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European collaboration on relative effectiveness assessments: What is needed to be successful?

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ABSTRACT

Objective: The objective of this study is to identify the possible barriers and critical success factors for the implementation of European collaboration in the field of relative effectiveness assessment (REA) of drugs.
Methods: Data were gathered through semi-structured interviews with representatives from eight European health technology assessment (HTA) organisations involved in assessment of drugs for coverage decision-making (AAZ, AIFA, AHTAPol, HAS, HVB, IQWIG, NICE and ZiN).
Results: Potential barriers identified mainly relate to methodology, resources and challenges with implementation in the respective national processes (e.g. legal restrictions). The most critical success factors for production of cross-border assessments were the continuous cooperation of competent partners, and the quality and timely availability of the assessment.
Conclusion: Further adaptation of the process and methods is required for optimal collaboration. In the near future it can be expected that cross-border assessments will meet in particular the needs of smaller/middle-sized European countries and also European countries with less developed HTA systems as the potential efficiency/quality gains

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are the highest for these countries. Therefore, national implementation of cross-border assessments is especially likely in these countries in the coming years. Once more experience is gained with cross-border assessments, and successes become more evident, efficiency/quality gains may also be likely for some larger countries with well established processes.

1. Introduction

Insurance entities in many nations use health technology assessments (HTA) to prioritise drugs for reimbursement [1]. European countries employ different analytical frameworks to guide their assessments of drugs as part of the coverage decision making process [2]. Most assessments include a variety of criteria, of which clinical effectiveness and safety relative to the comparator (also referred to as relative or comparative effectiveness) are the most widely used. Examples of other relevant criteria are cost-effectiveness, budget impact, drug/innovative characteristics, availability of therapeutic alternatives, equity considerations, public health impact and research and development [2].

Although coverage decisions for drugs in Europe are mostly made at a national or regional level and may differ between countries, this does not preclude member states from sharing the scientific assessments on which their decisions are based [3]. Increased European collaboration and harmonisation in the field of relative effectiveness assessment (REA)/health technology assessment (HTA) may save resources and prevent duplication of work for both manufacturers and coverage decision agencies [2–4]. However, it could also carry the risks of losing local contextualisation, of the application of standards that are not universally accepted and slowing the rate of development and innovation in the analytical disciplines supporting the assessments [3].

In 2005, the European Commission established that a REA, a specific element of HTA, is a relevant tool to identify the most valuable drugs, and allow containment of drug costs as well as a fair reward for innovation. The Commission set up a Working Group on Relative Effectiveness as part of the High Level Pharmaceutical Forum (2006–2008, see Fig. 1) with the aim to support Member States in applying REAs. The High Level Pharmaceutical Forum consisted of Ministries of the Member States as well as relevant stakeholders. In 2008, the High Level Pharmaceutical Forum endorsed the definition of relative effectiveness as: *the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice* [5]. As this definition includes harms, the concept is similar to what in many countries is referred to as the net therapeutic benefit or relative therapeutic value. This is confirmed by the statement of the High Level Pharmaceutical Forum that the aim of REA is *to compare healthcare interventions in daily practice and classifying them according to their added therapeutic value*.

The work of the High Level Pharmaceutical Forum on REA was continued by the European network for Health Technology Assessment (EUnetHTA) (see Fig. 1). Between 2010 and 2012, work package 5 of EUnetHTA Joint Action 1 (WP5/JA1), developed several products and tools that aim to facilitate collaboration in this field [6]. Most important were a structure for jointly producing and reporting scientific relative effectiveness information for trans-national use (HTA Core Model® for Rapid Relative Effectiveness Assessment of Pharmaceuticals) and methodological guidelines on issues relevant to REAs. The development of the HTA Core Model® for Rapid REA of Pharmaceuticals was based on the work of EUnetHTA on the original HTA Core Model® [7] but adapted to suit the expectation and requirements of rapid REAs of drugs [6]. The nine methodological guidelines focus on issues that assessors are frequently challenged with: endpoints (clinical endpoints, composite endpoints, surrogate endpoints, safety and quality of life), comparisons (choice of appropriate comparator and direct and indirect comparisons) and level of evidence (internal validity of randomised controlled trials and applicability) [8]. Both Model and Guidelines were tested by a pilot assessment of the drug pazopanib for renal cell carcinoma [9]. Currently, the Model and Guidelines are being further piloted as part of WP5 Joint Action 2 (WP5/JA2, 2012–2015) [10,11].

As European countries have different healthcare systems with their own dynamics, they may have different challenges for collaboration in the field of REA. Literature data on challenges, barriers and factors facilitating international collaboration on cross-border HTAs is scarce [12–14]. Recently Huić et al. [14] concluded that timely and efficient collaborative HTA processes on relative efficacy/effectiveness and safety on different types of health technologies are possible in Europe but there are still barriers to overcome.

In order to maximise the likelihood of successful collaboration in the field of REA, we wanted to research the challenges and success factors on collaboration in more detail. Therefore, the objective of this study is to identify the possible barriers and critical success factors for the implementation of European collaboration in the field of REA of drugs.

2. Methods

2.1. Study design and period

A qualitative cross-sectional study was conducted for which eight interviews were performed between 8th and 16th January 2013.