



ORIGINAL ARTICLE

Quality indicators for extra-analytical processes in clinical laboratory: Ten years' experience



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Abstract

Introduction: The selection and definition of quality indicators is essential for proper control of processes. This is not always easy, particularly with extra-analytical indicators, due to the complexity and degree of comparison of processes between laboratories, and the fact that data collection is not always automated. For this reason, the indicators and specifications need to be dynamic and re-designed in accordance with changes in the system. The aim of this paper is to describe the methodology used in the selection and definition of quality indicators, and their specifications for extra-analytical processes in public laboratories in Catalonia.

Material and methods: During the study period (2004–2013), the members of the working group reported the mean annual value for each indicator, and the overall yearly mean of all participants was calculated. These results were compared and analyzed during periodic meetings, with regards to the pre-established specifications of the different laboratories.

Results: Quality indicators and their specifications are presented. The evaluation of the validity of each quality indicator was made taking into account aspects including usefulness of the indicator in process monitoring, a clear definition, and a precise and reliable quantification. This methodology has made it possible to contrast the validity of the indicators or to reconsider the specification.

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PALABRAS CLAVE

Indicadores de calidad;
Especificaciones de calidad;
Procesos del laboratorio;
Gestión del laboratorio

Conclusions: The last 10 years' experience of the Catalan Health Institute Working Group on Quality Indicators in designing indicators and establishing quality specifications has proved very useful for improving the monitoring of processes in clinical laboratories included in the group. © 2016 AEBM, AEFA y SEQC. Published by Elsevier España, S.L.U. All rights reserved.

Indicadores de calidad para los procesos extra-analíticos en el laboratorio clínico: 10 años de experiencia

Resumen

Introducción: La selección y definición de los indicadores de la calidad es imprescindible para controlar adecuadamente un proceso. Ello no siempre es fácil, sobre todo en el caso de los indicadores extraanalíticos, dada la complejidad y grado de comparabilidad de los procesos entre laboratorios y la necesaria recogida de datos que en muchas ocasiones no está automatizada. Asimismo, los indicadores y especificaciones deben ser dinámicos y rediseñarse en función de los cambios del sistema. El objetivo de este trabajo es describir la metodología utilizada en la selección y definición de indicadores de calidad y especificaciones para los procesos extraanalíticos en los laboratorios públicos de Cataluña.

Material y métodos: Durante el período de estudio (2004-2013), los miembros del grupo han informado del valor medio anual para cada indicador, y se ha calculado la media anual de todos los participantes para cada uno de ellos. Estos resultados se han comparado y analizado a través de reuniones periódicas, con respecto a las especificaciones preestablecidas de los diferentes laboratorios.

Resultados: Se presentan los indicadores de calidad y sus especificaciones. La evaluación de la validez de cada indicador de calidad se llevó a cabo teniendo en cuenta los aspectos incluyendo la utilidad del indicador en la supervisión de procesos, una definición clara y una cuantificación precisa y fiable. Esta metodología ha permitido contrastar la validez de los indicadores o reconsiderar la especificación.

Conclusiones: Los últimos 10 años de experiencia del Grupo de Trabajo del Instituto Catalán de la Salud de Indicadores de Calidad en el diseño de indicadores y en establecer especificaciones de calidad ha demostrado ser muy útil para mejorar el seguimiento de los procesos en los laboratorios clínicos integrados en el grupo.

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Introduction

Quality indicators are a key element to evaluate and monitor any Quality management system and should be designed in order to detect at an early stage, variances in systems and implement correction measures and/or prevent errors which could have an impact on patient safety.¹ To carry through the support activities for the diagnostic and follow up the different health conditions, laboratories should establish quality specifications in all processes that take place both inside and outside the lab, from the moment a doctor asks for a blood test until the results of such are received.

The Catalan Health Institute Working Group on Quality was created in 2004, composed of the responsible for quality in public laboratories in Catalonia, of the Institut Català de la Salut (ICS) which caters for a population of seven million people. The main purpose of the Group was to select and define the most appropriate Quality Indicators to monitor laboratory processes and to fix their quality specifications or acceptability limit, in the interests of patient safety.

The aim of this paper is to describe the methodology used in the selection and definition of quality indicators and their

specifications for extra-analytical processes in public laboratories in Catalonia. We also present their modification taken from the evaluation of the corresponding data from 2004 to 2013.

Subject and method

The composition of the working group has varied over time due to the reorganization of the laboratories within the Catalan public health system (ICS). Finally, the study group was made up of 12 laboratories, 4 of which worked in the area of primary health care, 2 in hospital care and the other 6 in both primary and hospital care areas. All of them have a management System of Quality control available according to the ISO 9001 norm, except one, which conforms to the 15189 norm.

Comparison of the different types of processes was a previous step to the study of indicators, agreeing on classify them in key, strategy and support processes.

In the first stage,^{2,3} indicators for the different processes were set out, the frequency of measurement, the

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