State-of-the-art Approach to Goal Setting

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KEYWORDS

• Quality assurance • Laboratory testing • Analytes • Quality specification

KEY POINTS

- A consensus of 4 external quality assurance programs combined their data to calculate the minimum acceptable quality specifications for laboratory testing.
- Where other sources of quality specifications may be too stringent for the current market, or may be too lenient given the clinical demands on the test result, these state-of-the-art goals may be practical and useful.
- More than 4 million test results from more than 4000 laboratories covering 82 different analytes were examined.
- Two main approaches were used: (1) defining the 95% percentile and comparing with other quality specifications, and (2) using an iterative approach to increase the quality specification until 90% of laboratories could achieve 75% of their results within the specification.
- Seventy-two out of 82 analytes followed procedure 2.

INTRODUCTION

Spanish clinical laboratories are involved regularly in external quality assurance programs (EQAPs), also known as proficiency testing. This participation is mandatory for clinical laboratories in most autonomic regions of Spain, although there is not a requirement for reaching a predetermined quality specification for each analyte.

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The EQAP organizations that cover most of the hospital and primary care laboratories, private institutions, and public institutions working all over the country are 4 scientific societies, covering various laboratory disciplines: the Spanish Association of Pharmaceutical Analysts, Spanish Association of Medical Biopathology–Laboratory Medicine; Spanish Society of Laboratory Medicine, and Spanish Society of Hematology and Hemotherapy.

Although these organizations are competitors, they decided to work together on defining common quality specifications, based on scientific evidence. The aim of this study was to establish common specifications that are considered the minimum level of quality that each laboratory has to reach, to ensure harmonized analytical services. An additional purpose was to avoid the possibility of a legal imposition concerning quality specifications from the administration, defined without any scientific basis.

For this reason, a committee of experts from the 4 scientific societies was created in 2007, with the aim of agreeing on common analytical minimum quality specifications for total error, which have to be achieved by laboratories enrolled in any of the 4 EQAPs.[1]

The basis for the rationale was to use results from the 4 EQAPs, according to lowest level defined in the hierarchical model of Stockholm,[2] transferred to an ISO (International Organization for Standardization) technical report,[3] and further confirmed in the Milan strategic conference,[4] which are based on the current state of the art from the EQAP results.[5]

These 4 EQAP organizations have performances that make it feasible to agree on the level of quality required of participant laboratories:

- Working from the ISO/IEC (International Electrotechnical Commission) 17043:2010 standard.[6]
- Following recommendations of the IFCC/Education and Management Division/ Committee of Analytical Quality.[7]
- Using confidentiality as an essential ethic criterion.
- Being nonprofit organizations, independent of commercial interests.
- Having great experience in the field (the scientific societies began to organize programs around 1980).
- Using blind stabilized control material, with the overall or peer-group mean of participant results as a consensus value for comparison, after exclusion of outliers.
- Distributing 12 (biochemistry) and 24 (hematology) control materials per year, and asking for monthly results.
- Covering a wide range of concentration values for each analyte, including critical values for medical decisions.

The 4 programs are certified according to the ISO 9001 standard[8] and are in the process of accreditation, according to the ISO 17043 standard.[6]

MATERIAL AND METHODS

The materials used in this study were all results obtained from 2005 to 2010, 6 cycles of EQAP programs of the 4 societies, being the results of 2005 and 2006 and the basis of a preliminary study[1,9]; in total, 6 cycles of EQAP programs of the 4 societies were considered. All these data were compiled in a database, called Datum, which includes the 82 analytes included in at least 2 programs of the 4 societies (25 basic biochemistry, 15 hormones and tumor markers, 22 hematology and coagulation, 3 immunology, 12 urine, and 5 therapeutic drugs tests).