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ORIGINAL ARTICLE

Analysis of the selection process for new drugs in a tertiary hospital 2004-2007

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Abstract
Objective: The purpose of this study is to describe the structure of the CFyT, the Pharmacy and Therapeutics Committee, and a tertiary hospital's selection process for new drugs.
Material and methods: All annals of the PTC and the New Drug Incorporation Guides (GINF) to incorporate new drugs received at Hospital Virgen del Rocío between 2004 and 2007 were reviewed. We carried out a descriptive study which collected variables having to do with the drug (drug type, type of register, route of administration and legal category), the petitioner (responsible division, professional category and request type) and the result of the evaluation (final decision, elapsed time between the request and the decision).
Results: Of the 72 requested drugs, 45 (62.5%) were approved: six as equivalent treatments, 36 (80%) with specific recommendations, and three (4.2%) with no restrictions. Twelve drugs (81.1%) were not included due to insufficient evidence of their effectiveness compared with the current treatment. The most frequently-requested drug type was the antineoplastics, most commonly requested by Oncology and Haematology divisions. We highlight the fact that many of the petitioners included clinical trials (97.2%) and data referring to costs (84.7%).
Conclusions: There is a high level of compliance with the GINF guide in our centre, which guarantees that the P&TC's final decision is based on scientific evidence.

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PALABRAS CLAVE
Guía para la Incorporación de Nuevos Fármacos;
Selección;
Nuevos medicamentos;
Comisión de Farmacia y Terapéutica;
Guía Farmacoterapéutica

Análisis del proceso de selección de nuevos medicamentos en un hospital terciario. Años 2004-07

Resumen

Objetivo: Describir la estructura de la Comisión de Farmacia y Terapéutica y el proceso de selección de nuevos medicamentos de un hospital terciario.

Material y métodos: Se revisan todas las actas de la Comisión de Farmacia y Terapéutica y las Guías para la Incorporación de Nuevos Fármacos recibidas en el periodo 2004-2007 en el Hospital Universitario Virgen del Rocío. Se realiza un estudio descriptivo que recoge variables relacionadas con el fármaco (grupo terapéutico, vía de registro, vía de administración y categoría legal), con el solicitante (servicio al que pertenece, categoría profesional y tipo de petición) y con el resultado de la evaluación (decisión final adoptada y tiempo de retraso entre la petición y la decisión).

Resultados: De los 72 medicamentos solicitados, se aprobaron 45 (62,5%), 6 como equivalentes terapéuticos, 36 (80%) con recomendaciones específicas y 3 (4,2%) sin ninguna restricción. De los fármacos no incluidos, en 12 (81,1%) fue por insuficiente evidencia de su eficacia comparada con el tratamiento actual. El grupo terapéutico solicitado con más frecuencia fue el de los antineoplásicos, destacando Oncología y Hematología entre los peticionarios. Destaca el alto porcentaje de solicitantes que aportaron ensayos clínicos (97,2%) y datos referentes al coste (84,7%).

Conclusiones: Existe un alto grado de cumplimentación de la Guía para la Incorporación de Nuevos Fármacos en nuestro centro que garantiza una decisión final por parte de la Comisión de Farmacia y Terapéutica basada en la evidencia científica.

Introduction

The European Union policy on drug registration does not allow evaluation of new medications in the context of the rest of the existing alternatives, which obliges hospitals to perform their own evaluations.[1,2] This function falls to the responsibility of the Pharmacy and Therapeutic Commissions (PTC).[3] The final decision of whether or not to incorporate a medication into use at a hospital and the establishment of conditions of its use, in the case of inclusion, must be made under regulated procedures based on an analysis of the available evidence.[4]

In spite of the coincidence between the various institutions regarding the criteria that are used to evaluate the medications and tools to be used, an appreciable level of variability between the decisions adopted by the PTCs at different hospitals has been identified.[5-7]

This variability could be due to the disparities between the tools used in the selection process for medications and the differences in clinical practice that could implicate differences in equality and accessibility of certain treatments.[8] Therefore, it is necessary to use standardised tools (application guides, evaluations, and work protocols). It is also necessary to evaluate the validity of these tools, their level of implantation and completion, as well as product quality.

In an earlier publication by our group, the PTC activity at our hospital was evaluated along with the implantation of the Guide for Incorporation of New Drugs (GINF) during the 2002-2003 period.[9] Other studies have evaluated the implantation of other tools,[10] such as the report model established in 2005 by the GENESIS group.[11]

The objective of this study was to describe the structure of the PTC and the selection process for new medications in a tertiary hospital during the 2004-2007 period.

Material and methods

We performed a descriptive analysis of the characteristics for the process of application and decision making of the PTC at the Virgen del Rocío University Hospital, based on a previous article published by our group.[9]

The study sample was made up of all of the applications for incorporation of new medications received in the PTC during the period of 2004-2007. The commission reviews all of the available drugs at the hospital, including relevant compassionate use and foreign drugs, works in accordance with a standardised protocol that complies with standard principals.[12,13] and is based primarily on two instruments: the GINF request guide[14] and the GENESIS evaluation report.

We identified all of the medications that requested an evaluation during this period through the PTC. For each drug, variables related to the medication (therapeutic group, method of registration and administration, and legal category), with the petitioner (professional affiliation, professional category, sex, and type of request), and with the GINF request (one variable for each of the questions on the questionnaire not previously covered).

Our study variables were the same as those that appear on the questionnaire for compliance by the petitioner. As a result, the variables collected for each medication were: therapeutic group according to the first digit in the ATC