Clin Chem Lab Med 2007;45(5):672–677 © 2007 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2007.122

Quality indicators and specifications for key processes in clinical laboratories: a preliminary experience

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Abstract

Background: The aim of this study was to identify process indicators for the three phases of laboratory activity and their corresponding quality specifications in our setting (primary care centers, and second- and third-level hospitals that provide public healthcare services in Catalonia).
Methods: Every 2 months, working group members met to present data obtained for quality indicators for the current processes in their laboratories. The results collected were for indicators recorded monthly from 2005 and for indicators recorded less frequently from 2004. The medians of the results obtained in all laboratories were calculated and the values obtained were established as the current specifications for the corresponding indicators.
Results: The laboratories participating in this working group use 12 indicators for the key processes (three for preanalytical steps, four for analytical steps and five for postanalytical steps). The preanalytical indicators are erroneous request, erroneous sample, and samples not taken, with specifications of 4.1%, 5.0% and 1.7%, respectively. A new indicator for the analytical step is the percentage of external controls exceeding the specification (0.8%); specifications for the other three well-recognized indicators (imprecision, bias and total error) are not the subject of this study. For the postanalytical phase, the indicators (and specifications) include duplicate hard copies of reports sent to centers or clinical units (1.6%), failure in critical value reporting (0.5%), reports exceeding delivery time (0.7%), reports from referred tests that exceed delivery time (8.9%), and incidents related to the data processing network between centers (25 events per year).
Conclusions: The process indicators reflect the state-of-the-art of the laboratories comprising our working group. Current performance for the analytical phase is satisfactory because it is entirely in the hands of the laboratory, while the main problems in extra-analytical phases reside in activities performed outside the laboratory (sample collection and transport, as well as non-electronic report delivery).
Clin Chem Lab Med 2007;45:672–7.

Keywords: laboratory processes; quality indicator; quality specification.

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Introduction

The Institut Català de la Salut (ICS; Catalonian Health Institute) is a body comprising all the primary care centers and second- and third-level hospitals that provide public healthcare services to the Autonomous Government of Catalonia. The ICS covers all the healthcare needs of the population of Catalonia (7,000,000 inhabitants). Clinical laboratories within the ICS have implemented a process-based quality management system certified under the EN-ISO 9001 standard, which has been complemented with certain points from the EN-ISO 15189 standard. The system involves the use of performance indicators for both analytical and extra-analytical processes, with the ultimate objective of facilitating actions to improve the quality of these processes.

Application of EN-ISO 9001 allows us to attain the following:

- A well-defined functional structure;
- Clear definition of the aims of the tasks involved;
- Harmonization of operating procedures;
- Registration of problems and systematic means for resolving them;
- Involvement of the entire staff in continuous improvement of the processes.

The weak points of this quality system include:

- Bureaucratic overload;

- No guidelines for identifying quality indicators for laboratory processes;
- No definition of quality specifications.

The bureaucratic overload generated can be resolved by expanding existing data-processing capabilities or incorporating currently available software, such as BDI-9000 (Johnson & Johnson, Barcelona, Spain), Certool (AENOR; Barcelona, Spain), Qualigram (Office Organization, Barcelona, Spain), or others.

Adopting a team approach with the participation of various laboratories can minimize any lack of experience in identifying indicators and defining quality specifications. The working method would involve assessment of the processes implemented in each center, evaluation of the indicators used to assure that they are sensitive and specific for the processes examined, and comparison of the values obtained among laboratories during a certain period of time. For this purpose, a working group was created comprising the majority of primary care and hospital laboratories within the ICS.

The aim of this study was to identify process indicators for the three phases of laboratory activity and their corresponding quality specifications in our setting.

Materials and methods

Every 2 months the members of the working group met to present data obtained for the quality indicators of the current processes in their laboratories. The values collected were for indicators recorded monthly from 2005 and for indicators recorded less frequently from 2004.

The following preliminary steps were taken:

- Processes used in each laboratory were identified and given a standardized description;
- The indicators for each process were described;
- The formulas used for calculations were determined;
- The frequency of the analysis was determined;
- When necessary, the criterion to be followed to define the quality specification was stated.

The members of the working group arrived at the following premises by consensus:

- Three types of processes are involved: *key, strategic* and *support*. The key processes include pre-analytical, analytical, and post-analytical processes, and these are the subject of this document. The strategic processes (organization and distribution of resources, quality planning, project development) and support processes (relationship with the client, infrastructure maintenance, risk prevention and safety, purchases and training) will be developed in a future study.
- The indicators for activity should be differentiated from quality indicators. The former are descriptive and are used to assess the evolution of a process, but they do not have an explicit specification.
- The specifications for the remaining indicators should be defined, so that activity to reduce errors can be initiated when limits are not reached.
- Not all indicators can be used in all laboratories. Application of the indicators depends on the characteristics and organization of each center.

Quality indicators were defined taking into account the indicators each center had implemented to obtain certification. In general, the laboratories comprising this working group use the same indicators and hence it was only necessary to unify the specific terms applied to name them.

The working group considers that quality indicators should be relative measures, expressed as a percentage of the attributes or incidents of the processes examined relative to the total activity assessed. Hence, the method used to express indicators had to be unified because some laboratories used absolute numbers without first dividing the errors by total activity, making comparisons impossible.

Indicators are calculated every month or every 3 months for key processes, and yearly for strategic processes and support processes. For key processes, data corresponding to the first 3 months of 2005 were recorded for indicators of analytical quality and data from 2004 for indicators of extra-analytical quality. The medians of the results obtained in all laboratories were calculated and the values obtained were established as the current specifications for the corresponding indicators.

Results

The ICS laboratories participating in this working group use a total of 32 indicators to denote the quality of various laboratory processes. These include 12 indicators for key processes (three for preanalytical steps, four for analytical steps, and five for post-analytical steps), as well as eight indicators for strategic processes and 12 for support processes; the latter two groups are not considered in this work. The elements required to design the quality indicators are summarized in Table 1. These include:

- Definition of a suitable indicator for each process;
- The formula used to calculate the indicator;
- The frequency of measurement;
- A desirable specification.

Indicators of preanalytical processes

The majority of indicators for preanalytical processes assess activity undertaken outside the laboratory, including the task of filling out the request form, which is performed by physicians, and the sample collection process, involving scheduling and blood-drawing, which is performed by the primary care center or clinical department of the hospital. Incidents were recorded in each laboratory and related to the total number of requests and samples received.

Incidents related to requests include errors (data missing on the request form and administrative errors) occurring at the collection sites outside the laboratory (phlebotomy center or clinical ward), the sum of which is 4.1% of erroneous requests, as shown in Table 1. Incidents in which essential information was missing on the request form are stratified according to the data omitted (Table 2). The highest percentage of this type of error (5.87%) was within the section dedicated to ''identification (ID) linkage''. This is a concept inherent to our public health organization, in which the ID number and demographic data for each person registered in the public health service

Table 1 Quality indicators for key processes.

Indicator	Formula	Specification
Preanalytical process		
Erroneous request	100×no. of erroneous requests/no. of requests	4.1%
Erroneous sample	100×no. of erroneous samples/no. of requests	5.0%
Sample not taken	100×no. of patients not located/no. of requests	1.7%
Analytical process		
External control exceeds specifications	100×no. of constituents exceeding specifications/no. of control results assessed	0.8%
Analytical imprecision	Coefficient of variation	Ref. (1)
Systematic error	100×(mean value–target value)/target value	Ref. (1)
Total error	100×(single value–target value)/target value	Ref. (1)
Post-analytical process		
Hard copies of reports sent to centers or clinical units	100×no. of copies/no. of requests sent	1.6%
Critical value reporting	100×no. of reports with critical values/no. of requests	0.5%
Reports or results exceed delivery time	100×no. of reports or results exceeding delivery time/no. of reports issued	0.7%
Reports from referred tests exceed delivery time	100×no. of referred reports exceeding delivery time/no. of referred reports	8.9%
Incidents related to data-processing network between centers	No. of incidents/year	25

Data on the quality indicators is collected monthly.

are stored in a central data-processing network. ID linkage refers to the activity of adding this permanent patient information to the number the laboratory assigns to a request for an analysis. This is performed manually and it is at this point where errors can occur. These incidents are detected when the sample and request reach the laboratory.

Another indicator related to erroneous ID linkage reveals a shortcoming in the laboratory preanalytical process: requests with ID linkage problems that are not detected by the laboratory control system. The median value was 8.9%, but all the laboratories in the working group did not record this information, as it only applies to the primary care system. This indicator is calculated relative to the total number of requests with ID linkage problems and not the total number of requests received; therefore, it cannot be compared to the remaining indicators in Table 2.

Incidents related to the samples are shown in Table 3. This indicator also assesses the activity of the phlebotomy centers and the transport services. Registration of incidents relative to the samples is carried out according to the following criteria for errors detected:

- Specimen lost/not received (includes all types of samples);
- Insufficient specimen quantity (includes all types of samples);
- Erroneous collection container (includes all types of samples);
- Specimen hemolyzed (blood);
- Specimen clotted (blood).

The most common problem in this section is failure to receive the expected specimens in the laboratory (2.9%). When sample-related incidents were examined according to the type of specimen, the most frequent problem was found to be urine specimens lost/not received (1.4%). The overall percentage of erroneous samples obtained in 2004 was 5%.

In addition, a high rate of contaminated urine samples (4.4%) was detected. This value is omitted from the table, because it was calculated in relation to the number of cultures performed and not to the number of urine samples received.

Indicators of the analytical process

The following are the indicators for the analytical process:

- External controls exceed specifications;
- Imprecision;

Table 2 Quality indicators of the preanalytical process: erroneous requests.

Process	Activity	Stratification	Incidents, %
Preanalytical outside the laboratory	Data missing	No physician identification	0.123
		No demographic data	0.01
		Test not specified	0.01
		No diagnostic orientation[a]	0.12
	Administrative error	No request number	0.01
		Request not ID-linked[b]	5.87
		Request erroneously ID-linked	0.17

Median percentage of incidents over requests observed in laboratories participating in the working group. [a]Only in hospital laboratories; [b]only in primary care laboratories.

Table 3 Quality indicators of the preanalytical process: erroneous samples.

Process	Erroneous specimen type	Incidents, %
Preanalytical	Specimen not received	2.9 (2.0–6.1)
	Specimen insufficient	0.15 (0.07–0.8)
	Wrong container	0.03 (0.02–0.2)
	Hemolyzed specimen	0.8 (0.06–1.2)
	Clotted specimen	0.55 (0.36–0.96)
	Others	0.57

Median (interval) percentage of incidents over samples. Partial count (one laboratory does not record the incidents listed).

- Systematic error;
- Inaccuracy.

The percentage of external controls for which values fall outside the specifications defined by the Sociedad Española de Bioquímica Clínica y Patología Molecular (SEQC, Spanish Society of Clinical Biochemistry and Molecular Pathology) external quality assessment schemes is shown in Table 4. The results for all external quality assurance programs in which the laboratories of the working group participated during the first 3 months of 2005 were recorded. The number of constituents with results outside the specifications for each laboratory and program were counted and the median of all values obtained was calculated. The overall results were 1.0% for quantities in the serum biochemistry program, 0.2% for hematology and 1.3% for microbiology. The total average for external quality assessment failures in our laboratories was 1%.

Table 4 Quality indicators of the analytical process: percentage of control results exceeding limits.

Program	No. of analytes	Rejections, %
Biochemistry-Serum	29	1.7
Biochemistry-Hormones	15	2.2
Biochemistry-Proteins	7	0.0
Biochemistry-Urine	10	0.0
Biochemistry-Glycohemoglobin	1	0.0
Biochemistry-Gases	24	5.6
Biochemistry-Cardiac markers	6	0.0
Biochemistry-Tumor markers	8	0.0
Biochemistry-Emergency unit	18	1.1
Urinalysis	7	0.0
Autoimmune	7	0.0
Biochemistry mean	12	1.0
Red/white cells and platelet count	18	2.1
Coagulation	6	0.0
Functional antithrombin III	2	0.0
Oral anticoagulation treatment	2	0.0
Fetal and A_2 hemoglobin	4	0.0
Factor VIII	2	0.0
Automatic reticulocyte count	2	0.0
Protein C resistance	2	0.0
Leukocyte differential	10	0.0
Erythrocyte sedimentation rate	2	0.0
Hematology mean	5	0.2
Microbiology-Bacteriology	6	0.0
Microbiology-Mycology	1	0.0
Microbiology-Microscopy	1	0.0
Microbiology-Serology	10	5.0
Microbiology mean	4.5	1.3

Median results are presented.

The indicators for imprecision, systematic error and inaccuracy were calculated from the results for internal and external controls available in each laboratory. The group considers that it is not necessary to present this information in the present study. The desirable limits, which have been described and are internationally accepted (1–3), are also omitted.

Therefore, this document only includes some of the indicators for the analytical process. Since the values obtained are quite similar between the laboratories, minimum and maximum values are not presented.

Indicators for the post-analytical process

The incidents recorded for the post-analytical process relating to reports for the year 2004 are shown in Table 1, divided according to the following criteria:

- Copies of reports;
- Reports with critical results that require notification (this item is not calculated in all the laboratories);
- Report delivery time exceeds the established time interval. Some laboratories consider the reports for referred tests separately (the count can be made with either tests or reports, as long as the number of incidents is divided by the total activity being assessed);
- Technical problems with the data-processing network when delivering reports to the primary care centers or hospital wards.

The first three indicators are calculated in relation to the number of reports or the number of requests; the scattering of values between laboratories was small and the poorest results were related to the creation and delivery of hard copies of reports. The laboratories provide separate reporting of incidents related to referred reports that exceed the delivery time; the result obtained is approximately 8.9%. Technical problems with the data-processing network were expressed in absolute numbers; the median obtained for the working group was 25 incidents during 2004, although not all of the participating laboratories provided data for this indicator. The frequency of post-analytical errors is shown in Table 1.

Discussion

This initial effort by our working group examines the way in which incidents are recorded in a group of pri-

mary care and hospital clinical laboratories and attempts to unify the criteria used in this respect. It covers problems related to both the analytical and extra-analytical phases, and establishes the current state-of-the-art of laboratory performance in our public health setting. This approach has yielded a preliminary basis for defining quality specifications in our clinical laboratories, which might be useful for all medical laboratories as a point of reference. The results presented here have to be taken as values subject to adjustment and should be periodically reexamined (e.g., yearly) and narrowed according to the improvements achieved by trouble-shooting and process changes. The final purpose of this effort is to reduce laboratory error from a pragmatic viewpoint. In other words, we are not attempting to eliminate all error from key processes, but instead, to implement an achievable, progressive decrease in errors over all the laboratories in our public health system.

A general overview of the results of this analysis showed considerable disparity between the participating laboratories in the number of extra-analytical incidents recorded, which gave the impression that some laboratories were performing much better (or worse) than others. To obtain an idea of the magnitude of the problem, we compared our mean results with those for other external comparisons. We found that the frequency of request-related incidents in our setting was lower than the rate obtained by laboratories participating in the intercomparison program of the College of American Pathologists (CAP) (4–6). This seemed encouraging, but the working group suspected that the lower rate of incidents was not a consequence of better performance than the comparison laboratories, but rather the result of deficient recording of problems, since the system had been recently implemented.

In the management of samples, for which the recording of problems has been reliably performed for some years, 5% of samples had errors. Division of this finding into basic elements showed that the main problem was in samples that were not received (2.9%), followed by hemolyzed samples (0.8%). The values for lost samples are higher than those obtained in the SEQC program (7) for the preanalytical step (0.23%) and those within the CAP intercomparison program (0.22%). We believe that a great part of this problem resides in the sample collection process. Sample collection in all the primary care centers and in the clinical units (but not outpatient units) of our hospitals is not under laboratory supervision and depends entirely on the professional capability of persons who are not affiliated to the laboratory. Sample-related incidents are approximately two-fold more frequent in primary care settings than in hospitals, although in centers with a smaller workload and fewer staff rotations, there are fewer incidents. We believe these results indicate a flaw in the system that could be improved by granting the laboratory the power of decision-making in the sample collection process.

With respect to the indicator for erroneously ID-linked requests with control failure on the part of the laboratory, the working group recommends that these incidents are recorded in all laboratories able to do so because of the repercussions of this error on the traceability of results. This item is an important indicator of preanalytical administrative control within the laboratory.

The laboratories in the working group have concluded that a new indicator of incidents related to sample management within the laboratory (e.g., loss of samples, poor organization of sample storage facilities, broken tubes) should be implemented, since it is a direct part of laboratory activity.

The results for the analytical process reveal that failure to reach analytical quality in external quality assessment programs was 0.8%, a value similar to the 1.1% found in laboratories in the USA. This value can be considered to express the current situation of the laboratories comprising the working group (state-of-the-art). It indicates that the analytical quality of the working group laboratories is acceptable and that each individual laboratory should attempt to maintain errors below the overall mean and to initiate corrective actions when errors exceed this value.

In the postanalytical process, we highlight the relatively high percentage of report copies that had to be reissued, and delivery of reports outside of the established interval for referred tests due to delays in the referral laboratory. Work should be continued on the indicators related to the data processing networks that connect the laboratory with the exterior.

Finally, specific opportunities for improvement include: 1) place the sample collection procedure and transport under laboratory authority; 2) automate the pre-analytical process (e.g., computerize requesting, establish network documentation, and use robotic sample processing); 3) implement a single patient history number for hospitals and primary care centers; 4) improve the data-processing infrastructure (robust connections) between laboratories and external sites to expedite reporting of results; and 5) perform periodic review of current quality specifications based on the state-of-the-art to update the preliminary values.

Conclusions

The laboratories comprising the working group offer the following conclusions from the present study:

- The results for the process indicators reflect the true situation in the laboratories comprising our working group (state-of-the-art) and therefore are considered the preliminary quality specifications in our setting for the three phases of laboratory activity.
- Current performance for the analytical phase is satisfactory, mainly because internal and external quality control has been in practice for a number of years and, above all, because it is entirely in the hands of the laboratory.
- The main problem in the preanalytical phase resides in activities performed outside the laboratory, particularly in sample collection and trans-

port. The provision of numerous sample collection points to make phlebotomy more convenient for the patient has resulted in a large percentage of lost samples. In the post-analytical phase, delayed delivery of reports for referred analyses was another indicator of problems originating outside the laboratory.

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Received January 9, 2007, accepted February 2, 2007