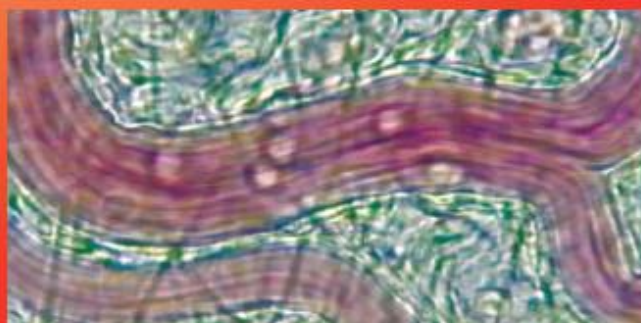


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*Bulletin of the Portuguese Society of Hemorheology and Microcirculation*

# BOLETIM

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**QUALITY IN THE CLINICAL LABORATORY – FROM STANDARDS TO AUDITS****QUALIDADE NO LABORATÓRIO CLÍNICO – DOS PADRÕES ÀS AUDITORIAS***Maria Manuel Campos<sup>1</sup>***ABSTRACT**

This article supports data, insights and possible ways to assess and improve quality in clinical laboratories. They are numbered as follows:

- I – Introduction – risk management and its impact
- II – Quality, benchmarking, standards, certification and accreditation
- III – Laboratory quality – assessment and improvement
- IV – Proactive approaches and implementation of a quality program.

The quality, effectiveness, excellence, satisfaction, improvement and accountability of health services have great impact.

Endeavour and empowerment of people engaged in work organizations inspire the ownership and good outcomes are achieved when healthcare corresponds to needs of patients, relatives and providers.

**Keywords:** Quality, laboratory, risk management, standards, audits

**RESUMO**

Este artigo apresenta informação, progressos e atitudes exequíveis para avaliar e melhorar a qualidade nos laboratórios clínicos. O conteúdo está ordenado da seguinte forma:

- I – Introdução – Gestão do risco e seu impacto
- II – Qualidade, *benchmarking*, padrões, certificação e acreditação
- III – Qualidade no laboratório – Avaliação e melhoria
- IV – Abordagens pró-ativas e implementação de um programa de qualidade.

A qualidade, efetividade, excelência, satisfação, melhoria e fiabilidade dos serviços de saúde evidenciam grande impacto.

O empenho e capacitação dos colaboradores nas organizações inspiram sentimentos de pertença e bons resultados são obtidos, quando os cuidados de saúde correspondem às necessidades dos doentes, familiares e cuidadores.

**Palavras-chave:** Qualidade, laboratório, gestão do risco, padrões, auditorias

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## INTRODUCTION – RISK MANAGEMENT AND ITS IMPACT

Care Pathways determine a multidisciplinary practice defined locally, following the guidelines or available evidence for specific groups of patients or customers. These paths are like standard operating procedures (SOPs) in action and integrate the clinical process allowing a complete evaluation of results; they could identify bottlenecks<sup>1</sup>.

The planning is improved with measurable quality targets, better communication, lower internal variations and research activities<sup>1</sup>.

### Four elements of quality proposed by the World Health Organization (WHO):

- Professionalization (technical quality)
- Efficiency of resources use
- Risk management (including risks with the delivered service)
- Satisfaction with the service received<sup>1,2,3</sup>.

An organization comprises the instrumental side (hardware) that is represented by planning and control, and the behavior side (software) that is expressed by communication and development<sup>4,5</sup>. Assessment, communication and risk management make it possible to analyze near misses and error trajectory and develop some preventive and corrective actions<sup>4,5,6</sup>.

### Some definitions mean important feedbacks in daily practice:

- 1) **Effectiveness** is the extent to which planned outcomes, goals, or objectives are achieved as a result of an activity, strategy, intervention or initiative intended to attain the desired effect, under ordinary circumstances. Being effective means achieving organizational goals<sup>1,3</sup>.
- 2) **Efficiency** is the ratio of the output to the inputs of any system. An efficient system or person is one that achieves higher levels of performance (outcome, output) relative to the inputs (resources, time, money) consumed<sup>1,3</sup>.
- 3) **Efficacy** is the extent to which a specific intervention, procedure, or service produce the de-

sired effect, under ideal conditions (controlled environment)<sup>1,3</sup>.

- 4) **Levels of use in health system:** patients/ customers, health professionals, provider institutions, health care purchasers and government or policy makers – an individual basis is followed by self-regulation and external regulation as well as a national framework which produce strategies for coordination of continuous high standard services with transparency, accountability, equity and effectiveness<sup>1,3</sup>.
- 5) **Risk:** the combination of severity and occurrence probability of a harmful event. The main risk and result determinants are complexity (constant) and performance (variable). For good risk management it is crucial to identify and analyze the root and trajectory of the problem as well as evaluate, control and prevent<sup>4,6,7</sup>.
- 6) **Error:** a deviation from truth, accuracy or precision; a failure of a planned action; the use of a wrong plan to achieve an aim<sup>5,6</sup>.
- 7) **Near-miss:** an unplanned event that did not result in injury, illness or damage, but had the potential for such. This situation can be individual (human causes), technical (equipment, software) and organizational (policies and procedures). Multiplicative effect on the dynamics of these events (small changes can arouse big effects)<sup>5,6</sup>.

The error trajectory analysis is essentially retroactive (Root Cause Analysis)<sup>5,6</sup>.

When we define the most important points in the Error Management we must not forget risk stratification (scores) and periodic control of results by audits, records of nonconformities, notification of adverse events/ near misses and of course a redefinition of strategies, a compliance to guidelines, safe documentation and some recovery mechanisms<sup>8</sup>.

The errors may be by commission, omission, performance failure or mistakes made in either the application of rules or their total disregard<sup>5</sup>. The detection and management of errors include variables, compensation effects, feedback analysis and the implementation of preventive and corrective measures. It is crucial to consider the multiple actions of these events on work dynamics: small variations may cause disproportionate effects<sup>5,7</sup>.

Table 1. Models and tools in quality and risk management<sup>6,11</sup>

Statistical Process Control	Easy in routine application for the determination of stability and predictability of a process
Zero Failure Principle	The goal is to minimize undesirable failures and accidents
Design of Experiment	Cause-and-effect relationship (managing inputs and optimizing outputs)
Fault Tree Analysis	Deductive analysis (diagram to identify failure causes)
Failure Mode and Effect Analysis	Potential failure impact; detection and prevention measures; responsibility and scheduled improvement
Progressive Worst Case Scenario Analysis	Impact through extreme conditions
Quality Function Deployment	Emphasis to customer satisfaction and improvement of product design – “Positive Quality”
Hazard Analysis and Critical Control Points	Threat analysis, critical point control and monitoring, preventive and corrective actions, and checking efficiency and system records
LEAN	Emphasis to speed, efficiency and removing waste (identify customers, map the value stream, create flow, establish pull approach and seek continuous improvement)
Six Sigma	Emphasis to precision and accuracy (define, measure, analyze, improve and control)

**Proactive Risk Management** comprises innovation and change from a functional point of view and is predictive, measurable and controls the risk. By conceptual anticipation of eventual problems the root causes of the risk can be identified not just their effects or symptoms. It is very important to establish risk priorities without creating errors. The process of workflow management has a modeling phase (build-time) with the common objective of compliance and improvement, and an implementation or instance phase (run-time) represented by execution/performance<sup>9</sup>.

Staff is a key aspect in any organizational structure and it is important to assure a correct number of qualified workers, training and description of functions, responsibilities and position in the service organogram. These premises must be in strict relationship with the SOPs for an efficient and safe job performance and for protection of patients<sup>10</sup>. There are some models and tools (retroactive and proactive) we can use in risk management quality systems and main features are presented in the Table 1<sup>5,6,11</sup>.

#### QUALITY, BENCHMARKING, STANDARDS, CERTIFICATION AND ACCREDITATION

**Quality Control** is a process within the Quality Assurance Program. The aim is to collect evidence

that the desired level of quality is achieved, and the process itself has no impact on the product quality. Internal and External Assessments provide data to analysis, correction and improvement<sup>3,6,12</sup>.

**Quality Assurance** is the backbone of the Laboratory Quality System. It includes Quality Control, Proficiency Testing and Comparability<sup>3,13</sup>.

**Quality Management System (QMS)** works on the organizational level to implement an overall quality policy<sup>3,13</sup>. It refers to the organizational resources, processes and procedures to implement quality management, which is broader than both quality assurance and quality control (Figure 1)<sup>6,10</sup>.

**Quality System** enables standardization to best practice. Quality is the ability to consistently provide laboratory results efficiently and effectively. We should adopt a QMS model to guide our design and implementation. Time estimated to a full achievement is around five years<sup>12,13</sup>.

**Benchmarking** can be defined as a continuous and systematic process of evaluation of products, services, organization and work methodologies, as exemplified and recognized by the best practices. The goal is to compare performance and identify opportunities for improvement – a bypath for excellence<sup>1,3,14,15</sup>.

**Certification** is a procedure by which an independent body gives written assurance that a product, process or service conforms to specific requirements<sup>12,13,16</sup>.

Figure 1. Policies, Good Practices, Risk and Quality Management<sup>6,10</sup>

**Accreditation** is a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks; it includes an evaluation of competency<sup>12,13,16,1</sup>.

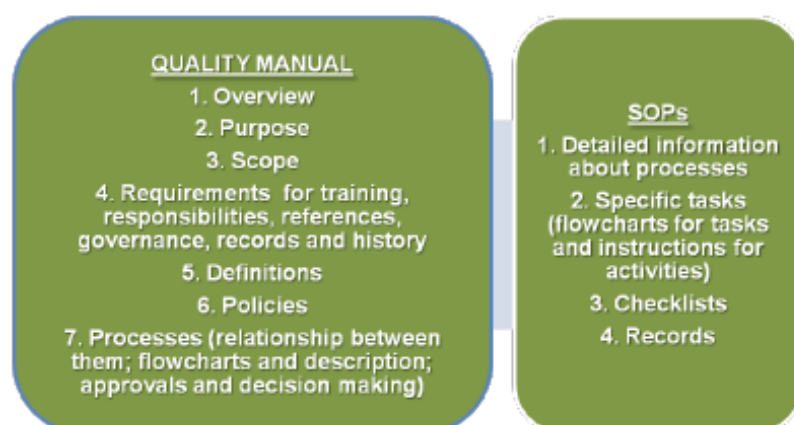
A **certification or accreditation body** is an organization or agency with the authorized right and authority to inspect a facility, and provide written evidence of its compliance (Certification) and competence (Accreditation) with a standard<sup>12,13,16,17</sup>.

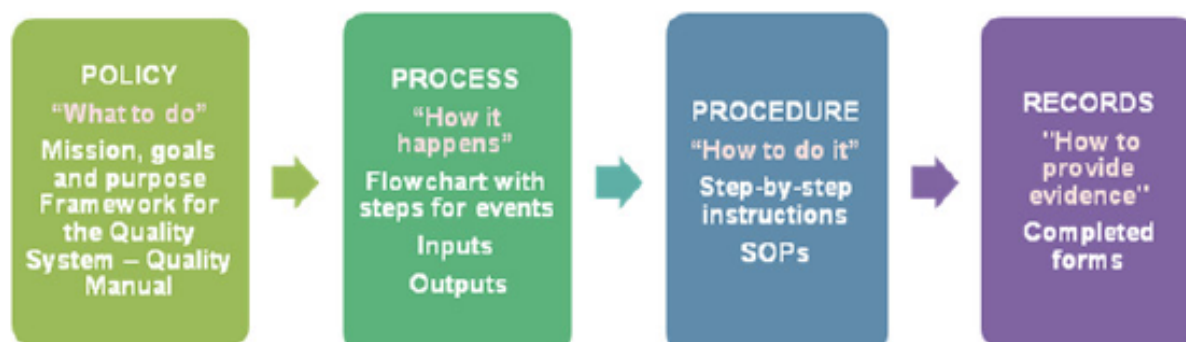
**Audit** is a systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which required

criteria are fulfilled. It could be external (conducted by groups or agencies from outside the laboratory) and internal (assessors are the laboratory staff; they allow the laboratory to look at its own processes)<sup>12,13,16,1</sup>.

**Proficiency testing schemes** are inter-laboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel<sup>13,17</sup>.

The **Quality Manual** is an overview of the organization, mission statement, vision statement, objectives and scope and must include the Quality Policy (Figure 2)<sup>12,13,18</sup>.

Figure 2. Quality manual and standard operating procedures<sup>12,13,18</sup>

Figure 3. Levels of documentation (documents and records)<sup>12,13</sup>

An SOP is a document which describes regular operations relevant to the examination quality and to other processes. The aim of an SOP is to carry out operations correctly and must be available to the staff at the place where the work is done. They are a practical way of translating policies into action and describe how processes should be carried out (Figure 2). Job aids or work instructions are like supplements of SOPs and are shorter versions of SOPs in a visible location<sup>12,13,18</sup>.

Policies, processes, procedures and records can be controlled in a stepwise fashion (Figure 3)<sup>12,13</sup>.

## LABORATORY QUALITY – ASSESSMENT AND IMPROVEMENT

The key message is that quality system enables standardization to best practice<sup>12,13,16</sup>.

Laboratory Requirements – Standards (at a glance):

- National and international organizations recognized in the Laboratory Quality field<sup>12</sup>
- The WHO has created Standards for some specific fields<sup>13</sup>
- The International Organization for Standardization (ISO) has produced a lot of guidelines and standards<sup>16</sup>
- The Clinical and Laboratory Standards Institute (CLSI) – alone or in association with other organizations – has made work in this matter<sup>17</sup>.

The Table 2 shows some features related to the laboratory quality management using ISO standards<sup>16,19</sup>.

Table 2. ISO Standards with great impact in laboratory field<sup>16,19</sup>

The ISO 9000:2000 addresses general QMS requirements and applies to laboratories.
The ISO 9001:2015 will ensure that quality management is now completely integrated and aligned with the business strategies of organizations.
The ISO 15189:2012 is related to quality and competence in medical laboratories.
The ISO 19011:2011 sets guidelines for auditing management systems.
The ISO 31000:2009 endorses principles and guidelines for risk management.
The ISO 45001:2016 is related to occupational health and safety management.
The ISO/IEC 17011:2004 specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies.
The ISO/IEC 17025:2005 is related to competence of testing and calibration in laboratories.
The ISO/IEC 17043:2010 specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes.

ISO and IEC (International Electrotechnical Commission) technical committees collaborate in fields of mutual interest.

In terms of laboratory quality systems, the relevant ISO standards are ISO 9000, which addresses quality management issues, and ISO 17025 and 15189, which address requirements for testing and calibration laboratories and medical laboratories, respectively<sup>16</sup>.

### 1) Organization

Policies, processes and procedures include vision, mission, ethics, principles and goals of the or-

Figure 4. Organization, Policies, Resources and Processes<sup>13,20</sup>

ganization and define responsibilities and roles of the workforce.

See Figure 4 for detailed structure<sup>13,20</sup>.

## 2) Personnel

Recruiting and retaining qualified staff is crucial as each employee's job description and new employee's guidance. Provide opportunities for continuous education and policies relevant to personnel must be combined with knowledge, skills and motivation<sup>13,20</sup>.

Lay out all activities, specific responsibilities, training, workplace, policies and procedures, work schedules and competency<sup>13,20</sup>.

Competency may be defined as the application of knowledge, skills and behaviors used in performing specific job tasks. If more than one person makes the same error, consider the root cause of the error, such as equipment malfunction and operating procedure ambiguity<sup>13,20</sup>.

## 3) Equipment

A good equipment management program provides a high level performance, reduces variation in test results and repair costs, and increases technician's safety and customer satisfaction. It has to meet physical requirements for installation and the staff follows manufacturer's specifications. Maintenance should be planned and replacement of instrument carried out when repair is not possible<sup>13,20</sup>.

Troubleshooting: manufacturers often provide flowcharts that help to solve problems. Identification of routine problems related to technical duties and responsibilities and their explanation for a corrective action<sup>13,20</sup>.

Backup instruments: they can maintain the routine when a machine breaks down until repair<sup>13,20</sup>.

## 4) Purchasing and Inventory

Supplies and reagents must be always available when needed. Reagents and supplies mustn't be lost due to improper storage or used beyond expiration. Main concepts: uninterrupted flow of needed materials, efficiency and effectiveness of the laboratory<sup>13,20</sup>.

## 5) Process Control

Emphasis on requisitions and forms, safety practices, handling urgent requests, collection, labeling, preservation and transport, storage, retention and disposal of samples<sup>13,20</sup>.

The tracking system includes:

- 1) After registration or log of all incoming samples with generated laboratory identification number, the traceability of the original sample must be allowed.
- 2) Safety requirements must be assured concerning transport of samples<sup>13,20</sup>.

Establishment of a policy for sample storage and disposal in a clear sample management directly affects patient care and outcome<sup>13,20</sup>.

## 6) Information Management

Documents provide information about policies, processes and procedures. Once the forms are used to record information, they become records<sup>13</sup>.

Details about documents and records are showed in the Table 3<sup>13,20</sup>.

Table 3. Documents and Records – Access, Integrity, Archive and Recovery<sup>13,20</sup>

Where to keep documents and records
Paper-based system
Computer-based system
Combination of paper and electronic system
Regular backups
Accessibility, accuracy, timeliness, security, confidentiality and privacy of patient information

## 7) Documents and Records

Documents provide instructions or description of processes; records provide evidence about the quality of products and services<sup>13,20</sup>.

Records make proof if processes were carried out as intended<sup>13,20</sup>.

Details showed in Tables 4, 5 and 6<sup>13,20</sup>.

## 8) Occurrence Management

This process identifies and handles errors and near-misses. These events must be addressed to change processes and prevent errors of happening again. Most of the error sources occur in post-examination

Table 4. Quality Manual<sup>13,20</sup>

Quality manual
The quality manual sets across the whole documentation of the laboratory.
It contains a quality policy and describes the processes that take place in the laboratory in order to fulfill the requirements of particular standards.
The quality policy should refer to management, quality evaluation, health and safety, laboratory methods and procedures which relate to the same areas.
It shows the organization and responsibilities within the laboratory.

Table 5. Procedures<sup>13,20</sup>

SOPs
Consistency, accuracy and quality
Detailed, clear and concise and easily understood
Reviewed, approved and updated
Header
Steps and details
Specific of the laboratory and different from manufacturer's instructions
SOP number and version number
Date of issue and of expiry
Title and author
Status
Department of holders/ users; name of holders
Historical data (dates of previous issues)

Table 6. Documents and Records<sup>13,20</sup>

Document Control – Documents	Document Control – Records
Uniform format that includes a numbering system/ version (date)	Permanence and accessibility
Formal approval / Inventory of all documents	Continuous monitoring
Available at the point of use	Tracking of samples
Distribution, accessibility and revision processes	Evaluating problems
Forms and worksheets	Security and management
Stakeholders	THEY ARE NOT REVISED OR MODIFIED
Archive of outdated documents (old versions)	

and pre-examination. Correction of occurrences can be done by preventive, remedial and corrective actions. Management of nonconformities is crucial. Root case analysis is the approach to find superficial causes of a problem, but also deeper or core problems. Roots and triggers could be represented by the Ishikawa's fishbone diagram of domino effect<sup>1,13,20</sup>.

## 9) Assessment

It is necessary to determine effectiveness of a laboratory's QMS by internal and external audits, and evaluation of performance in an external quality assessment program. Accepted standards form the basis for laboratory monitoring<sup>1,13,20</sup>.

During audits, information is collected about:

- Processes and operating procedures; staff competence and training
- Equipment; environment; handling of samples
- Quality control and verification of results; recording and reporting practices<sup>1,13,20</sup>.

Audit report and plan of action:

- Review the recommendations of assessors; identify gaps and nonconformities
- Plan to correct nonconformities<sup>1,13,20</sup>.

All results and actions taken should be documented in a written report<sup>1,13,20</sup>.

#### 10) Process Improvement

The classical PDCA (Plan, Do, Check and Act) model represents easily the main concepts to monitoring and quality improvement<sup>13</sup>. Remedial, corrective and preventive actions take place in this matter<sup>20</sup>. Quality indicator (QI): Established measures used to determine how well an organization meets requirements and operational expectations. Evaluate costs, benefits and priorities before choosing QI. They have short-term and long-term implications and fewer are better than many<sup>3,13,20</sup>.

Examples: patient identification, hemolyzed and clotted samples, insufficient quantity or incorrect proportion in the tube, inappropriate container and results turnaround time<sup>13,20</sup>.

#### 11) Customer Service

Customers include patients, physicians, public health agencies and the community. Customer satisfaction is a major component of a QMS. The primary clients are health care providers and patients. The laboratory can receive complaints, but also questionnaires asking some specific questions to allow feedback and improvement<sup>1,13,20</sup>.

#### 12) Facilities and Safety

Some topics require a lot of endeavor and investment:

- Power supply, water systems, ventilation, cleaning, standard safety practices for handling hazardous materials, disposal of bio-

logical and chemical wastes, warnings, safety precautions for radiation and fire, instructions for the use of fire extinguishers, circulation pathways of biological samples among different sections are general conditions concerning work environment.

- Avoid needle recapping and put sharps in specific containers.
- Biological spills and decontamination measures.
- Ergonomics: prevention of musculoskeletal syndromes, fatigue and injury; provision of personal protective equipment such as gloves, goggles, masks and laboratory coats.
- Risk assessment of laboratory-acquired infections.
- Emergency response planning<sup>1,13,20</sup>.

#### PROACTIVE APPROACHES AND IMPLEMENTATION OF A QUALITY PROGRAM

By the establishment of priorities, sharing of expertise and presentation of tools, theoretical models can make practical work easier. Strategies and tactical planning form the baseline and target architecture of a quality management system, followed by process and competence management<sup>4,21</sup>. Customer evaluation generates a feedback to all build-time and run-time processes<sup>9</sup>. The financing of resources (human and material – clinical and laboratory equipment, information technology-records and responsibilities) and services is fundamental<sup>10,21</sup>. To achieve good risk management it is crucial to identify and analyze the root and trajectory of a problem, which, in turn, will lead to its proper evaluation, control and prevention. Good practice compliance, upgrading of professionals and implementation of a quality management system with the report of adverse events are milestones in the quality assurance<sup>22,23</sup>. The Proactive Risk Management comprises innovation and change by a functional point of view: predictive, measurable and controlling the risk<sup>12,23</sup>. See table 7 for details<sup>13,20</sup>.

The tools employed in the risk management stand in the risk assessment and error communication followed by control and revision processes, making changes where necessary to improve performances and overall quality<sup>5,6,13,20</sup>.

**Table 7.** Implementation of an Integrated Quality Management Program in a Laboratory<sup>43,46</sup>

Steps	Implementation
1.	Mapping the laboratory work process (workflow)
2.	Assessment of pre-, intra- and post- analytical phases
3.	Laboratory management team
4.	Descriptive quality system model designed like a puzzle
5.	Document structure and version control
6.	Training and assessing competency
7.	Process control (internal and external)
8.	Quality goals and indicators
9.	Improvement

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