minimum	Specification	Formula	Units
Client relationship							
Internal client satisfaction (physician)		8.4	8.8	6.5	8.4	Sum of points given in the enquiry/ no. enquiries answered	Score over 10
External client satisfaction (patient)		8.0	8.5	7.9	8.0	Sum of points given in the enquiry/ no. enquiries answered	Score over 10
Written complaints		2	10	0	2.0	Number	No.
Verbal complaints		14.5	33	5	14.5	Number	No.
Consultations and suggestions		25.3	48	0	ND	100×no. of suggestions/no. enquiries sent	%
Instrument maintenance							
Corrective maintenance of analyzers		3.6	7.8	0.7	3.6	Sum no. breakdowns/no. instruments	Fraction
		1.7	3.8	0.02	1.7	100×no. h maintenance/no. h functioning	%
Infrastructure maintenance							
Serious incidents		6.0	28	0	0	Number	No.
Safety and risk prevention							
Number of work-related accidents		2.9	8.9	0	0	100×no. accidents/no. personnel staff	%
Purchases and storage							
Non-conformities to providers		4.0	15	0	4.0	Number	No.
Incidents in referred tests		0.6	1.9	0.4	0.6	100×no. incidents in referred tests/ no. referred tests	%
Personnel training							
Evaluation of training		8.0	9.4	6.9	8.0	Sum of points given in each session/ no. of sessions	Score over 10
Training for each group	S	3.3	10.9	1.0	3.5	100×no. h received/no. h worked	%
	T	3.5	16.2	0.7	3.5	100×no. h received/no. h worked	%
	A	1.3	2.4	0.1	3.5	100×no. h received/no. h worked	%

ND, no defined; S, staff personnel; T, technical personnel; A, administrative personnel.

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Instead, laboratories handle problems in these areas according to the individual criteria used at each site.

Establishment by peer group consensus of indicators for the support and strategic processes, that are essential for proper laboratory functioning, is a means to optimize the decisions regarding corrective measures in these areas. In addition, consensus definition of the desirable specifications for these indicators (limits of acceptability) will allow laboratory professionals to identify aspects requiring improvement on a more reliable basis than personal judgment.

In the Spanish public health system, all clinical laboratories function according to a similar management model, which implies that certain activities, such as purchasing equipment and consumables, and hiring employees are under the direction of the Administration (in the case of Catalonia, the ICS), other activities are managed directly by the laboratories, and some, such as maintenance of equipment, are a combined responsibility. Therefore, the laboratories in this system do not have the freedom to organize their activity exclusively according to technical criteria related to their profession.

Strategic processes

Quality planning *Goals reached* One of the indicators for quality planning is based on definition of the specific related objectives that should be attained during the year (e.g., 100% notification of critical laboratory results, recording transport time from sample drawing on the wards to reception in the laboratory, writing up a manual with chemical safety procedures) and these may differ between centers. The degree to which these goals were achieved in our working group laboratories varied substantially (52%–100%). Some laboratories had set objectives, but could not reach them because of insufficient resources (e.g., reporting of critical results without an adequate informatics network). Others did not have the outside cooperation required (e.g., no direct relationship with phlebotomists in the wards). Nevertheless, some goals that only depended on the laboratory personnel, such as formulation of a safety manual, were easily attained. In light of the data obtained regarding the present status, the working group has concluded that if objectives are realistically defined, the quality specification for this indicator should be 75%–80% at this time.

Referred tests Another indicator that expresses proper quality planning in our setting is the percentage of referred tests, i.e., those sent for analysis outside the laboratory. Ideally, all the tests offered by a health center should be performed in the center's laboratory. Nevertheless, in a public health network such as ours, hospital referral laboratories necessarily perform a wider variety of tests than primary care laboratories. Test referral is a potential source of errors (e.g., loss of samples, loss of analyte stability) and other associated problems (e.g., danger of contaminating the carrier and the environment).

The values obtained in this section were divided into two groups: primary care laboratory and hospital laboratory. There is a low rate of referred tests with narrow dispersion in hospitals (0.07%–0.12%) and higher values with wide dispersion (0.3%–2.0%) in primary care laboratories. This fact reflects the diversity of these services, according to the size of the population attended and, consequently, the specification is stratified according to the laboratory type.

Project development

Within the strategic process termed project development, the indicator *Projects carried out* obtained a median of 100%, but one laboratory only reached 52% and another 67%. Taking into account the same considerations mentioned in *Goals reached*, where attaining the goal is subject to political, economic and other outside circumstances that might affect execution of the projects, the quality specification for this item was estimated at 75%–80% as the preliminary value.

Support processes

Support processes are entirely within the sphere of the coordinating professional in charge of laboratory quality. Hence, it was easier to establish consensus indicators for this group.

Client relationship To assess satisfaction with the laboratory service, questionnaire surveys were carried out on both internal clients (physicians) and external clients (patients). The medians obtained were slightly different, with values of 8.4 for physician satisfaction and 8.0 for user satisfaction with the laboratory services. Although the level of satisfaction is acceptable overall, the working group wishes to comment that the patient's perception of laboratory quality is mainly focused on the activity of sample collection, waiting room comfort and phlebotomist competence (non-laboratory administered personnel) than on aspects totally managed by the laboratory staff.

Client complaints The indicators for this section include written and verbal complaints without distinguishing between physicians and patients, although most laboratories only record written complaints. As a general observation, the number of written complaints was quite low. Rather than attributing this to an extremely favorable perception of laboratory functioning, the group is conscious that other factors may have an influence on this item. For example, because of our political history, people are generally not aware that they have the right to complain. As regards written complaints, the laboratory of the hospital with the largest number of physicians, specialties, and complex tests showed a value far above the others, and the complaints mainly came from physicians. Regarding verbal complaints, the number recorded differed considerably between laboratories. The working group believes that the criteria for recording this item should be standardized among laboratories. Despite

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these limitations, the median of complaints per year (2 written and 14 verbal) is considered the preliminary desirable specification for these indicators.

When establishing the potential indicators for this process, the working group considered that the consultations and suggestions of clients might have provided another parameter to reflect the client's perception of laboratory quality. However, in practice there was no established method for collecting these data; hence, the information was calculated based on the responses to questions about this item on the satisfaction questionnaire. The median value found was 25.3 suggestions per 100 surveys distributed, with a considerable dispersion between laboratories (0%–48%). Although these results provide a preliminary view of this aspect, the group decided not to use this value to determine the desirable specification until a standardized system for recording this item has been implemented and when values that are more reliable are obtained.

The process **instrument maintenance** in this study is mainly focused on automatic analyzers. What it attempts to measure is the consequences of aging of the analyzers, and the study laboratories were using two indicators for this purpose: 1) number of breakdowns per year per instrument, and 2) number of hours needed for repairs per 100 h of instrument functioning. The working group accepted both formulas as valid indicators for the same process, with laboratories using the one they found the most convenient.

A breakdown is defined as interruption of the functioning of an analyzer, requiring an external technician service. Calculation of the number of breakdowns per year per instrument gave a median of 3.6. This value was quite homogeneous, with differing results in only two laboratories: 0.7 in a hospital laboratory and 7.8 in a primary care laboratory with quite old analyzers. For this reason, the median was considered a relatively solid specification for this item. It is difficult to judge if 3.6 breakdowns per instrument and year is good enough or not; this value is considered the starting point for evaluating instrument's robustness.

The same was true for the number of hours needed for repairs per 100 h of instrument functioning, with the median obtained (1.7 h) being considered the quality specification at this starting point. When applying the six sigma metrics (2), the value of 1.7% h for repairs (exclusively), which corresponds to 17000 dpm (defects per million), results in a 3.7σ. According to the sigma metric, this value does not imply very good quality (3). So, again, the 1.7% of hours for repairing instruments is considered the starting point for evaluating repair efficacy.

The next process examined, **infrastructure maintenance** (Table 2), also brought to light differences between the participating centers, with a range of 0–28 incidents per year. It is important to remember that the calculation of this item was made with data from only 1 year and standardized criteria to define this item had not yet been established. For example, not all the laboratories recorded problems with the informatics network, such as power failures and disconnections, which are not attributable to laboratory functioning but should be treated as serious incidents related to infrastructure maintenance. Observation of the disparity in this item led the group to set a criterion to define incidents in this process: serious events that stop laboratory functioning for at least half the workday. The group considers that there should be no incidents of this type; hence, the specification for this item is zero.

As regards the process **safety and risk prevention,** a work-related accident is defined as one that occurs during the workday (including the trip to and from work) and requires the laboratory worker to be attended by the corresponding health care service (e.g., Preventive Medicine Department). Again, values between centers for this indicator differed considerably, with a range of 0–8.9 accidents per 100 employees per year. These differences are attributed to the fact that many workers are not aware that these incidents should be reported. The preliminary data on this indicator are, therefore, not considered reliable and the desirable specification has again been set at zero.

The process **purchases and storage** is focused on suppliers, who are defined as companies that provide instruments, reagents and other material, external laboratories, and the transport services. Calculation of the indicator *non-conformity to the supplier* is based on incidents implying a failure to meet pre-established requirements (e.g., product characteristics, delivery time) agreed upon by the laboratory and supplier, expressed as a formal written complaint. The median obtained is four non-conformities per year, which is accepted as the preliminary specification for this item. Although a standardized method for determining supplier performance had not been implemented before this effort, the working group has formed an opinion regarding this indicator based on experience. Historically, our laboratories had a direct relationship with the supplier and any incidents occurring were immediately reported and resolved. A new centralized system of purchasing is being implemented in several laboratories in the Catalan health system and the working group believes that this has led to an increase in the number of incidents related to this process (depletion of stocks, loss of traceability of products, delivery to the wrong center), which has had a negative impact on the quality of our laboratory services.

The indicator *incidents in referred tests* expresses the problems occurring in tests sent to external laboratories. The proposed specification of 0.6% has been reached by all the participating laboratories except one, in which the recorded value is 1.9%, which may indicate problems in this referral laboratory that require investigation.

The **personnel training** process is important in the healthcare setting. The indicator evaluation of training, which was quite good in all the laboratories studied (median 8.0 over 10 points), reflects satisfaction on the part of the personnel undergoing specific train-

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ing for their work tasks, hence the median obtained is considered a reasonable specification.

Data from the indicator, *hours of training*, were highly discrepant between the participating centers and between the various groups (staff personnel, technicians, and administrative personnel) within each center. One factor with a great impact on this item is the personal motivation of each worker (degree of specialization, interest in learning, right for seniority status, opportunities for promotion, etc.). Another aspect to keep in mind is that the budget set aside for training laboratory workers is non-existent or quite limited in some centers, such that persons interested in further training have to seek alternative sources for financial support. The opinion of the working group is that training is likely adequate, but is not reflected by systematic recording of this activity, which should be standardized. As a general criterion, the value of 3.5%, the median of training hours received by the technical personnel, is considered a good specification for all the groups involved.

Conclusions

Strong points

- Effective attainment of objectives and execution of projects in the majority of laboratories expresses the high degree of dedication of the personnel involved.
- The favorable responses to the surveys indicate satisfaction on the part of our clients, both internal and external, in relation to the laboratory services provided.
- Most laboratories in the group are equipped with up-to-date analyzers, a fact that is reflected in the indicator for instrument maintenance.
- Laboratory personnel judged that the training they received was adequate and well presented.

Recommendations for improvement

- The specifications proposed in this study are preliminary and still cannot be considered the desirable level of quality to be attained. Follow-up of the indicators, at least at middle term, is needed to establish values that are more robust.
- The practice of formulating complaints and suggestions needs to be enhanced among the laboratory users in our setting. Additionally, proper infrastructure and personnel trained to collect and analyze this information is required.
- The new centralized system for purchasing, established for economic purposes, is perceived to generate obstacles that impede fluid daily laboratory activity with regard to consumables and instrument maintenance. This might be improved with enhanced dialogue between the central management and laboratory directors.
- An alarming series of serious incidents related to the basic infrastructure (e.g., electric system, building deficiencies) requires prioritization for improvement to assure proper laboratory functioning.
- A standardized training program with adequate funding should be implemented for all the groups working in the health system.

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