

# Quality improvement program; bioethics and medical relevance for clinical laboratories

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## Summary

To efficiently meet the needs of Evidence-Based Medicine, Medical Laboratory Professionals shall provide verifiable support through constantly growing activities, demonstrating expertise in multiple disciplines including medical biochemistry, cytology, haematology, immunology, endocrinology, microbiology, molecular diagnostics, genetics, and nuclear medicine.

This requirement has generated increasing impact of Total Quality Management on performance. Given this situation, last decades have evolved in the three stages of the analytical process in accordance with ISO / IEC 15189 covering quality comprehensively, including ISO/IEC 17043 for Proficiency Testing Providers. In order to achieve the highest level of quality medical laboratories must work on the basis of the Code of Ethics of the Pan American Health Organization which significantly emphasizes combating “dichotomy” that shall be considered as illegitimate paybacks that inevitably harm patients and other customers.

In the Latin American Association of Medical Pathology and Laboratory Medicine we are committed to continuously working with improving the quality of Latin American Medical Laboratories. Once we understood this and took on the task to provide an instrument of international standard and particularly tailored to fulfil the needs and possibilities of our region. Indeed, we proceeded to consult with members of with a proposal that was overwhelmingly accepted to carry it forward. This is how PROMECAL Quality Improvement Program was established to improve performance of Latin American Medical Laboratories. A pro bono and voluntary programs for all laboratories wishing to participate can do so without cost problems inherent in programs Accreditation and Certification.

The fundamental of this program is that it provides to be treated on the basis of the principles of ethics, suitability, competence and medical relevance for what can only be carried out between pairs exclusively, i.e., only between authentic medical laboratory professionals.

**Abbreviations:** EBM, evidence based medicine; QIP, quality improvement program; PROMECAL, programa para la mejora de la calidad (Spanish)

## Introduction

In order to respond efficiently to Evidence-Based Medicine our task as Clinical Laboratory Professionals is to provide medically relevant, verifiable sustenance for this constantly growing activity on multiple disciplines. This requirement generates a greater challenge,

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workload and impact on Total Quality Control. Given this situation in the last decade, Quality has evolved not only through ISO / IEC 15189:2007 but also to ensure accuracy, ISO / IEC 17043:2010 is now also required for Proficiency Testing Providers.

Given this, in the Latin American Association of Clinical Pathology and Laboratory Medicine ALAPAC / ML we felt the need and obligation to contribute to quality improvement of Latin American Clinical Laboratories. Thus, we developed the Latin American Program for Quality Improvement, a gratuitous and voluntary program for all laboratories willing to participate solving the inherent problem of unaffordable costs of Accreditation and Certification Programs.<sup>2</sup> The central feature of this program is that it provides sustention to be treated on the basis of a principle of suitability and competition, in order to be carried out exclusively among peer connoisseurs, between authentic Clinical Laboratory Professionals.<sup>3</sup>

## Description

PROMECAL Quality Improvement Program arises on the principles of Bioethics and Medical Relevance with extensive knowledge and experience on Clinical Laboratory Science, providing the following basic tools.

- 2013.001 GUIDE: Latin American Guide for Clinical Laboratory Quality: Bioethics and Medical Relevance.
- 2013.001 CHECKLIST: Audit for analysis of clinical laboratories, bioethics, quality, and Medical Relevance
- 2018.002 GUIDE: English version.

## Scope and purpose

The Latin American Guide for Clinical Laboratory: Bioethics, Quality and Medical Relevance are of great importance since it summarizes the specifications that must be met for the organization and operation of the Medical Laboratories under PROMECAL. The Guide was developed based on five fundamental premises, and an accurate glossary.<sup>4-6</sup>

## Premises

- i. **Medical relevance:** Quality or condition of transcendence, significance, usefulness or significance for the diagnosis,

prognosis or treatment. Individually or in public health perspective.

**ii. Fitness:** Necessary conditions to perform a function (attitude, aptitude, ability, sufficiency). Evidence that must exist between the characteristics of a person, or the characteristics of a particular element and function, activity or work to be performed.

**iii. Dichotomy:** The concept refers itself to the law that states that any proposition can be true and false at the same time. The payment made by certain private Laboratories to Physicians and Businesses in order to receive more customers is an unfair practice. For the sake of mutual professional respect and morality, professional laboratory practices should not perform dichotomy with others inside or outside the health field, as this is an act contrary to professional dignity which harms the country's health system. NOTE. The practice of dichotomy disqualifies the Laboratory in achieving Recognition Diploma on Bioethics, Quality and Medical Relevance automatically regardless of compliance with all other requirements of PROMECAL 2013:001.

**iv. Audit:** Internal or external evaluation whose purpose is to analyze and assess, with a view to the possible corrective actions, internal control of organizations to ensure the integrity of its assets, the veracity of their information and maintain the effectiveness of its management systems. In the specific case of the PROMECAL, peer audits can only be done by trained, qualified and documented Laboratory Professionals.

**v. Recognition:** The action of distinguishing the suitability of an organization or a person among others due to their characteristics, qualities, performance and results.

Mutual recognition: Consideration of two people or organizations that have reciprocal suitability and value.<sup>7-9</sup>

**Glossary:** More than 100 terms have been defined including the following:

**i. Quality:** The degree to which a set of inherent characteristics fulfils the established requirements.

**ii. Competition:** Comprehensive action to identify, interpret, argue and resolve problems with competence and ethical context, integrating the knowledge of being, knowing how, knowledge to know.

**iii. Quality management:** Set of coordinated activities to direct and control an organization regarding to quality management at all levels of the establishment.

**iv. Clinical laboratory:** A public, private or social organization, independent or linked to another healthcare facility whose purpose is to perform physical, chemical or biological analysis of various biological components and products of the human body the results contribute to the study, prevention, diagnosis, resolution and treatment of health problems.

## Description

To facilitate implementation, we developed [www.qualitat.cc](http://www.qualitat.cc) where freeware is available including several tools.

**i. Evaluation of the structure, process and performance:** As previously mentioned PROMECAL fundamental axis is the GUIDE 2013:001 & GUIDE 2018:002.eng plus an automated

Audit Format that allows Clinical Laboratories to apply an internal evaluation of structure, process and outcomes to detect opportunities for improvement.<sup>10-13</sup>

**ii. Medical relevance exercises:** In addition to participating in the Internal Audit Program Laboratory Professionals can participate monthly in Clinical Pathology Cases and Medical Knowledge Assessment. The annual round of Medical Relevance Programs consists of twelve-monthly cycles.

**iii. Diploma promecal on bioethics, quality and medical relevance:** The achieve recognition it is necessary to have participated in at least 10/12 monthly cycles. In addition to demonstrating compliance with all requirements of the Audit. The Diploma will be awarded to the Laboratory. No personal recognition is available.

**iv. Improvement plan:** Upon detecting the presence of opportunities for improvement or when there are non-compliant results during audits and clinical pathology exercises, participants can resort to the availability of articles, books, atlases, tutorials and even consulting via email with whom they can find useful guidance and recommendations to improve performance.

## Conclusion

Our Mission is to collaborate with Clinical Laboratory Professionals reliably, detecting and exploiting improvement opportunities, providing a Comprehensive System including Planning, Organization Development and Control through Training Programs, Counselling, Mentoring and Coaching using cutting edge technology with efficiency, effectiveness and efficacy, capable to continually improve the quality and opportunity in decision-making, to ensure that participants report more reliable results that minimize risks and costs in order to provide more benefits for patients.

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## Conflicts of interest

The author declared that there are no conflicts of interest.

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