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GIENS WORKSHOPS 2015 /*Medical devices*

Organisational impact: Definition and assessment methods for medical devices☆

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Summary Health technology assessment (HTA) is a rapidly developing area and the value of taking non-clinical fields into consideration is growing. Although the health-economic aspect is commonly recognised, evaluating organisational impact has not been studied nearly as much. The goal of this work was to provide a definition of organisational impact in the sector of medical devices by defining its contours and exploring the evaluation methods specific to this field. Following an analysis of the literature concerning the impact of technologies on organisations as well as the medical literature, and also after reviewing the regulatory texts in this respect, the group of experts identified 12 types of organisational impact. A number of medical devices were carefully screened using the criteria grid, which proved to be operational and to differentiate properly. From the analysis of the practice and of the methods described, the group was then able to derive a few guidelines to successfully evaluate organisational impact. This work shows that taking organisational impact into consideration may be critical alongside of the other criteria currently in favour (clinically and economically). What remains is to confer a role in the decision-making process on this factor and one that meets the economic efficiency principle.

Abbreviations

AdHopHTA Adopting Hospital based HTA in the EU
ANAP *Agence nationale d'appui à la performance*
CEESP Economic and Public Health Evaluation Committee (*Commission d'évaluation économique et de santé publique*)
CEDIT Committee for Evaluation and Dissemination of Innovative Technologies (*Comité d'évaluation et de diffusion des innovations technologiques*)
CHU French University Hospitals
DGOS *Direction générale de l'offre de soins*
DSS *Direction de la sécurité sociale*
ECHTA European Collaboration for Assessment of Health Interventions
EUnetHTA European Network of Health Technology Assessment
HAS French National Authority for Health (*Haute Autorité de santé*)
HTA Health Technologies Assessments
KCE Belgian Health Care Knowledge Centre (*Centre fédéral d'expertise des soins de santé*)
MD medical devices
NHS UK National Health Service
OI organisational device
PHI public health interest
VSM value stream mapping

Introduction

In France, health technology assessment (HTA) is a fast-developing discipline, no matter what the end-purpose may be (assessment with a view to national adoption at State and local government level, local hospital evaluation, etc.). It initially focused on evaluating the clinical benefit (efficacy in relation to risk, place in diagnostics or therapeutic strategy, clinical utility). Then, due to a health system under increasing economic pressure, the health-economic field gradually took precedence. In fact, in 2008 and at national level, France endowed itself with an authority devoted this area within the French National Authority for Health (*Haute Autorité de santé* [HAS]), the Economic and Public Health Evaluation Committee (*Commission d'évaluation économique et de santé publique* [CEESP]).

However, HTA models like the one provided by the European Network of Health Technology Assessment (EUnetHTA) reveal the value of taking other fields into account in order to consider the overall aspects of benefits that any one health technology may contribute to the health care system.

This is all the more meaningful when HTA focuses on the area of medical devices (MDs).[1] Indeed, as is emphasized in the article published following the round table at the 2014 Giens workshops on the non-clinical impact of MDs [1], a purely clinical evaluation does not summarise the full effect had by any specific MD. Contrary to a drug, MDs are extremely varied in nature and are ''operator-dependent'', whether the latter be health professionals or individual patients. One distinction between the clinical and non-clinical impact was endorsed by the consensus reached among the participants in this round table discussion: ''The clinical criteria are the morbidity and mortality criteria. Certain intermediary criteria are also considered to be clinical criteria, as are those having a direct or indirect impact on morbidity and mortality. Non-clinical criteria encompass all the other criteria as a whole. They may have an individual or collective impact. They concern the patients, their

[1] Medical devices (defined in article L. 5211-1 of the French Public Health Code) are health technologies that encompass a very broad range of products, whether single-use or reusable and for individual or collective use, including notably implantable materials/devices, consumables, or even medical equipment. Medical devices used for in vitro diagnostics (MD-IVD), defined in article L. 5221-1 of the French Code of Public Health also fall within the field of reflection below.