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VP81 Health Technology Assessment And Rare Disease Decision Making: Focus On Orphan Drugs

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INTRODUCTION:

Health Technology Assessment (HTA) is applied to determine the value of innovative technologies. It usually relies on robust assessment of the clinical cost-effectiveness of the technology, while clinical and economic evidence required for this purpose are often not available for orphan drugs (OD) (1,2). The objective of the study is to undertake a systematic comparison between HTA agencies worldwide in order to identify similarities and differences in the methods and processes in HTA of OD.

METHODS:

A cross-sectional web-based survey was conducted between September 2013 and May 2015. The data were obtained from a semi-structured questionnaire. We received responces from 161 HTA organizations based in 39 countries.

RESULTS:

HTA of OD is performed by agencies in South America (38.5 percent), followed by agencies in Australia (37.5 percent) and Europe (36.1 percent). The agencies in high income countries produce more assessments of OD (36.8 percent), which in 31.2 percent they determine as innovative technologies compared with 11.8 percent of the units based in low income countries and active in OD assessment (11.1 percent). We prove association ($p < .05$) between (i) the type of HTA and income per capita; the level at which the organization operates; its main activity; and the level of recommendation dissemination; (ii) the main target group and consumers of the final HTA product; the stage of evolution of the technology, on which it is likely to be assessed; and approaches to identify innovative technologies. The most active in the preparation of HTA reports are biomedical companies or other organizations in the private sector (50.0 percent) and organizations in the pharmaceutical and/or medical industry (66.7 percent). HTA bodies that assess OD develop (36.0 percent) and distribute recommendations (35.9 percent) nationally; their main activity is to produce guidelines for good clinical practice (46.9 percent). Agencies that perform OD assessment are active in evaluation of innovative (37.2 percent) and emerging (35.9 percent) technologies, which are able to be identified by developing early warning systems (32.0 percent).

CONCLUSIONS:

Making coverage decisions based on HTA recommendations control the technologies introduction into the healthcare system, that is why it's very important that this tool is properly adjusted to the specific needs of OD assessment (3).

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VP83 How To Identify Technologies Eligible For Health Technology Assessment: A Bottom-Up Approach

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INTRODUCTION:

Governance of health technologies in Emilia-Romagna region, Italy, includes a local and a regional level. Medical devices (MDs) are requested by clinicians to hospital committees that may carry out an evaluation at local level or ask for a regional evaluation using Health Technology Assessment (HTA) methodology. Until the past year, committees weren't provided with a clear pathway to identify technologies for regional HTA evaluation. The aim of this study was to describe a bottom-up, shared approach to produce a tool with elements to be considered when judging if a technology is eligible for regional HTA or not.

METHODS:

To identify elements, we adopted a qualitative approach and the methodology of focus group (1,2) which consisted in starting from health professionals experience to build a shared knowledge. Two panels of stakeholders were convened, the first one comprising regional decision-makers deciding whether to reimburse and introduce a MD in Regional Health System; the second panel comprised regional clinicians that use, test and ask for MDs. Panels were asked to capture possible elements of MDs that should be considered for identifying the most promising and interesting ones for a regional HTA.

RESULTS:

The two panels (seventeen regional clinicians and twenty-two decision makers, respectively) had two operative meetings and worked in parallel. At the end of the second meeting, a draft of the tool with elements identified by both groups was built. Panels were asked to test the draft on few medical devices and identify possible tool's criticalities limiting transferability. Tool resulted user-friendly and complete, requiring no changes. The final version, approved by two panels convened together during the last meeting, reports thirty-two distinct items referred to five domains (that is, potential: innovativeness, clinical, economic, and organizational impact, environmental factors). Each item must be valued on a Likert scale. The tool will be applied on every MD requested by regional clinicians and before implementation it will be tested during a 6-month pilot phase beginning March 2017.

CONCLUSIONS:

The process was plain and feedback from stakeholders has been positive. The tool is expected to increase transparency and homogeneity in identifying technologies eligible for regional HTA.

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