

Review

Implementation of the External Quality Assessment Program in Brazil

Marcos Kneip Fleury*¹, Maria Elizabeth Menezes², José Abol Correa²

¹Department of Clinical Analysis, Federal University of Rio de Janeiro, Rio de Janeiro, Brazil

²National Program of Quality Control (PNCQ), Brazilian Society of Clinical Analysis, Rio de Janeiro, Brazil

*Corresponding author: mkfleury@gmail.com

Abstract

The External Quality Assessment (EQA) in Brazil is performed by the National Health Ministry for diseases that are under supervision of Public Health Department. In addition to the government program, the Brazilian Society of Clinical Analysis and the Brazilian Society of Medical Pathology are allowed to provide their programs under the Supervision of National Agency for Sanitary Surveillance (ANVISA) that regulates laboratories to perform EQA programs.

Key words: quality assurance; external assessment; proficiency testing

Received: October 20, 2016

Accepted: January 08, 2017

Introduction

External Quality Assessment (EQA) and Proficiency Testing (PT) are valuable tools in the quality improvement process. EQA in clinical laboratory could be described as a set of systematic, data-guided activities, designed to bring improvements in health care delivery, and the combined efforts of everyone to make changes that will potentially lead to better patient outcomes, better system performance, and better professional development (1,2).

To be successful, PT instructions must be followed carefully, all paper work completed accurately, and results submission deadlines met. All PT results, as well as corrective actions, should be recorded and the records maintained for an appropriate period of time. PT is a tool to measure laboratory performance. Therefore, there must be no difference in the treatment of PT samples and the patient's sample. Proficiency testing providers make every effort to produce samples that exactly mimic, or closely resemble, usual samples received from patients. PT samples must be processed by normal testing method(s) and involve personnel who routinely perform the testing.

The internal quality control (QC) involves in-house procedures for continuously and concurrently assessing laboratory work so that results produced by the laboratory can then be decided whether they are reliable enough to be released for supporting quality patient care. The mean and standard deviation (SD) values must be calculated or evaluated before a new lot of QC material is used. The SD value should be derived from the laboratory established precision goals for each analyte (3). Acceptable ranges (confidence limits) must be defined for internal quality control material. Where acceptable ranges are set to limits other than $\pm 2SD$ based on current analytical performance, the rationale for the limits should be documented.

Several efforts have been done for making EQA/PT schemes web friendly in recent years. Both data entry and result review are available via internet in many programs. This strongly reduces time in sending and receiving EQA/PT reports. It also reduces the risk of manual transcription of data and results.

EQA in Brazil

The EQA in Brazil is performed by the National Health Ministry for diseases that are under supervision of Public Health Department. Brazilian clinical laboratories must follow a specific sanitary legislation since 2005. The RDC 302/2005 is a broad technical regulation aiming to guarantee the quality of the examinations carried out by approximately 17.000 laboratories existing in the country (4). In this way, the internal quality control, with the new legislation, has become a mandatory task within the laboratories, aiming to assure the quality of the laboratory results.

In addition to the government program, the Brazilian Society of Clinical Analysis (SBAC) and the Brazilian Society of Medical Pathology (SBPC) are allowed to provide their programs under the Supervision of National Agency for Sanitary Surveillance (ANVISA) that regulates laboratories to perform EQA programs.

The National Program of Quality Control (PNCQ), supported by SBAC, is a producer of quality control samples for EQA that had started to organize and to coordinate programs for the External Quality Assessment Laboratory forty years ago. Currently 63 schemes covering 352 different tests are available.

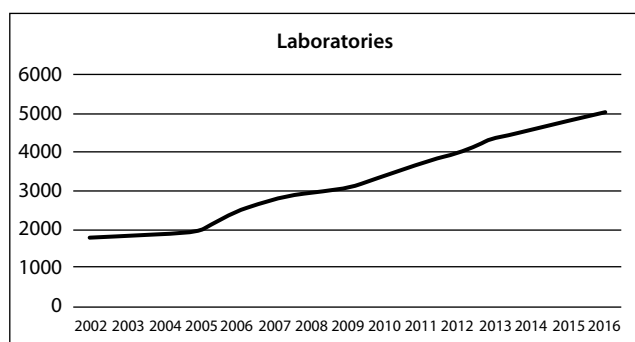
PNCQ sends periodically (monthly or quarterly) multiple samples to the laboratories for analysis and/or identification in the first or second week of the month. The participating laboratory receives the samples, analyses them and sends the results until the 5th day of the following month. Each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others. Upon receipt, the results are grouped by method or equipment, and analysed to calculate the mean, SD and coefficient of variation using its own software (5). The Program releases the results, which are available to members on the PNCQ site in 48 hours.

The PNCQ's participating laboratory can establish the mean and SD values, as well as elaborate the internal control charts, using the "PRO-IN Real Time" program, available at its website. The use of

this tool eliminates the need for manual preparation of the Levey-Jennings Chart and the participant laboratory can view and compare their averages with that of all other participants.

Following the regulation of RDC 302 in 2005, quality control programs in Brazil experienced a significant increase in the number of participants (Figure 1). According to information from CNES – DATA-SUS, there are about 16,700 clinical analysis laboratories and 5,800 pathology/cytology laboratories in the country located mainly in the southeast (38.9%) and northeast (27.3%) regions (6). These numbers include laboratories that are in hospitals, clinics and other health facilities with or without hospitalization.

By now, the Program has 5.028 participants distributed as 4871 clinical laboratories, 50 cytopathology laboratories, 17 centres of molecular biology diagnostic and 90 blood banks. The Program reaches all the 26 states of the country, 7 countries of South America, besides Costa Rica, Italy, Spain, Portugal and Finland. Among the participants, there are 270 Public Health Units, 14 Federal and



Year	Laboratories, N	Year	Laboratories, N
2002	1774	2010	3345
2003	1829	2011	3694
2004	1863	2012	3951
2005	1974	2013	4352
2006	2486	2014	4556
2007	2805	2015	4823
2008	2985	2016	5028
2009	3087		

FIGURE 1. Number of active laboratories participating the Program per year

State Universities and 175 Laboratories outside the country.

Because of the size of the country and the distance of some of the partner countries in Latin America and Europe, we started, in 2009, the production of lyophilized samples to ensure the sample quality and stability even without fast and adequate delivery. In 2010, PNCQ started production of freeze-dried samples of bacteria and distribute them to participants of the Program. In 2015, the Program produced 861,573 samples; 619,674 lyophilized. At the moment the Program analyses 3,5 million results by year. All the samples are continuing tested for homogeneity and stability in order to provide the quality of the produced samples.

Conclusions

The EQA and PT are valuable tools in the quality improvement process of clinical laboratory services (7,8). However, the primary objectives of EQA are educational, and may be supported by specific schemes aimed to extend the evaluation throughout all phases of the testing cycle, including interpretation of results.

In pursuit of that goal, the SBAC works together with the PNQC looking for the awareness of laboratory professionals for their continued professional development. The existence of the two organizations, walking together for 40 years brings a mix of its activities and purposes. The constant partnership can be evidenced in the numerous events that SBAC and PNCQ complete themselves in its main objectives.

The main mission of the Program is to help laboratories to implement the external and internal quality control in order to ensure the quality of test results and obey the country's laws. There is a partnership between SBAC and PNCQ offering discounts on quality programs to SBAC members. The PNCQ also organizes during the SBAC Conference a set of workshops addressing the key questions of the participants sent to scientific advice during the year.

In all editions, the SBAC Conference also offers the training course for quality auditors and the course of PNCQ manager. These courses provide an opportunity to members to implement the quality system in their laboratories or improve the management of quality processes achieving qualification to perform audits.

Accreditation of the Quality Management System (DICQ) is a significant differentiation for the clinical analyses laboratories (9). Not only with relation to the control of all the procedures or the productivity increase with the use of standardized documents, but also to demonstrate their competence through formal compliance with a set of internationally-recognized requirements for the planning and implementation of proficiency testing programs. There are currently 300 laboratories accredited by DICQ in Brazil. Accreditation provides to the users an increased confidence that the schemes are being operated competently in accordance with specified technical and management system requirements.

Potential conflict of interest

None declared.

References

1. Lynn J, Baily MA, Bottrell M, Jennings B, Levine RJ, Davidoff F, et al. The ethics of using quality improvement methods in health care. *Ann Intern Med* 2007;146:666-674. <https://doi.org/10.7326/0003-4819-146-9-200705010-00155>.
2. Sierra-Amor RI, López-Martínez M. Medical Laboratory Accreditation according to ISO 15189:2003. The Mexican Experience. *Biochem Med (Zagreb)* 2007;17:188-92. <https://doi.org/10.11613/BM.2007.017>.
3. Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions. Approved Guideline - Third Edition CLSI document C24-A3*. Wayne, PA: CLSI; 2006.
4. Agência Nacional de Vigilância Sanitária (ANVISA). [Resolução RDC nº 302 de 13 de outubro de 2005. Dispõe sobre Regulamento Técnico para funcionamento de Laboratórios Clínicos]. (in Portuguese).

5. Sciacovelli L, Zardo L, Secchiero S, Plebani M. Quality specifications in EQA schemes: from theory to practice. *Clin Chim Acta* 2004;346:87-97. <https://doi.org/10.1016/j.cccn.2004.02.037>.
6. Instituto Brasileiro de Geografia e Estatística (IBGE). Available at <http://www.ibge.gov.br/home/default.php>. Accessed December 5th 2016.
7. Westgard JO. Managing quality vs. measuring uncertainty in the medical laboratory. *Clin Chem Lab Med* 2010;48:31-40. <https://doi.org/10.1515/CCLM.2010.024>.
8. Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to improve the clinical laboratory; Approved Guideline - Second Edition*. CLSI document GP27-A2. Wayne, PA: CLSI; 2007.
9. Sistema Nacional de Acreditação DICQ/SBAC. Available at: <http://acreditacao.org.br/>. Accessed November 30th 2016.