

Quality management systems in the clinical laboratories in Latin America

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ABSTRACT

The implementation of management systems in accordance with standards like ISO 9001:2008 (1,2) in the clinical laboratories has conferred and added value of reliability and therefore a very significant input to patient safety. As we know the ISO 9001:2008 (1) a certification standard, and ISO 15189:2012 (2) an accreditation standard, both, at the time have generated institutional memory where they have been implemented, the transformation of culture focused on correct execution, control and following, evidence needed and the importance of register.

INTRODUCTION

In the last decades, in the health sector but especially in the clinical laboratories, the implementation of management systems under requirements of international standards has increased and improved the knowledge and functioning of processes with increasing the results, information and data which provide to the health care process and help to enhance the quality of life and generate a positive impact in health facility in terms of costs (decrease the need of unnecessary diagnostic procedures).

Likewise, the management system has been a tool, which has improved its operative and technical processes and adopted systemic methodologies for resolving problems on a day to day basis and give answers to questions in the actual context, where the quality and security of the results is increasingly under scrutiny.

QUALITY MANAGEMENT SYSTEMS

In the past 2 decades, Latin-American professionals of clinical laboratory have focused their efforts to meet demands of patients, the requirements from the clinicians and regulatory organisms, and have focused on implementing international certified standards, for example the ISO 9001:2008 (1, 2). Despite limited resources, professionals of clinical laboratory have worked relentlessly to implement management systems for the achievement of organizational goals. Today, in the XXI century, in the year 2015, we understand that the management system helps answer the needs of a process and have been flexible, dynamic, and simple with contribution to the organization in order to achieve an internal balance that guarantees sustainability. It has been realized that implementation of quality management benefits patient care, and it may not be promptly evident, but such an investment results in long-term sustainability.

The management of quality can be defined as a set of activities that is developed with which an organization can operate and promotes fulfillment of its mission and reach its vision, through a systemic methodology that permits continual improvement under excellent planning of all its processes, including execution and verification. The implementation of corrective and preventive actions is a must; the subsequent improvement is evidence of organizational learning. It is the authors' personal experience of 20 years in implementing quality managements systems that the eventual end benefactor is the patient.

MANAGEMENT SYSTEMS—ISO 9001:2008 AND ISO 15189:2012 STANDARDS

In Latin-America, for many years, the clinical laboratories implemented the ISO 9001:2008 (1) standard for their management system, this constituted a true challenge because this standard is not specific for clinical laboratory processes and in some requirements was short in the “must” for the particularities of laboratory. However, the model was implemented and with the ISO 9001:2008 (1) our laboratories gained experience with registry, methodology for documenting their procedures, control mechanism and follow-up. They implement very important components like program of internal audits that result in management indicators; these are elements that were not materialized in the ISO standards. Additionally, with the follow-up of measuring instruments, for first time, the phrase “metrology” is real in the clinical laboratories and inside the language of our professionals, the traceability, calibration, reference materials are part of the day to day procedures of all laboratories (3).

The significant lapses of the ISO 9001:2008 (1) were soon clear to all. The ISO 15189:2012 (2) specific standard for quality requirements and competence for clinical laboratories is

widely delineated. The accreditation for our quality management system in clinical laboratories with conformity to quality requirements and competence of ISO 15189:2012 (2) standards is a real context and the correct way for us that we have been committed with the quality of results and security of the process in clinical laboratory. This standard ISO 15189:2012:2012 (2) implies a system of management of quality with risk approach; this guarantees migration from a reactive approach to a preventive and proactive model. With the exhaustive incorporation of “musts” toward patient security, identification of technology risks and reactivity, we have succeeded in confirming to the global guidelines of the World Health Organization (WHO) as regards to patient security, techno vigilance, and reactive vigilance and hemovigilance as applicable. In terms of clinical effectiveness, it streamlines the responsibility of clinical

laboratory in the notification of critical results, definition, communication and impact measurement, as well as tied all the aspects related with the information system and the mechanisms of verification, control and security of auto verification process or auto validation through mild ware; this was beyond contention in previous versions. Additionally, the requirement of validation/verification/evaluation of methods, insurance of quality, the obligation to participate in programs with other laboratories accredited with ISO 17043 (4) the need of measure the uncertainty e.g., parameter of exactness in the result, have been the challenge in the academy for our analysts and has generated an improvement of competences. As such, today we have the professionals of best domain and empowerment, not only in statistical tools but also in knowledge of assay tools and control of variables.

Table 1 Laboratory certification and accreditation in Latin American countries

Country	Certification body	Accreditation body	Certification	Accreditation	
			9001:2008	17025:2005	15189:2012
Argentina	IRAM (Instituto Argentino de Normalización y certificación)	OAA (Organismo Argentino de Acreditación)	46	143	8
Bolivia	IBNORCA (Instituto Bolivariano de Normalización y calidad)	NAI	8	NAI	NAI
Brazil	ABNT	cgcre / INMETRO	10	4260	NAI
Chile	INN	INN (Instituto Nacional de Normalización)	NAI	1109	15
Colombia	ICONTEC	ONAC	89	191	6

Costa Rica	INTECO	ECA (Ente Costarricense de Acreditación)	5	73	5
Cuba	NAI	ONARC (Organismo Nacional de Acreditación de la República de Cuba)	3	NAI	NAI
Ecuador	INEN	SAE (Servicio de Acreditación Ecuatoriano)	NAI	NAI	NAI
El Salvador	CONACYT	OSA (Organismo Salvadoreño de Acreditación)	NAI	NAI	NAI
French Guyana	NAI	NAI	NAI	NAI	NAI
Granada	NAI	NAI	NAI	NAI	NAI
Guatemala	COGUANOR. NE	OGA (Oficina Guatemanteca de Acreditación)	NAI	NAI	NAI
Mexico	IMNC (Instituto Mexicano de Normalización y certificación)	EMA (Entidad mexicana de acreditación)	NAI	23000	127
Paraguay	INTN	ONA (Oficina Nacional de Acreditación)	NAI	17	NAI
Panama	COPANIT	CNA (Consejo Nacional de Acreditación)	NAI	NAI	NAI
Peru	INDECOPI	INDECOPI	NAI	58	NAI
Uruguay	UNIT	OUA (Organismo Uruguayo de Acreditación)	NAI	24	3
Venezuela	FONDONORMA	SENCAMER	2	35	NAI

* NAI: Not available information

CONCLUSION

The management systems have contributed significantly to decrease the variability of procedures through the standardization and the possible use of means available with eventual benefit to patient care. Added to this, the goal that is possible, visible and quantifiable in the transformation towards the culture of improved quality and security of patient care. The actions towards continued improvement, the search of excellence and zero mistakes is invaluable for attainment of precise information to professionals in this discipline.

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