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LETTERS OF DIRECTOR

The Clinical Laboratory in the continuous improvement of quality

El Laboratorio Clínico en la mejoría continúa de la calidad

Dear Sr. Director;

In the clinical laboratory setting, quality is synonymous with safety. Today, every effort must first be made to detect errors before putting the patient in risk. At present, analytical quality is perhaps more critical because patient tests are performed by different measurement processes, in different laboratories and by personnel with different laboratory skills. [1] Greater rigor is therefore required.

Motivated by the reading of the article *"External assessment of quality in clinical chemistry in Pinar del Río"*, published in La Revista de Ciencias Médicas de Pinar del Río Vol. 22, No. 2 (2018), we desire to address a group of reflections related to this topic.

The importance of the Clinical Laboratory in the care system is sustained, on the one hand, by its clinical weight, since it is undoubtedly the most widely used diagnostic tool, as it is present in 80 % of clinical decisions and, on the other hand, by the consumption of resources for the system which, in terms of direct costs in the laboratory, represents a proportion of around 12 % of the total hospital expenditure.

In the last 30 years clinical laboratories have had an exponential development as a result of the boom in Chemistry, Molecular Biology, Technology and Information Technology, hence the cost per test has increased by 130 %, which, together with the excessive use of laboratory tests (for various reasons), implies a higher cost per patient.[2]

Currently, the main reasons for requesting laboratory studies are: to confirm, establish, or rule out a diagnosis; to discover a subclinical disease; to obtain prognostic information concerning a disease; and to know the therapeutic response.

The Quality Management System in which it is based consists of the following phases: pre-analytical, analytical and post-analytical in which Internal Quality Control and External Quality Control are applied, each one with its individual characteristics for each phase.[3]

The first tests of quality assessment with the objective of designing strategies to improve their performance were developed by Leve and Jennings, [4] who proposed the adjustment of the industrial quality control procedures used by Shewhart to clinical laboratories, thus becoming the first evidence of the application of control charts in the clinical laboratory area.

The subsequent works conducted by Westgard and Groth, [5] proposed that quality control should include two types of control rules: those sensitive to the detection of systematic error (bounds and trends) and random errors (increased imprecision). Over time they have developed to have, at present, with the combination of rules known as Westgard rules or multi-rules of quality control.

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The changes that the clinical laboratory has undergone since then have also affected the typing of errors that mark the strategic lines for achieving quality and accreditation. In the 1970s, errors were mostly seen in the analytical phase with the increase of technology, today they are less because 80 % of the burden of errors, is in the pre-analytical and post-analytical phases (more in the first one, because the computerization has benefited the last one). (2)

For this to take place there is the cycle of laboratory tests. This process begins with the doctor in front of the patient, who after a particular questioning and clinical examination guides the studies to be conducted, with the corresponding explanations: what the analysis will consist of and whether to take measures prior to the study in addition to the corresponding fast. From this moment the sample begins its transfer throughout the laboratory. The results are evaluated according to the diagnostic impression and to the concordance (or not) the results are compared with the attending physician, the results obtained are compared with the first impression of the physician, through questioning and clinical examination, or new studies are indicated.

Internal Quality Assurance is not a replacement for External Quality Assurance. Both must be present. External quality assessment (EQA) involves several laboratories, as it analyzes the same control sample. This allows an individual laboratory to compare its performance with the rest of the group. In addition, it allows detecting equipment failures, reagent problems and revealing difficulties and deficiencies of analytical procedures that only manifest themselves during their extensive and long term use; these strengths allow evaluating and putting into practice the corrective measures in time.

Everything concerning the Internal Quality Control is applied, and we have established the external control among our units for several years, from these results we foster ourselves to detect, foresee and correct the errors that affect the reliability of our results and we must point out that for some time ago it was included in the national quality control.

As nowadays laboratory errors are mostly dependent on the pre-analytical phase and this, in turn, on a good job performed by the doctor, and nurse, the preparation of patient along with the obtaining of samples, that is why we request you, fellow Director, the diffusion of this work that is aimed at doing our bit to the quality and reliability of laboratory studies.

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