

3. Iskrov G, Stefanov R. Post-marketing access to orphan drugs: a critical analysis of health technology assessment and reimbursement decisionmaking considerations. *Orphan Drugs: Research and Reviews*. 2014;4:1-9.

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

AUTHORS:

Susanna Maltoni
(susanna.maltoni@regione.emilia-romagna.it), Maria
Domenica Camerlingo, Antonella Negro, Luigi Palestini,
Giovanni Ragazzi, Fabio Trimaglio

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.

REFERENCES:

1. Bloor M, Frankland J, Thomas M, Robson K. *Focus Groups in Social Research*. 2001. London SAGE Publications Ltd, 110 pages.
 2. Morgan DL, Krueger RA. *The Focus Group Kit*, Volumes 1-6. 1997. SAGE Publications Ltd.: <http://sk.sagepub.com/books/the-focus-group-guidebook>
-