

Review

Risk management in laboratory medicine: quality assurance programs and professional competence

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Abstract

To guarantee excellent performance and service, the process of identifying and treating error risks must be integrated into the total testing process. Quality Assurance Programs (QAPs) represent an important tool that allows us to identify errors and pinpoint any need for further systematic investigations, and to rectify procedures to improve the inputs and processes by which the service is delivered. The models used by the laboratory to assure quality and manage the risk of errors have been modified in line with an approach in which the identification of quality goals and the redefinition of professionals duties and responsibilities are indispensable. Error risk is currently high in some areas of laboratory activity, and QAP is needed now more than ever.

The present paper provides some descriptive examples of an approach that can be followed to manage an External Quality Assessment Scheme (EQAS) and quality indicators (QIs), the main tools used by laboratories to assure the quality of their service, for the prevention of error risk. In particular, we describe the correct approach to choose EQAS, to use information from the EQAS report, to design a QI model, and to analyze any QI data. The examples highlight that any well-designed quality system can be ineffective if it is not managed by highly competent professionals with a deep sense of responsibility.

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Introduction

Laboratory medicine has a strong impact in the prevention of risk to the patient and laboratories must

implement procedures to minimize further risks of errors. Quality Assurance Programs (QAPs) represent an important tool that allows us to identify errors and pinpoint any need for further systematic investigations, and to rectify procedures to improve the inputs and processes by which the service is delivered. These programs must be considered a reactive activity driven by professionals in an environment in which the pressure of cost containment and the accountability principle emphasize the need to assess the appropriateness of healthcare. The use of QAPs drives the search for solutions to deficiencies and requires the implementation of corrective actions for quality improvement. Likewise, the professionals involved have to assume an implicit concern and accountability for quality, and they must also be able to make changes whenever necessary. Laboratory professionals have long carried out activities intrinsic to QAPs, but they are now required to adopt a new approach: their accountability for healthcare provided has greatly increased. However, being accountable does not only mean being held responsible for one’s own actions, but also accepting responsibility, and acknowledging and honoring one’s own duties.

The models used by the laboratory to assure quality and manage the risk of errors have been modified in line with an approach in which the identification of quality goals and the redefinition of the duties and professional responsibilities are indispensable (1–4).

To make any activity effective, it is therefore of utmost importance to identify the goals to achieve and to define the approach that professionals must follow. Quality system models teach us that the different activities of a process transform input into output, which are of added value if the goals meet user requirements and the error risk is under control.

The numerous activities within the total laboratory process can be very complicated, calling for collaboration with other services (suppliers) and clinical departments. Great competence and expertise are needed if the risk of errors is to be minimized.

The mission of the laboratory is to provide information in answer to a clinical question to help clinicians to undertake the right action for each patient. To perform this task effectively, the laboratory must use adequate procedures in agreement with approved quality specifications, as these underpin the correct performance of each activity and the careful checking of every aspect involved in the process (5).

The role of laboratory professionals in reducing error risk is preponderant, especially in the checking phase of the process involving selection of activities

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to monitor; clear definition of the problem; identification of processes affecting any problems; listing the steps in the process; identifying possible causes of any problem; collecting and analyzing data related to any problem; identifying root causes of any problem; establishing criteria for selecting a solution; generating potential solutions for the root causes; implementing the solution chosen; evaluating results; collection and analysis of data on the solution; identifying systemic changes and training needs for full implementation; adopting the solution; planning monitoring of the solution; and searching for other improvement opportunities (6–8).

Error risk is currently high in some areas of laboratory activity and QAPs are needed now more than ever. In particular, care should be taken to supply the following:

- *Analytical result*, guaranteeing its correctness (imprecision and bias) and its clinical significance when compared with reference range/decisional levels (RL);
- *Clinical advice* conducive to choosing more appropriate testing for the clinical question (diagnosis, prognosis, therapeutic treatment, monitoring) and for the interpretation of results;
- *Clinical audit* with diagnostic protocols and scientific recommendations to improve diagnostic algorithms and communication flow, to optimize the times to operate on behalf of the patient, thus safeguarding the clinical outcome;
- Planning and carrying out of *education and continuous training programs*, not only for laboratory staff, but also for professionals outside the laboratory whose activities impact on the laboratory process: formulation of the request in relation to the clinical question; taking and treating of blood samples before they are sent to the laboratory (from clinical departments, other laboratories, etc.); and the use and interpretation of laboratory results.

External Quality Assessment Schemes (EQAS) and quality indicators (QIs) are the main tools used by laboratories to assure the quality of their service.

External Quality Assessment Scheme

Adequately designed and managed EQAS allow laboratories to evaluate and monitor the performance and quality of their analytical data. Numerous guidelines published by international organizations (IFCC, NCCLS, CLSI, ILAC, etc.) have defined quality specifications to use and have recommended that data from EQA reports should also be used. Participation in an EQAS does not guarantee the reliability of laboratory analytical results, since their effectiveness closely depends on the commitment of laboratory specialists to accountability and competence. Quality can be improved only by accurately identifying errors and making appropriate changes to the procedures and processes involved.

For the EQAS to be an effective tool in quality assurance, laboratory professionals must be committed to:

- Choosing EQAS that can provide consistent information;
- Using the information from EQAS reports competently.

Choice of EQAS

Unlike elsewhere, in Italy EQAS can be managed by different bodies: regions, professional or private bodies and/or manufacturers of diagnostic systems. Consequently, several schemes managed by different bodies are available for the same discipline. In the absence of any regional obligation, the laboratory can choose its EQAS on the basis of: quality specifications; granting of accreditation or certification; its number of analytical tests; and the costs and availability of other services (professional advice, training).

The choice of EQAS is of crucial importance because EQAS designed according to inadequate criteria could provide incorrect information. EQAS information is used by the laboratory to verify its operating procedures and to carry out, where needed, appropriate corrective actions. Unacceptable performance should encourage the laboratory specialist to investigate the cause and to undertake appropriate corrective actions to eliminate the problems and prevent repetition. It may be necessary to modify the procedures used and to make decisions regarding patient results already issued and to manage the related consequences. Therefore, in the logic of risk prevention, the laboratory must carefully choose the EQAS in which it plans to participate after thoroughly analyzing the quality specifications declared by the scheme organizers. The laboratory must pay particular attention to:

- Features of control samples: origin (human or not), commutability, number of analytes analyzed, range of concentrations (clinically relevant), number and frequency of distribution;
- Criteria for data processing: parametric or non-parametric method; grouping of results (overall, method or diagnostic system-related); minimum number of results for processing; criteria for excluding outlier results;
- Criteria used for assessment of analytical performance (target value and acceptability limits);
- Availability of technical advice and assistance (interpretation of EQA report, judgement of performance, analytical problems, informative aspects);
- Opportunities for participants to comment on and contribute to the schemes.

However, because of the economic pressures that healthcare systems are subject to, the choice made is often based on costs rather than on the quality specifications, with the risk that an EQAS does not comply with accreditation/certification standard requirements or scientific recommendations, thus providing misleading information.

Laboratory professionals must be able to evaluate criteria adopted in the EQAS design, manage EQA results, and choose the most reliable scheme available. We provide here some examples showing the different aspects that professionals must take into consideration in order to make the right choice.

Example 1 When there is no standardization between diagnostic systems (as occurs when a new test is introduced) and participant results are processed as a homogeneous method group, an EQA report could provide information that does not reflect the real analytical performance of the laboratory and of its diagnostic systems. In this case the correct procedure should be performance assessment with reference to a consensus value calculated from results for the same diagnostic system. This guarantees correct assessment of analytical performance (diagnostic system, instrument, operating procedures, etc.), highlights the standardization problem and encourages improvement achieved in collaboration with diagnostic system manufacturers.

Incorrect information can cause the laboratory to modify its operating procedure to align its result to an incorrect consensus value. Table 1 shows an EQA report for the Scheme for Biochemical Markers of Myocardial Damage of the Center of Biomedical Research (CRB), which highlights the lack of standardization between diagnostic systems for troponin I for a sample distributed in the 2003 cycle. Table 2 shows the results obtained in a sample distributed in a 2006 cycle, indicating that better standardization was achieved thanks to action taken by manufacturers, EQAS coordinators and laboratories.

Example 2 In some EQAS the laboratory submits its results via a web site that immediately displays an assessment of its results (median, standard deviation, CV%, histogram of data distribution, etc.). In these schemes the analysis of results by EQAS coordinators

to highlight and correct obvious mistakes made by the laboratory (random and transcription errors, incorrect units, results following inversion of survey samples, etc.) before processing is not contemplated. Gross errors can invalidate the correctness of the statistical data (consensus value) and consequently the information provided in an EQA report (judgement on performance). Any advantage of the immediate return of EQA information may therefore be wiped out by incorrect information.

Example 3 The use of information from Interlab Programs (IPs) [programs of inter-laboratory comparison in which the results of internal quality control (IQC) from different laboratories are processed and assessed together] rather than that from EQAS is risky for the laboratory in view of their differences in control materials, criteria for the checking and treatment of results, consulting services and educational aspects. The material distributed in an EQAS must comply with the quality specifications required: it must have an appropriate matrix and resemble as closely as possible the relevant clinical material; show no effects on method-related bias; have unknown value; have different concentrations in different surveys; and be different from IQC material.

Since the main aim of EQAS is to verify the reliability of laboratory performance with regard to patient results, EQA samples must be as similar as possible to real clinical samples and, above all, behave in the same way as clinical samples in measuring systems. The control materials used in IPs do not always present these features, and the concentration values of IQC material are known and are the same all the time. For statistical evaluation, EQA organizers guarantee homogeneous criteria for data treatment and processing (i.e., identification and elimination of outlier values and obvious mistakes), and they are managed by professionals without any conflict of interest. In processing of IP results, usually no provision is made

Table 1 Performances of diagnostic systems for troponin I used by laboratories participating in an EQAS for Biochemical Markers of Myocardial Damage.

Diagnostic system	Number	Median, $\mu\text{g/L}$	SD, $\mu\text{g/L}$	CV, %
Abbott Axsym	15	308.50	46.78	15.2
Beckman Access AccuTnl	21	5.10	0.62	12.1
Dade/Behring Dimension	30	29.48	2.90	9.8
Dade/Behring Stratus CS	10	25.40	2.68	10.5
Biosite Triage	6	42.10	3.63	8.6

Results obtained in a sample of the third survey of the 2003 cycle.

Table 2 Performances of diagnostic systems for troponin I used by laboratories participating in an EQAS for Biochemical Markers of Myocardial Damage.

Diagnostic system	Number	Median, $\mu\text{g/L}$	SD, $\mu\text{g/L}$	CV, %
Abbott Axsym	27	5.68	0.73	12.79
Beckman Access AccuTnl	35	3.59	0.42	11.77
Dade/Behring Dimension	52	3.34	0.28	8.45
Dade/Behring Stratus CS	15	4.50	0.42	9.39
Biosite Triage	4	7.57	1.46	19.34

Results obtained in a sample of the sixth survey of the 2006 cycle.

for previous analysis of data, with the processing phase occurring immediately after the input of results and the display of statistical data. The laboratory can verify the results provided by other participants and the correctness of its results before inputting its results. Moreover, IP management is traced back to the manufacturer, with a possible commercial interest.

No continuous advisory service to help participants using data and resolving unsatisfactory performances is provided in IP. However, this activity is of crucial importance because communication and comparison regarding small laboratory problems can highlight wider problems involving several laboratories, problems that can be resolved through coordination between participating laboratories, EQA organizers and diagnostic systems manufacturers.

The EQAS report provides information that is a continuous stimulus to improve the performance of laboratories, in particular: judgement of performance; advice on resolving unsatisfactory performance; cooperation with diagnostic system manufacturers to promote standardization; information, education and training.

Even if an IP is well designed, it cannot replace the EQAS. To adequately monitor its own performance and prevent error risk, the laboratory must reflect on the opportunity to use a procedure that addresses:

- Immediate identification of the control sample with known and constant values over time;
- Use of the same control samples to accept or reject a single analytical run and to assess the quality of its analytical performance;
- Assessment of diagnostic system performance using control samples that do not comply with accepted quality specifications;

- Assessment of different state-of-the-art of diagnostic systems using control samples supplied by any rival manufacturer (conflict of interest).

The main differences between EQAS and IPs are summarized in Table 3.

Use of EQAS information

Participation in an EQAS does not guarantee effective laboratory performance (9). Laboratory professionals should have an active and accountable role and use information provided in EQAS reports, such as those of CRB, which address:

- Assessment of analytical performance expressed as judgement (excellent, good, acceptable, unacceptable) and communication of persistent poor performance;
- Assessment of performance of diagnostic systems used in laboratories, such as median/medium, standard deviation (SD), inter-laboratory variability (CV%). Overall, method and diagnostic system-related data are processed using a non-parametric method, on the basis of constituent features;
- Visualization of a diagram showing each participant the results obtained on a control sample against its own RL and against those of other participants.

On receiving the above information, laboratory staff must check the judgement obtained (excellent, good, acceptable, unacceptable) and also verify the performance trend over time. If an *excellent* performance obtained in a previous survey becomes *acceptable*, the analytical system may be drifting out of control, calling for careful verification and close monitoring. Likewise, repeatedly *unacceptable* performances cannot be attributed to random error, although their

Table 3 Main differences between EQAS and IPs.

	EQA Program	Interlab
Control samples	Different from IQC and in accordance with quality specifications	IQC sample
Sample	Desirable treatment as patient sample	Identifiable immediately
Manufacturer of sample	Not traceable and, if possible, independent	Traceable and conflict of interest
Concentration samples	Unknown and different in the time	Known and the same all the time
Data treatment	Same among participants	Different among participants; selection of results to communicate on the basis of different laboratory criteria
Statistical processing	Entrusted to laboratory professionals	Entrusted to manufacturers (conflict of interest)
Report information	Statistical data and assessment of analytical performance	Only statistical data
Improvement stimulus	High: communication of unsatisfactory performance; advice to resolve problems; promotion of work groups to carry out improvement projects	None
Education and training	Available and continuous	Unavailable
Advisory service to laboratories	Available and continuous	Unavailable
Advisory service to manufacturers	Available and continuous	Unavailable
Attention to pre-analytical phase	Possibility of specific surveys	None
Attention to post-analytical phase	Possibility of specific surveys	None
Assessment of clinical cases	Possibility of specific surveys	None

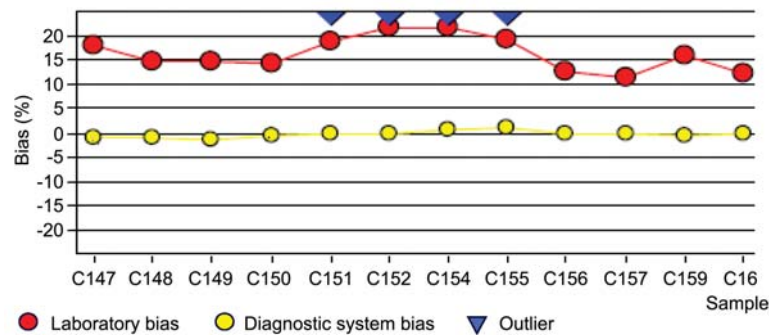


Figure 1 Magnesium: performance of a laboratory obtained in an EQA cycle (12 control samples).

cause may be difficult to identify and the solution to the problem may be complex. The competency, accountability and degree of involvement of laboratory staff in analyzing, researching and resolving problems are the hallmark of the quality and reliability of a laboratory. Some examples of unacceptable performances and related corrective actions are reported.

Example 1 Figure 1 reports the performance obtained by a laboratory in an EQA cycle for magnesium. The laboratory concerned obtained an unacceptable performance in all six surveys of the EQAS cycle. Despite continuous searching, the laboratory did not identify the root cause and could therefore not undertake any corrective action. Its data analysis appeared unproblematic: IQC and calibration procedures were correct, instrument maintenance and examination procedures were carried out according to the manufacturer's instructions, the performance of the diagnostic system was satisfactory (Figure 1 highlights that the percentage bias was approx. zero in all surveys), and the EQAS was reliable, granting Clinical Pathology UK accreditation.

Staff commitment and confidence in information provided by EQAS data resolved the problem: the staff continued their search for causes by carrying out further trials. In particular, they:

- Requested further control samples (those already tested had provided unacceptable performance) from the EQAS coordinator;
- Tested the control samples several times in different ways: all constituents included in EQAS, or only magnesium;
- Analyzed the new data obtained.

The data analysis highlighted the following:

- The results were the same when the staff tested the control samples for all constituents required by EQAS in the same sequence;
- The result for magnesium was correct when the staff tested the control samples for all constituents required by EQAS in different sequences;
- The result for magnesium was correct when the staff tested only for this component in control samples.

The possible causes were interference by the reagent used to test constituents examined prior to magnesium and insufficient cleaning of needles. On investigating these, it was found that every time that magnesium was tested after creatine phosphokinase (CK), higher concentration values were obtained. This can be explained by the fact that the CK reagent contains magnesium ions, which interferes with the magnesium test because of insufficient instrument cleaning. To resolve this problem, technical specialists from the manufacturer implemented new and further cleaning with sodium hypochlorite between different constituent tests. The corrective action was effective, and in the subsequent EQAS surveys the laboratory performances were satisfactory (Figure 2).

EQAS reports, which provide statistical data on the performance of diagnostic systems used by laboratories, allow laboratory staff to analyze the state of the art and the performance of their diagnostic system compared to those of other laboratories, thus helping them to choose a new system or to change any unsatisfactory diagnostic system.

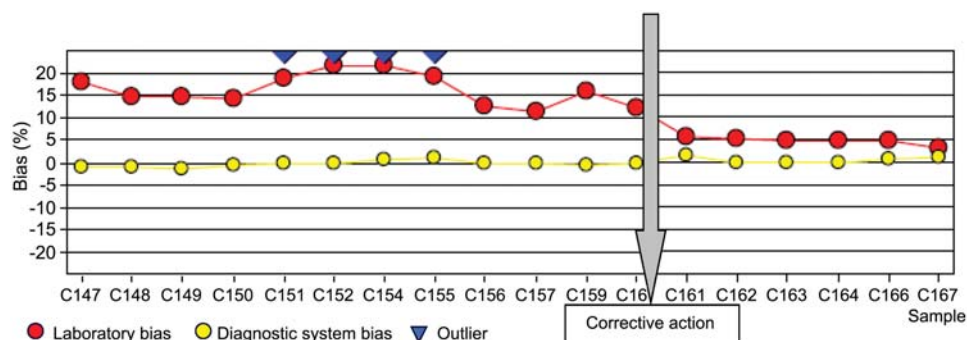


Figure 2 Magnesium: performance of a laboratory obtained in an EQA cycle before and after the corrective action was undertaken.

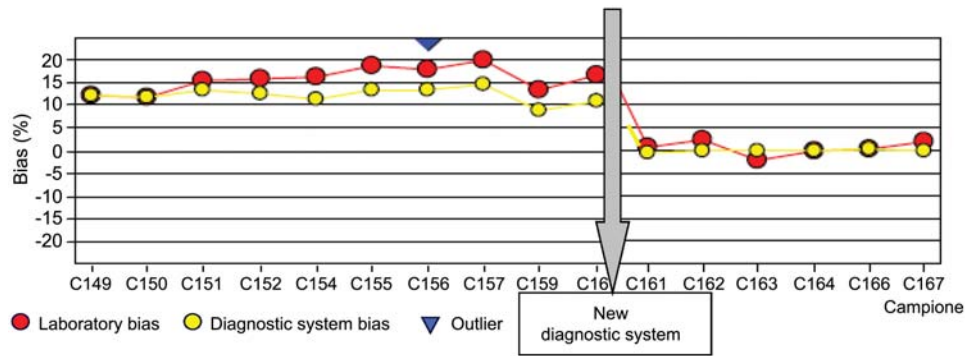


Figure 3 GGT: performance of a laboratory and its diagnostic system before and after the change in the diagnostic system.

Example 2 Figure 3 shows the laboratory performance for γ -glutamyltransferase (GGT): for the first 10 samples, performances are unsatisfactory. The laboratory results were aligned with results from other laboratories using the same diagnostic system. However, the diagnostic system was not aligned with the other diagnostic systems using the same method. Unsatisfactory laboratory performance therefore depended on a lack of standardization in the diagnostic system used. The problem was resolved by changing the diagnostic system and subsequent EQA surveys showed that the laboratory had achieved satisfactory performances.

Some EQAS provide information on the RL used by participating laboratories, thus enabling them to verify the appropriateness of their RL. The laboratory can compare its own RL with those of laboratories using the same, or different, diagnostic systems. When a laboratory highlights a lack of agreement between its data (results and/or RL, clinical significance) and data from other laboratories, it must first verify that all data sent to EQAS organizers are correct (diagnostic system used, RL values, measurement units, results, etc.). For example, a laboratory may change its analytical system, but fail to review the RL applied, giving rise to results with incorrect clinical significance.

When RLs agree with those of laboratories using the same diagnostic system but are not in line with those for laboratories using different diagnostic systems, although scientific recommendations suggest using the same RL, their origin must be verified. This step should be taken when the laboratory uses the RL reported in manufacturer data sheets without previously verifying their suitability.

The use of an inappropriate RL can harm patients, leading, for example, to incorrect diagnosis and therapy. EQAS reports providing information on this aspect are extremely useful in preventing and monitoring error risk. Figure 4 provides an example of an RL without standardization used by laboratories for troponin I.

The competence and accountability of laboratory staff, the promotion of work groups to study the causes of variability, and the involvement of manufacturers of diagnostic systems and EQA organizers can be effective tools in maximizing agreement and promoting the standardization of RLs.

Quality indicators

The use of QIs in QAPs results is useful in monitoring the activities and processes that must be corrected or improved upon. QIs, which can measure the frequency of an event and indicate the quality of an activity, do not provide answers but indicate potential problems that need to be resolved.

If adequately designed, the QIs model allows for scoring of defined goals, indicates the corrective actions required, and plans for improvement (10).

To design a QIs model, it is necessary to:

- Identify the activities and processes that are crucial to guaranteeing the service quality;
- Set goals to achieve for each activity and process identified;
- Define the data for selection, and the times and methods for data collection;
- Establish times for the analysis of data collected.

The number and type of QIs must be estimated on the basis of the complexity and size of the organization and the mission and goals of the service. The effectiveness of models is closely tied to the goals chosen and the ability to analyze collected data and take the right decisions. The effectiveness of a QIs model must be periodically verified. If goals are not achieved or the indicators are not meaningful, they can be replaced, integrated or eliminated; if necessary, new goals can be identified.

QIs can be an indispensable QAP tool, allowing the measurement, documentation and improvement of processes. The following are examples of the use of QIs in monitoring important aspects of laboratory activity.

Example 1: advisory service

The advisory service provided by laboratory specialists is important in several different situations and steps of the total testing process, and calls for specific knowledge and competence. In particular, laboratory specialists interact with:

- Clinicians, providing advice and education on indications for the most appropriate test to answer a given clinical question, on interpreting results by

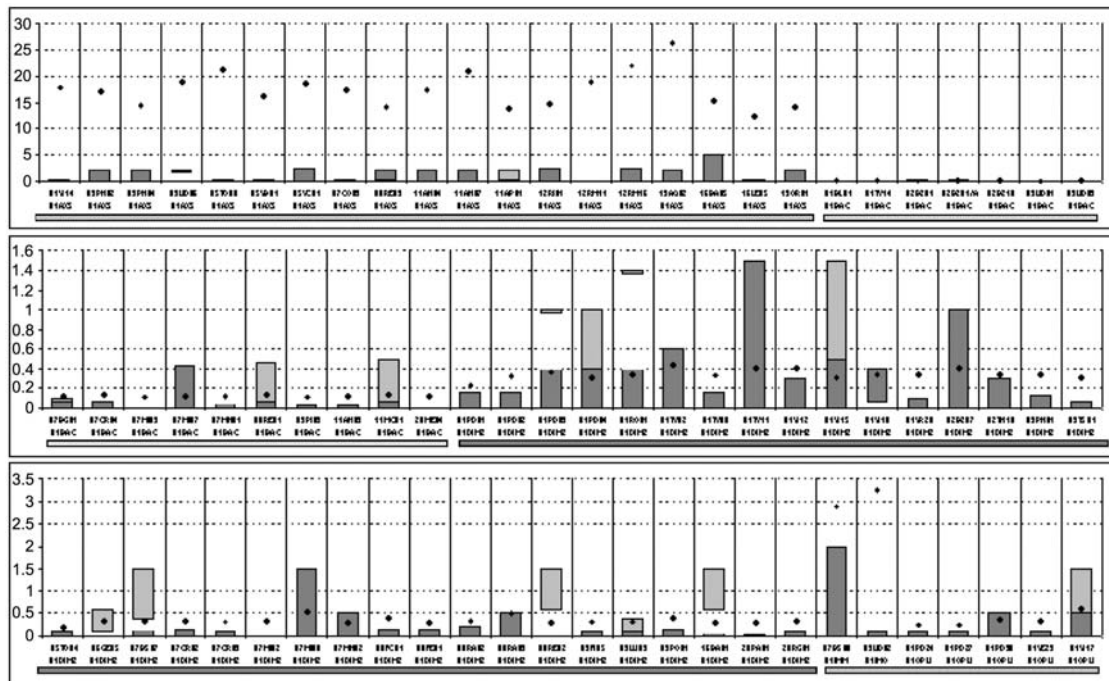


Figure 4 Troponin I: reference range (dark gray rectangle), decisional levels (clear gray rectangle) and result (black point) reported by each laboratory participating in EQAS for Biochemical Markers of Myocardial Damage. The horizontal lines differentiate the several diagnostic systems used. Abscissa: laboratory code and method code; ordinate: concentration values ($\mu\text{g/L}$).

formulating interpretative comments, and making suggestions for further investigations (11);

- Manufacturers of diagnostic systems, assessing new methodologies and technologies;
- The scientific environment, collaborating to issue scientific recommendations.

The evaluation and monitoring of the above activities are of paramount importance because incorrect information can have a negative impact on patient health. Laboratory information is effective when it answers clinical questions, and the clinician undertakes the right choice for the patient. This activity calls for sound specialized competence.

Table 4 reports on a QIs and its application that can be used to monitor the ability of laboratory professionals to help clinicians to request appropriate tests.

The results of a trial conducted by CRB demonstrated that few clinical requests specified the clinical question: an analysis of 5000 clinical requests from five laboratories in the Veneto Region demonstrated that in approximately 76% of cases, no clinical question was specified, whereas more frequently clinicians contacted the laboratory for suggestions. This stresses the need to improve this aspect. Laboratory professionals can organize meetings to inform clinicians about better tests by sending them informative brochures, divulging scientific recommendations, and by persuading them to indicate the clinical question in their requests. In fact, the possibility to evaluate the appropriateness of required tests allows the activation of diagnostic algorithms by laboratory professionals, thus ensuring that the patient receives timely and effective treatment.

Likewise, additional brief interpretative comments on the patient's result report and/or the provision of advice on any action that should be undertaken has an impact on the patient. Laboratory staff providing interpretative comments must therefore have the appropriate expertise: inappropriate or misleading comments can have a negative impact on patient outcome. It is therefore necessary to verify the efficacy of the interpretation provided by laboratory staff. The use of an indicator can highlight education and training needs of laboratory staff and the effectiveness of communication between the laboratory and clinical departments. Table 4 provides an example of possible QIs.

Some EQAS promote specific surveys to verify the consensus between laboratories for interpretative comments added to medical reports. The results demonstrate that there is a general consensus between participants regarding syndromes suggested by the interpretation of results (12, 13). Furthermore, most participants also agreed on further investigations to be carried out for several different diseases.

Example 2: continual professional development

Each activity, however well designed, is effective only if the staff are qualified and responsible. Education, training and continual professional development are crucial to meet this need. When managing this aspect, it is very difficult to ascertain training needs and to assess the efficacy of any training provided. Training needs may be identified via several activities, including: analysis of errors; audit of user satisfaction; implementation of new methodologies/technologies;

Table 4 Examples of possible quality indicators to apply in order to monitor some aspects of laboratory process.

Quality Indicator	Data to collect	Steps	Times	Goals	Responsibility
Evaluation of the appropriateness of the clinical request from general practitioner	Number of appropriate tests (with respect to clinical question); number of tests in requests that report clinical question (percentage)	<ul style="list-style-type: none"> a) Select requests with clinical question and count the required tests (<i>total no. of tests</i>) b) Analyze clinical question, identify the appropriate tests and count the appropriate tests (<i>no. of appropriate tests</i>) c) Analysis of data collected with respect to defined goals d) Possible action (corrective or improvement) 	A week per month (first week) for 3 months (January, March, May)	Action goal: 40% Improvement goal: 60%	Nurses, data collection medical staff, data analysis
Evaluation of the effectiveness of interpretative comments	Number of interpretative comments in medical report that impacted positively on patient outcome (percentage)	<ul style="list-style-type: none"> a) Identify a clinical department to collaborate with and verify its availability b) Collect, sort and count the actions undertaken consequently to interpretative comments provided (in terms of appropriateness and times) c) Evaluate patient outcome d) Count positive and negative outcomes e) Analysis of data collected in comparison with defined goals f) Possible corrective actions 	Every day per month for 3 months in a year	Goal: 100%	Laboratory medical staff steps a), b), d-f), department clinicians steps c) and f)
Evaluation of the effectiveness of clinical audit	Number of guidelines issued in cooperation with clinicians per year	<ul style="list-style-type: none"> a) Selection of a topic (processes for which the appropriateness is uncertain) b) Identification of multidisciplinary team c) Identification of the scope of guidelines d) Collection of evidence, including existing guidelines e) Formulation of guidelines f) Pilot testing and review g) Presentation and dissemination h) Monitoring, evaluation, review i) Counting of the number of guidelines/recommendations issued with the cooperation, at least, of a member of laboratory staff 	Once a year	Goal: 1	Steps a-h) laboratory specialists, department clinicians, general practitioners, step i) quality manager of the laboratory

Table 5 Percentage of errors for input of patient data and tests required from 2001 to 2006.

Input errors, %	Year					
	2001	2002	2003	2004	2005	2006
Patient data	0.29	0.14	0	0	0	0.01
Tests	0.78	0.61	0.87	1.3	2.19	1.08
Other	0.04	0.19	0.46	0	0.26	0.1
Total	1.14	0.95	1.18	1.3	2.45	1.2

clinician requests; organizational changes; analysis of complaints; and improvement projects. The effectiveness of training is closely linked to criteria for planning and delivery (competence of speakers; relevance of topics; adequate time; organizing ability; etc.) and to fulfillment of needs.

Table 5 reports data obtained on using a QI for the pre-analytical phase, pointing out training needs based on an evaluation of errors due to the input of clinical requests for ambulatory patients. In particular, information on errors in the input of patient data and tests requested (missing; added; misinterpreted) was obtained by comparing the clinical request with the computer-generated patient sheet. Moreover, problems concerning samples (incorrect container, insufficient quantity, wrong transport, missing, coagulated) requiring patient recall were also verified. Data analysis evidenced an increase in error rates in the year 2005, caused by hiring new staff that, notwithstanding pre-employment training, encountered difficulty in interpreting some tests requested, particularly when hand-written. To eliminate this cause of error, additional training was organized; data collected in 2006 showed a decrease in error rates. These results demonstrate that the continuous checking and monitoring of operating procedures using suitable indicators allows errors to be identified and appropriate corrective measures to be taken, thus assuring good laboratory practice.

Specific EQA surveys assess aspects of the laboratory process calling for highly competent staff and thus allow identification of the necessity for further training. For example, an EQAS "Urinalysis Performance" was managed by CRB, which sent urine samples to participants for physical and chemical examinations, and some photographs for microscopic examination to identify the type of cells, casts, crystals, and other components (bacteria, mucus) that can be present in urine.

The answers obtained were assessed by a specialized clinician (nephrologist), who also provided clinical information and some scientific references for each clinical case. Some elements of sediment are re-proposed with different photographs. The laboratory was thus not only informed of its own performance, but could also measure, by analyzing performances obtained in repeated surveys, the effectiveness of the corrective actions undertaken to resolve unsatisfactory performance.

Example 3: clinical audit

The clinical audit is the main activity employed in risk management for the prevention and resolution of crit-

ical aspects (14). Clinical audits prevent errors by analyzing processes involving different professionals from laboratories and clinical departments. Cooperation and scientific comparison between professionals from different disciplines play a crucial role in achieving a high-quality service.

The main aim of the clinical audit is to prevent all conditions that can favor an adverse event and to improve laboratory information to benefit patient outcome. The development of multi-disciplinary scientific recommendations and guidelines are examples of clinical audit activities.

Data showing user requirements, methodological and clinical needs, and adverse events are the input for preparing a clinical audit; improvement plans and priorities for action are the output. Professionals, who play a crucial role, are indispensable in promoting new methodologies and advocating their correct application to satisfy clinical requirements; they are, moreover, responsible for critically evaluating, adapting, updating and piloting externally produced test guidelines and translating them into practical recommendations. The publication of guidelines does not directly translate into successful implementation. A QI to monitor this activity is shown in Table 4.

Conclusions

The attainment of quality goals in a clinical laboratory requires a QAP involving virtually everything and everybody in the clinical laboratory. An error in any step during reception, processing and analysis of a sample and the reporting of a laboratory test result invalidates the quality of analysis and causes the laboratory to fall short of its quality goals.

To guarantee excellent performance and service, the process of identifying and treating error risk must be integrated into the activity of the laboratory as a part of both the quality system and any accreditation/certification procedures. Unsatisfactory clinical performances must be promptly identified to guarantee patients that quality improvement processes are carried out effectively and are integrated with the quality programs of the host system. Concepts concerning good practice and innovations must be systematically divulged and applied.

All the information on using and following procedures in accordance with professional quality criteria is available in the current scientific literature. Since no process can ever be entirely free of error risk, a QAP is necessary for the identification, resolution and prevention of errors. A particularly critical element in

QAP is the link between the identification of a problem and the implementation of the most appropriate solution to that problem.

The present paper has provided some descriptive examples of an approach that can be followed to manage EQAS and QIs, which are important QAP tools for the prevention of error risk. The examples highlight that any well-designed quality system can be ineffective if it is not managed by highly competent professionals with a deep sense of responsibility. Adequate QAPs can, moreover, encourage staff to cooperate with clinicians to maximize diagnostic reliability and safeguard the monitoring and treatment of patients.

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