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Review

Quality indicators and specifications for the extra-analytical phases in clinical laboratory management

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Abstract

Background: Quality management systems should cover all the steps involved in the overall testing and non-testing processes.

Aim*:* To identify quality indicators for extra-analytical processes in the clinical laboratory and to specify acceptability limits, in order to provide a useful tool for continuous improvement of laboratory service.

Methods: A literature review by Medline search was performed using the keywords: *Q-Tracks* and *Q-probes* alone, and *management*, *error*, *mistake*, and *indicator* crossed with *quality*, *laboratory* and *medicine*. The indicators retrieved were organized according to the various laboratory processes. Their expression was standardized in relation to the total activity of each process reported in each paper reviewed. The magnitude of the errors reported was considered to be the current state of the art for the extra-analytical step and was proposed as the quality specification.

Results: Examples of indicators and specifications for the pre-analytical process:

- Analytical request: Error in patient identification (0.08%), request unintelligible (0.1%).
- Sampling: Requested but not collected (7%), redraws (2%).
- Transport and reception of samples: Inadequate transportation conditions (0.005%), hemolyzed sample (0.2%).

Examples of indicators and specifications for the post-analytical process:

- Report validation: Test not performed (1.4%), test performed but not requested (1.1%).
- Intra-laboratory reports: Laboratory reporting errors (0.05%), delivery outside specified time (11%).
- Consulting service: average time to communicate critical values for inpatients (6 min).

Conclusions: These extra-analytical indicators and their specifications, expressed in a standardized manner, constitute a preliminary basis for comparison of individual laboratory performance with the purpose of improving laboratory quality.

Keywords: extra-analytical phase; quality indicator; quality management and quality specifications.

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Introduction

Development of a system for quality management is essential for proper laboratory organization and continuous improvement (1, 2). Clinical laboratory quality systems require vigilance of all the processes involved in the production of results, including the extra-analytical processes, in order to detect errors and undertake remedial actions (3).

Internal quality control (planning to achieve predetermined quality), external quality assessment (laboratory performance evaluation for legal or educational purposes) and, recently, external quality assurance (extra-analytical performance evaluation) of the analytical process are well known and widely used procedures in laboratory medicine (4–6). Regarding the extra-analytical processes, the Clinical Laboratory Improvement Amendments (CLIA) have stated that quality management programs should include evaluation of all the steps comprising the ''total testing process'' (2). Furthermore, the Joint Commission on Accreditation of Healthcare Organizations (JACHO) has suggested that external comparisons with other laboratories should be performed to assess individual laboratory performance and to initiate activity for improvement. This process is known as *benchmarking* (1). Benchmarking systems measure performance of all the processes by comparing the results generated with those of the leading laboratories (7).

Two external quality assessment programs designed by the College of American Pathologists (CAP), Q-Probes founded in 1989 (8) and Q-Tracks founded in 1998 (9), are benchmarking models. These programs deal with pre-analytical, analytical and post-analytical measures for quality improvement in all disciplines of laboratory medicine. Periodic or continuous measuring of key laboratory indicators of quality is done by hundreds of medical laboratories within these programs. A pre-analytical external program has been running in Spain since 1998 (10). Nevertheless, the limits of acceptability for the extra-analytical quality indicators have not as yet been defined.

Table 1 Quality indicators and specifications of the pre-analytical phase.

Quality indicator	Related to	Specification, %
Requests		
Error in patient identification (3)		0.08
Physician identification missing (3)		0.50
Erroneous specification of hospital unit (3)	no. requests	0.60
Request unintelligible (3)		0.10
Correction of errors on ordered test (1)		0.30
Sampling		
Uncollected phlebotomy request-inpatients (11)		7.00
Uncollected phlebotomy request-outpatients (12)		0.30
Tourniquets and holders contaminated with blood (13)		2.50
Needle stick injuries per 100,000 venipunctures (13)	no. requests	0.01
Samples redraw (1)		2.00
Collection of TDM* peak/trough samples at wrong time (14)		24.0
Errors found in identification wristbands (11)		3.00
Transport and receiving samples		
Inadequate sample collection and transport (1, 10)		0.004
Sample rejection (whole blood count) (16)		0.45
Sample rejection (chemistry) (17)		0.35
Sample lost/not received (10, 16, 17)		0.12
Improperly labeled container (16, 17)		0.002
Inadequate collection container (10, 16, 17)		0.015
Sample damaged in transit (16, 1)	no. samples	0.002
Sample clotted-hematology (10, 16)		0.20
Sample clotted-chemistry (17)		0.006
Sample hemolyzed-hematology (10, 16)		0.009
Sample hemolyzed-chemistry (17)		0.20
Laboratory accident (16, 17)		0.004
Insufficient sample volume (10, 16, 17)		0.05
Inadequate ratio volume sample/anticoagulant (10)		0.02

*TDM: therapeutic drug monitoring.

This study was undertaken to identify the quality indicators for the extra-analytical processes required by the clinical laboratory, to standardize their reporting to enable comparisons, and to establish their quality specifications (limits for acceptability). This information is useful for continuous improvement of laboratory services.

Materials and methods

A literature review by Medline® search of medical laboratory quality indicators was performed using the keywords: *Q-Probes* and *Q-Tracks* alone, and *management*, *error*, *mistake*, and *indicator* crossed with *quality*, *laboratory* and *medicine*. The findings from an external quality assessment scheme developed in Spain for the pre-analytical phase were also included.

The quality indicators retrieved were organized according to the various laboratory processes. In order to compare these indicators, the search results were standardized by expressing them in relation to the total activity of each process (number of requests, number of samples, etc.). The papers in which this information was not reported were excluded from the analysis. When more than one article was found describing an indicator, the standardized median value was taken as the specification.

Results

The indicators encountered in the literature search were grouped into one of the three main processes of the overall laboratory activity: pre-analytical, analytical or post-analytical processes. Within each of these groups, several subprocesses were distinguished. Thus, the pre-analytical phase (Table 1) included indicators related with requesting laboratory tests and collecting, transporting and receiving the samples (11–17). Two indicators for the analytical phase were found (Table 2), one concerned with internal control and the other with external control (18). The post-analytical phase (Table 3) included indicators related to validation of the laboratory report, issuing the report, consulting services and employee competence (19–24).

The number of laboratory processes and their volume were recorded, and the indicators retrieved were expressed in percentage relative to the total volume of the activity for each process. This reflects the frequency of errors per process and allows longitudinal and cross-sectional comparisons.

Nine out of the 36 papers reviewed were excluded from this study because the type of error was speci-

Table 2 Quality indicators and specifications of the analytical phase.

Quality indicator	Related to	Specification, %
Unacceptable results in internal controls (18)	no. results	0.07
Unacceptable results in laboratory proficiency testing (18)	no. results	1.4

Table 3 Quality indicators and specifications for the post-analytical phase.

Quality indicator	Related to	Specification
Report validation		
Reports with test requested but not completed (15)		1.4%
Reports with test completed but not requested (15)	no. reports	1.1%
Reports with physician name discrepancies (15)		1.9%
Intra-laboratory reports		
Laboratory reporting errors (1)	no. reports	0.05%
Delivery outside the specified time (16)		11.0%
Consulting service		
Average time to communicate critical values-inpatients (17)		6 min
Average time to communicate critical values-outpatients (17)	no. telephone inquiries	14 min
Telephone inquiries not resolved (18)		21.3
Laboratory computer availability		
Number of downtime episodes (19)	30 days	3 episodes
Cumulative median downtime (19)		4 h
Employee competence		
Non-technical employee failure rate (20)	no. employees	0.9–2.9%
Technical employee failure rate (20)		0.9–6.4%

fied, but the frequency was expressed in relation to the total number of errors, not the total volume per process.

Among a total of 40 quality indicators retrieved, six were found in more than one paper and all of them came from the American and Spanish programs.

- Incidents in sample collection and transport: 0.004% in Spain (10) and 0.005% in the USA (16);
- Sample volume insufficient: 0.06% in Spain (10) and 0.04% in the USA (6, 17);
- Collection container inappropriate: 0.02% in Spain (10) and 0.012% in the USA (16, 17);
- Sample hemolyzed (hematology): 0.21% in Spain (10) and 0.20% in the USA (16);
- Sample lost/not received: 0.23% in Spain (10) and 0.01% in the USA (16, 17);
- Sample clotted (hematology): 0.09% in Spain (10) and 0.30% in the USA (16).

Visual inspection of these results from Spain and the USA showed that the state of the art is similar in the two countries for the first five indicators, whereas for the last two, results differ considerably. No statistical comparison of these results could be done, because the information required for this task was not available in the papers reviewed.

The most frequent errors encountered were inappropriate samples recorded for therapeutic drug monitoring (24%) and unresolved phone calls to the laboratory (21%). The least frequent errors included samples damaged during transport (0.005%) and job-related accidents (0.003%).

Discussion

Quality assurance in the clinical laboratory is a multifaceted task that requires the detection of poor performance in the activity of each process. This is done with the use of indicators (numerical measurement of errors related to the total activity) and the establishment of limits of acceptability for these indicators, known as quality specifications. These are the limits within which the performance of a process can be considered to be satisfactory. When the indicators in any laboratory activity fall outside the acceptance limits, the need to initiate corrective actions in this area is manifested.

The quality indicators for the analytical phase of laboratory activity (imprecision, systematic error and inaccuracy) have been well defined and their specifications are internationally recognized for a large number of biological constituents (25–28). Nevertheless, as suggested by several authors, a large part of the errors occurring in the clinical laboratory may well be concentrated in the phases of laboratory activity that have been less extensively studied, the pre-analytical and post-analytical phases (3, 29, 30). Interestingly, the errors occurring in these extra-analytical phases (e.g., incidents during blood collection or lengthy wait for results) are precisely the problems most evident to those using the laboratory services, the physicians and their patients (2). An in-depth analysis of extra-analytical processes recently undertaken by Stroobants et al. (31) was extremely helpful for the present study in the stratification of laboratory sources of variation.

The articles reviewed in this study mainly measured errors occurring in the extra-analytical laboratory processes. In order to define the quality indicators based on this information, the results reported in these articles first had to be normalized in their expression. This was done by expressing the errors described in each paper in relation to the total activity for each process (number of samples, number of requests, number of reports, etc.), a complicated task because of the heterogeneity of the data retrieved. When more than one article referred to the same error, we calculated the median of the normalized results. This procedure determined the quality indicators and their frequency, and thereby established the state of the art for the laboratory activity.

Defining the state of the art provides the most elemental approach by which laboratories have a means

to compare their performance. This approach has been accepted as one basis to define specifications for analytical quality in the hierarchical model described in the Stockholm Consensus Conference (32) and this concept was used in the present study to define specifications for extra-analytical quality. Other approaches related more to the application of laboratory reports, such as clinical guidelines, have a higher position in the hierarchy; however, we found no information concerning the extra-analytical phase in these approaches when the present study was being conducted.

This study uses the mean of error to activity rate as the quality specification, a value that one might argue is not strictly a benchmark, but rather the average of participant performance. Nevertheless, laboratories concurring in extra-analytical external surveys are the best in their field and therefore can be considered as leaders in a good position to improve quality in laboratory medicine.

The largest number of quality indicators found in the literature search were those related to the pre-analytical process and particularly to sample reception, with specific applications in the areas of hematology and biochemistry. Some data from individual laboratories were available, but those providing the most extensive information were the Q-probe and Q-track surveys from the USA and the Sociedad Española de Bioquímica Clínica y Patología (SEQC) pre-analytical External Quality Control System (EQAS) for Spain, which included results from up to 700 laboratories in some articles. The results obtained from the USA and Spain were similar, once they had been standardized according to the activity of each subprocess (Table 2).

The specifications or limits of acceptability defined by the state of the art showed an extensive spectrum from very high to very low values. Intermediate specifications of 1% to 10% were the most frequent, and this is the range usually obtained for indicators of analytical quality.

The following findings stand out among the results of the study: the very high values for some indicators, such as therapeutic drug monitoring in inappropriate samples (24%), unresolved phone calls to the laboratory (21%) and reports issued outside of the time specified by the clinician (11%). Also the very low values for other indicators, such as samples damaged during transport (0.002%) and job-related accidents (0.003%). We believe that these low values are derived from a lax attitude in the surveillance for these items rather than the fact that the problems in these subprocesses have been resolved.

In the recent Euromedlab 2003 IFCC Congress it was seen that quality indicators for the extra-analytical processes in laboratory medicine are still not widely used (33). As advocated by Young, the importance of extra-analytical quality should be transmitted (34). The present study was undertaken to provide a preliminary practical basis aimed toward defining tools to improve these processes. Further efforts will contribute to establishing quality specifications for extra-analytical processes as effective as those currently applied to the analytical phase.

As a final note, we mention two quality indicators for the analytical phase found in one study reviewed (14). These indicators are related to quality management and are not usually taken advantage of in internal and external control protocols. They simply consist of counting the number of results falling within or outside the assigned values. Thus, they provide an overall picture illustrating *where* the errors occur in the technical processes and are a valuable complement to the information obtained from imprecision, bias and inaccuracy, which reports the *magnitude* of the errors.

Conclusions

Quality indicators show to what degree the laboratory performs well and are always expressed in numerical terms. In the analytical phase of laboratory activity, quality indicators express variability relative to the mean or the concentration, and in the extra-analytical phase these indicators express incidents or problems relative to the volume of activity. If extra-analytical incidents are simply reported in absolute terms without relating to the activity, it is not possible to interpret whether performance is adequate by any of the means for comparison. The use of relative terms additionally allows for detection of tendencies within the laboratory, which promotes the initiation of corrective actions.

Quality specifications were obtained for 40 extra-analytical quality indicators. The frequency of errors expressed by a quality indicator reflects the present situation (state of the art) and can be used as a quality specification.

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