The Current and Future Lifecycle Approach to Decision Making on Health Technologies

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KEY POINTS . . .

We need to facilitate efficient use of resources available for health technology assessment (HTA).

We need to create a sustainable system of HTA collaboration and knowledge-sharing.

We need to promote 'good practices' in HTA methods and processes.

This is one of three articles in this issue on the topic of decision making on health care technologies. This article by Dr. Kristensen presents EUnetHTA's approach and the HTA Core Model®.

The European Network for Health Technology Assessment (EUnetHTA) and the lifecycle approach is not a new thing for people working in this area. EUnetHTA, established in 2006, has been the scientific and technological backbone of the health technology assessment development in the European Union and among its member states. EUnetHTA supports collaboration between European HTA organizations that bring added value at the European, national, and regional levels. These collaborations facilitate efficient use of resources available for HTA, create a sustainable system of HTA knowledge-sharing, and promote good practice in HTA methods and processes.

EUnetHTA is an international network comprised of 68 organizations (38 associated partners and 30 collaborating partners from 28 EU member states, including Norway, Switzerland, Russia, and Turkey). The voluntary and collaborative spirit of EUneHTA among its participating states has always sought to combine volunteerism with an obligation to contribute and share. As a result, EUneHTA has seen many of its projects succeed by engaging in processes that have resulted in new legislation. What we need now, however, is more of the kind of cooperation that adds value for participants.

Bringing Added Value

The objective of the EUnetHTA Joint Action 2 (JA2) was to strengthen the practical application of tools and approaches to cross-border HTA collaboration. The JA2 aim was to bring collaboration to a higher level, resulting in better understanding for the Commission and Member States of the ways to establish a sustainable structure for HTA in the EU. JA2 further aimed to develop a general strategy that includes principles and an implementation proposal for a sustainable European HTA collaboration according to the requirements of Article 15 of the EU Directive on cross-border health care. The scope of our current work included bringing "added value" to EUneHTA partners, with a focus on creating a

Figure 1. The Domains of the HTA Core Model® - Assessing Dimensions of Value

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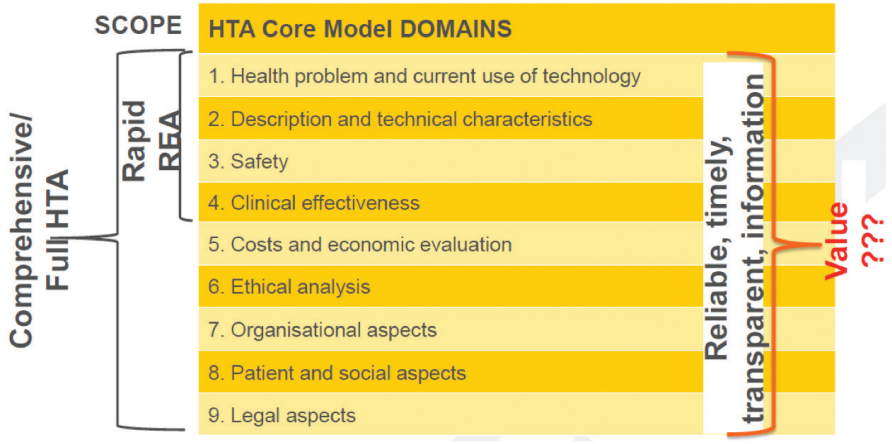

HTA indicates health technology assessment; RWE, real-world evidence.

sustainable system for sharing knowledge about quality and making sure we have good practices in terms of methodology and processes. This focus on good practices was not only a scientific focus; we also needed to apply good practices to normal, daily tasks related to project management, cooperation, and operations management.

We need the cooperation of both stakeholders and regulators as we develop instruments and pilot programs. We have done field testing of early dialogues and scoping meetings with technology sponsors, but we are now moving into a "real-world" phase of producing rather than piloting.

challenges encountered by technology assessors while performing a rapid relative effectiveness assessment or comprehensive HTA. The primary aim is to help the assessors of evidence interpret and process the data that are presented to them as part of an HTA.

It should be no surprise that companies can also use the HTA Core Model. One global company has already come to EUnetHTA to learn about the HTA model and is considering adopting it. Plus, there is another more active player—the payers—and we are encouraging them to get involved. It is encouraging to see that HTA is attracting the attention of experts working in regulation and health economics, and we welcome their participation because HTA is multidisciplinary and needs expertise from various stakeholder groups.

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Domains to Consider when Assessing Value

As we move forward with fostering practical cooperation, there are a number of domains to be considered: health problem, technology, safety, clinical effectiveness, costs, ethics, organization, patient and social aspects, and legal aspects (Figure 1). Under these domains is a hierarchy of topics and issues with more than 100 questions to be considered in assessments for specific purposes, such as cardiac problems or new drugs.

The HTA Model

The EUnetHTA Planned and Ongoing Projects (POP) database facilitates collaboration among European HTA agencies and reduces duplication of work. It allows EUnetHTA partners and associates to share information on planned, ongoing, or recently published projects of participating agencies, and to identify similar projects through a matching system provided by the online database.

There are currently 14 EUnetHTA methodological guidelines for HTA and rapid relative effectiveness assessment. Nine of the methodological guidelines were developed in JA1 and revised in JA2 to include medical devices; and 5 new guidelines were developed for HTA. These guidelines address methodological

The rapid and comprehensive approach is all about providing timely, transparent, and reliable information about the value of a drug, device, or intervention. This information can be used outside of the clinical or economic realms and used to focus on the patient or organizational level. Issues and questions should be transparently selected from the Model and considered throughout the entire lifecycle of the technology—from early scientific developments, to first market approval, and accessible until additional evidence generation.

There is open access to the HTA Core Model® at: http://www.eunethta.eu/hta-core-model. We are pleased to offer these tools to all stakeholders—not just those in Europe—to help promote knowledge-sharing, collaboration, and good HTA practices across the globe. ■

Additional information:
This article is based on a presentation at the plenary session, "Strategy in Motion: The Current and Future Lifecycle Approach to Decision Making on Health Technologies," given at the ISPOR 18th Annual European Congress, 9 November 2015. The preceding article from Hans-Georg Eichler (page 10) and following article from Mirealla Marlow (page 14) were also taken from this session.

This presentation arises from the EUnetHTA Joint Action 2 which has received funding from the European Union, in the framework of the Health Program.

To view Dr. Børlum Kristensen's presentation, go to: http://www.ispor.org/Event/ReleasedPresentations/2015Milan

WEB CONNECTIONS

What Does Broader Access to CMS Data Mean for Patients?
The Centers for Medicare and Medicaid Services (CMS) recently made an announcement allowing innovators and entrepreneurs to analyze and utilize datasets maintained by the federal agency. To find out more, go to: **http://www.resdac.org/cms-data/request/innovator-research.**

Do you know of any websites that you would like to share with the ISPOR community? If so, contact *Value & Outcomes Spotlight* at: vos@ispor.org