Thérapie 2015 Janvier-Février; 70 (1): 63—68
DOI: 10.2515/therapie/2015004

Assessment and Non-clinical Impact of Medical Devices

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Text received January 8th, 2015; accepted January 13th, 2015

Keywords:
medical devices;
assessment;
health technology assessment (HTA)

Abstract – Medical devices (MDs) cover a wide variety of products. They accompany changes in medical practice in step with technology innovations. Innovations in the field of MDs can improve the conditions of use of health technology and/or modify the organisation of care beyond the strict diagnostic or therapeutic benefit for the patients. However, these non purely clinical criteria seem to be only rarely documented or taken into account in the assessment of MDs during reimbursement decisions at national level or for formulary listing by hospitals even though multidimensional models for the assessment of health technologies have been developed that take into account the views of all stakeholders in the healthcare system In this article, after summarising the background concerning the assessment of health technologies in France, a definition of non-clinical criteria for the assessment of MDs is proposed and a decision tree for the assessment of MDs is described. Future lines of approach are proposed as a conclusion.

Abbreviations: see end of article.

† Articles, analyses and proposals from the Giens workshops are those of the authors and do not prejudic the proposition of their parent organization.

Article publié par EDP Sciences

1. Introduction

A medical device (MD) is defined in the Public Health Code (Article L5211-1) as follows: "A medical device is understood to be any instrument, appliance, equipment, material, product, except for products of human origin, or other item used alone or in combination, including the accessories and software involved in its functioning, intended by the manufacturer to be used in humans for medical purposes and whose principal intended action is not obtained by pharmacological or immunological means or by metabolism, but whose function can be assisted by such means. The software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes is also a medical device". The Public Health Code also defines active implantable medical devices and medical devices for *in vitro* diagnosis[1] which fall within the scope of the following discussion.

MDs therefore comprise a wide variety of products ranging from consumables to onerous imaging equipment, through implantable prostheses, technical aids for the disabled, bandages, splints, some softwares etc. Three main categories of MDs are usually distinguished:

1. disposable or single use consumables or implantable materials;
2. reusable materials;
3. equipment.

MDs are distinguished by several specific characteristics including two that are discussed in more detail below:

– a life cycle that can be very short: the pace of technological developments in this sector is rapid and the innovation cycles for a given product are about 2-5 years. In fact, it is often gradual technology developments that provide improvements in terms of diagnostic care, treatment or compensation of disability;

– a characteristic called operator-dependent: MDs are intended to be used by health professionals (physician, surgeon, nurse etc.), patients, or someone in their family circle. Because of this specificity, MDs are more or less operator-dependent hence the notion of benefits beyond the strict therapeutic (or diagnostic) benefit for the patient.

Technological advances in MDs therefore accompany changes in medical practice and may play an important role in the organisation of care (patient autonomy, reduction in the burden of care, access to care, impact on length of hospital stay, surgery etc.) or the safety of care (workplace safety for medical staff, improved ergonomics etc.).

However these not purely clinical criteria of MDs seem to be only rarely documented or taken into account in the assessments, either during assessments at national level for eligibility for reimbursement (National Committee for the Evaluation of Medical Devices and Health Technologies [*Commission Nationale d'Evaluation des Dispositfs Médicaux et des Technologies de Santé*, CNEDiMTS], Economic Evaluation and Public Health Committee [*Commission d'Evaluation Economique de Santé Publique*, CEESP]) or locally when deciding whether to adopt a new technology in a hospital, for example.

Given the observation that a purely clinical assessment often does not sum up the full impact of a MD, the relevance of the clinical assessment alone and its impact on decision making was questioned. The purpose of the round table was therefore: 1- to analyse to what extent non-clinical criteria are currently integrated or not in national and local assessments; 2- if it is legitimate and relevant to integrate these criteria in evaluations and if so, how? Finally; 3- if the inclusion of these criteria in assessments could have an impact on decision making.

2. Definitions

The purpose of MDs is not only therapeutic. It can be diagnostic but also to compensate for a disability. In the field of disability compensation, MDs are designed to increase patient autonomy and quality of life. In addition, many MDs are indirectly used for the management of patients. These devices are intended for health professionals and not patients. They can improve the safety of health interventions or a medical procedure without necessarily having an immediate or easily measurable impact on patient health. For example:

- improved ergonomics with an impact on users (medical staff, patients and caregivers);
- protection during medical procedures (prevention of blood exposure accidents, or risks related to ionizing radiation and chemicals);
- a reduction in the length of the learning curve and improved reproducibility of surgical operations;
- invasive surgical with less injury to the body;
- a reduction in the duration of surgery and/or length of hospital stay;
- development of home care for patients;
- increasingly early diagnosis for new treatment methods.

1. Article L5211-1 of the Public Health Code "Medical devices that are designed to be implanted in whole or in part in the human body or placed into a natural orifice, and which depend for their operation on a source of electrical energy or any source of power other than that which is directly generated by the human body or gravity, are called **active implantable medical devices**"
Article L5121-1 of the Public Health Code "*In vitro* diagnostic medical devices are those products, reagents, materials, instruments, and systems, their components and accessories, as well as specimen receptacles, specifically intended for use *in vitro*, alone or in combination, in the examination of samples from the human body in order to provide information about a current or potential physiological or pathological condition or a congenital abnormality, to monitor therapeutic measures, or determine the safety of harvesting human body parts or its compatibility with potential recipients."