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ORIGINAL ARTICLE

Importance of implementing an analytical quality control system in a core laboratory

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KEYWORDS
Analytical quality;
Control system specifications;
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Abstract
Introduction: The aim of the clinical laboratory is to provide useful information for screening, diagnosis and monitoring of disease. The laboratory should ensure the quality of extra-analytical and analytical process, based on set criteria. To do this, it develops and implements a system of internal quality control, designed to detect errors, and compare its data with other laboratories, through external quality control. In this way it has a tool to detect the fulfillment of the objectives set, and in case of errors, allowing corrective actions to be made, and ensure the reliability of the results.
Objective: This article sets out to describe the design and implementation of an internal quality control protocol, as well as its periodical assessment intervals (6 months) to determine compliance with pre-determined specifications (Stockholm Consensus[1]).
Materials and methods: A total of 40 biochemical and 15 immunochemical methods were evaluated using three different control materials. Next, a standard operation procedure was planned to develop a system of internal quality control that included calculating the error of the analytical process, setting quality specifications, and verifying compliance.
Results: The quality control data were then statistically depicted as means, standard deviations, and coefficients of variation, as well as systematic, random, and total errors. The quality specifications were then fixed and the operational rules to apply in the analytical process were calculated. Finally, our data were compared with those of other laboratories through an external quality assurance program.
Discussion: The development of an analytical quality control system is a highly structured process. This should be designed to detect errors that compromise the stability of the analytical process. The laboratory should review its quality indicators, systematic, random and total error at regular intervals, in order to ensure that they are meeting pre-determined specifications, and if not, apply the appropriate corrective actions.

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PALABRAS CLAVE
Calidad analítica;
Sistema de control especificaciones;
Regla operativa

Importancia de la implementación de un sistema de calidad analítica en un laboratorio de rutina

Resumen
Introducción: El objetivo del laboratorio clínico es proporcionar información útil para el cribado, diagnóstico y seguimiento de las enfermedades. Este debe garantizar la calidad del proceso analítico y extraanalítico, en base a unos requisitos establecidos. Para ello, se desarrolla y aplica un sistema de control de calidad interno, encaminado a detectar errores, y se intercomparan estos datos con otros laboratorios, a través de un control de calidad externo. Así, disponemos de una herramienta para detectar el cumplimiento de los objetivos establecidos, permitiéndonos implantar acciones correctivas, y asegurar la fiabilidad de los resultados, en caso de detectar errores.
Objetivo: : En este trabajo se describe el diseño e implantación de un protocolo de control de calidad interno. Además, su evaluación a periodos de tiempo regulares (6 meses), para determinar el cumplimiento de las especificaciones predeterminadas (Consenso de Estocolmo[1]).
Materiales y métodos: Se valoraron 40 magnitudes de bioquímica y 15 de inmunoquímica, utilizando 3 materiales de control diferentes. A continuación, se planificó un procedimiento operativo para desarrollar un sistema de control de calidad interno, calculando los errores del proceso analítico, así como fijando especificaciones de calidad, y verificando su cumplimiento.
Resultados: Se caracterizaron estadísticamente los datos calculando media, desviación estándar y coeficiente de variación; así como errores sistemático, aleatorio y total. Posteriormente, se fijaron las especificaciones de calidad y se calcularon las reglas operativas a aplicar en el proceso analítico. Finalmente, se compararon nuestros datos con los de otros laboratorios a través de un sistema de calidad externo.
Discusión: El desarrollo de un sistema de calidad analítico es un proceso altamente estructurado. Este debe diseñarse para detectar errores que comprometan la estabilidad del proceso analítico. A intervalos de tiempo regulares, el laboratorio debe revisar sus indicadores de calidad, error sistemático, aleatorio y total, con el objeto de saber si se están cumpliendo las especificaciones predeterminadas. En caso negativo, aplicar las acciones correctivas adecuadas.

Introduction

The objective of the clinical laboratory is to provide useful information for screening, diagnosis and monitoring diseases. For this reason, the laboratory performs determinations in patient's samples by measurement procedures that ensure to get credible and reliable information for clinical use. Within the analytical process, the laboratory must ensure its quality, not only verifying that pre-established requirements are met, but also confirming that the benefits obtained meet the expectations of both the requesting physicians and patients seen. Internal quality control is the initial stages of any system of quality management that is implanted in the clinical laboratory, and based on this analytical phase interleave control materials of their composition, qualitative or quantitative known, between patient samples. If these results are within pre-established limits, the laboratory considered that the analytical process works properly and accepts the run, being able to generate the analytical report.

Currently recommended quality control plan individually for each constituent as tolerable error limits and the analytical performance of methods are different, in order to achieve maximum analytical quality. Proper selection allows clinicians meet the quality requirements at the lowest cost, since the unnecessary rejection of analytical series is avoided and the number of controls is reduced.[2]

The steps in designing a protocol for analytical quality control are:

(1) Definition of the aim pursued (for example, satisfy medical needs for diagnosis, monitoring, treatment of the patient; meet legal requirements; achieve delivery defined by the manufacturer, etc).
(2) Definition of quality specifications selecting those appropriate indicators (imprecision, systematic error, total error) as well as the limits of acceptability thereof. Based on the 5 criteria proposed in the Stockholm Consensus[1] (imprecision and systematic error in specific clinical situations, biological variation, opinions of clinicians, expert recommendations, and state of the art), or reduced to 3 criteria proposed in the review carried out in the Milan Consensus[3] (expert opinion biological variability, and state of the art)
(3) Implement a strategy that is consistent with the defined goal (operating rules of quality control) whose purpose will warn us at what time the analytical process does not meet the specifications defined for what the laboratory should periodically check through analysis compliance results. This will allow us to detect errors that can analyze and establish corrective measures to avoid the negative repercussion in issuing results and ensuring the reliability thereof.[4] This implies prior knowledge of the imprecision and accuracy of each biological scale,