30-day cumulative morbidity and mortality rate of endovascular procedure associated with stenting. Medico-administrative databases provide information on age, sex, symptomatic or asymptomatic stenosis in-hospital mortality and long-term mortality (with a linkage to epidemiological data) and morbidity estimated by ischemic stroke.

RESULTS:

The database allowed selection of a cohort of 2,071 patients in whom carotid stenting was performed in 161 centers (40 percent of stents were implanted in 14 centers) with a follow-up of 1 year. Carotid stents were mainly implanted in asymptomatic patients (81.6 percent). Morbi-mortality in symptomatic patients at 30 days (9.2 percent: 5.7 percent stroke and 3.4 percent mortality) was similar with results observed in a French comparative study EVA-3S (9.6 percent: 2.8 percent stroke and 8.8 percent mortality). These data allow the concerned HAS (French Health Authority) committee to renew the reimbursement proposal of these stents.

CONCLUSIONS:

Medico-administrative database collecting robust criteria can be used to support reimbursement renewal of high risk implantable medical devices. The implementation of other criteria including the disease etiology and the complications imputability may allow to consider the use of these data for non-invasive MD.

OP125 A New Collaborative Approach To Assess Innovative Health Technologies

AUTHORS:

Michèle de Guise (michele.de.guise@inesss.qc.ca), Geneviève Plamondon, Mariève Simoncelli

INTRODUCTION:

Decision makers worldwide face the challenge of offering the best health care within a context of scarce resources. Technological developments have multiplied in the past decades, with the lifecycle of technologies becoming shorter. As a result, the traditional Health Technology Assessment (HTA) model is often caught in a too early, too late syndrome. In the province of Québec (Canada), there is no standardized process for assessing non-pharmaceutical technologies for reimbursement purposes, and technologies are therefore introduced via multiple sources. There are concerns that the introduction of some of the most promising technologies is delayed, and on the contrary, that others are introduced without providing a real added value to patients and the health system.

METHODS:

INESSS (Institut national d'excellence en santé et services sociaux), collectively with stakeholders of the Québec innovation field, has developed a dynamic process for assessing the added value of innovative technologies. POETIS (Processus optimisé d'évaluation des technologies innovantes en santé) aims to identify the technologies with the highest potential for positive impact on patients and the health system, in order to accelerate their implementation and promote their optimal use.

RESULTS:

POETIS comprises four phases aligned with the lifecycle of technologies: research and development, pre-implementation, limited implementation, and diffusion. It allows a continuum of assessment, from the promise of a technology to its real-world benefit. It differs from other approaches because of the sustained involvement of key stakeholders, including patients, and because it assesses technologies iteratively, therefore fostering their adaptation to better suit patients needs. It is hoped for the first technologies to be assessed in 2017.

CONCLUSIONS:

HTA has to adapt to the challenges of innovation, and this could be done with a lifecycle approach and an enhanced collaboration with end-users. Developed in Canada, the goals behind POETIS are common to many

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countries and the process could be adapted by other HTA agencies.

OP126 The European Network For Health Technology Assessment (EUnetHTA) Template To Aid Health Technology Assessment-based Decisions

AUTHORS:

Luciana Ballini (luciana.ballini@regione.emilia-romagna.it), Laura Bonvicini, Paolo Giorgi Rossi, Massimo Vicentini

ABSTRACT DATA FOR PRINT:

INTRODUCTION:

Health professionals often advocate and request innovative health technologies, perceiving Health Technology Assessment (HTA) as a delay or counterargument to their requests. To facilitate engagement of professionals and decision makers in the HTA process and endorsement of process outputs, a system for technology requests submission, based on the European Network for HTA (EUnetHTA) Submission Template, was established and subsequently piloted in a cancer research institute.

METHODS:

The "EUnetHTA medical devices evidence submission template" for companies (1) was adapted for use by professionals proposing a health technology for acquisition. Adaptation consisted mainly in: re-arrangement of chapters order with emphasis on the health problem, unmet needs, claimed additional benefits of the technology and potential for research; inclusion of information on costs/financial resources; and inclusion of a summary with a pre-defined set of brief statements to inform appraisal. The headings for the nine one-paragraph statements were: relevance of the health problem; degree of innovativeness of the technology; potential clinical impact; potential research relevance; comparative safety and effectiveness; economic impact; organizational impact; availability/quality of scientific literature; and degree of diffusion. Decision makers discussed the appraisal's statements with the proponents before reaching a conclusion.

RESULTS:

From January 2016 technology requests were examined only if presented through the submission template. Results from submissions of three innovative technologies for prostate cancer treatment, endovascular procedures and cataract surgery will be discussed. Acceptability of the submission template was high and professionals — supported by experts available in their institution (clinical engineers, epidemiologists and others) — were successful in completing the dossier. Decision-makers appraisal proved facilitated and transparent. Concerted decisions were taken within a few weeks from submission.

CONCLUSIONS:

The EUnetHTA tool proved flexible and valuable to initiate an HTA-based decision-making process. Appraisal was cooperative and proponents were involved in the decisions, through a process requiring a mean total time of 6 months. Participants' misgivings were overcome by transparency and objectivity of the process.

REFERENCE:

1. EUnetHTA Evidence Submission Template for Medical Device (available at http://www.eunethta.eu/outputs/submission-template-pharmaceuticals-and-submission-template-medical-devices)

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