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Development of archetypes for non-ranking classification and comparison of European National Health Technology Assessment systems

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ABSTRACT

Introduction: European countries are increasingly utilising health technology assessment (HTA) to inform reimbursement decision-making. However, the current European HTA environment is very diverse, and projects are already underway to initiate a more efficient and aligned HTA practice within Europe. This study aims to identify a non-ranking method for classifying the diversity of European HTA agencies process and the organisational architecture of the national regulatory review to reimbursement systems.
Method/results: Using a previously developed mapping methodology, this research created process maps to describe national processes for regulatory review to reimbursement for 33 European jurisdictions. These process maps enabled the creation of 2 HTA taxonomic sets. The confluence of the two taxonomic sets was subsequently cross-referenced to identify 10 HTA archetype groups.
Discussion: HTA is a young, rapidly evolving field and it can be argued that optimal practices for performing HTA are yet to emerge. Therefore, a non-ranking classification approach could objectively characterise and compare the diversity observed in the current European HTA environment.

1. Introduction

As with much of the rest of the world, healthcare expenditure in Europe is rising faster than national gross domestic product (GDP) [1]. Healthcare resources face an increasing demand from consumers resulting in a greater gap between public expectations and affordability [2]. With limited options for additional healthcare funding, policy/coverage decision makers are turning to Health Technology Assessment (HTA) in order to ensure healthcare resources are used efficiently. In general, HTA for coverage decision-making evaluates the added therapeutic benefits, the risks and the uncertainties of applying the new technology to the coverage population in the context of the local standard of care. In addition, HTA may also include economic assessment of the new technology. A typical output from HTA is a recommendation as to the use and/or relative value of the technology to the decision maker and payer [3–5].

One particularly impactful aspect of decision-making with regard to healthcare resource allocation occurs when

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HTA recommendations result in highly publicised negative decisions for non-coverage of new pharmaceuticals [6]. New pharmaceuticals only form a small proportion of most total healthcare budgets [7]. However, they can have an immediate budget impact and are a component of healthcare expenditure that, from a political perspective, are measurable and relatively easy to regulate in comparison to, for example, salaries of healthcare professionals, costs incurred from clinical errors or finding a consensus for general expenditure cuts in healthcare services [8–10]. The impact of HTA on new pharmaceutical coverage decision-making in Europe has caused concern amongst patient groups over access to medicines and rationing and by the pharmaceutical industry in relation to curbing innovation and the impact on pricing of new pharmaceuticals [11–13]. A key concern shared by these and other healthcare stakeholders, is the degree of variation by which HTA is conducted and applied across Europe [14].

The variation in philosophies and techniques across national and regional HTA bodies in Europe is a product of political, social and financial differences. European healthcare systems can be classified according to many different typologies of varying indicators [15,16]. However, they are generally based upon 3 different ideologies of social welfare; the Liberal/Beveridge model that provides modest benefits according to strict eligibility criteria and means testing, the Conservative/Bismark regime of social insurance coverage that provides benefits proportional to earnings and the Social Democratic/Scandinavian model of high universalism for the distribution of benefits [16]. Within the context of these different healthcare ideologies, HTA has developed as standalone agencies or as units within existing healthcare agencies and their remit and context varies considerably by country or region. The different systems have spawned different approaches to HTA, resulting in a diversity of organisational architectures and processes for HTA assessment [17]. Key aspects of the variation between European HTA systems are (1) the extent of information that is applied to the assessment of the new technology, especially the use of economic information (2) the level of independence between the processes for assessment, appraisal and decision-making and (3) the variation in methodologies used in the evaluations [18].

Although some factors are unique to each nation and therefore cannot be aligned, such as the political milieu and a country's ability to fund national healthcare schemes, the fundamental scientific criteria used for the HTA evaluation should have their basis in consistently applied, scientifically rigorous methodologies that encourage transparency of quality decision-making. The European Commission has recognised the need for a more efficient European HTA environment to help overcome inequalities in patient access to therapies [19]. Accordingly, this organisation has recently amended the Transparency Directive to ensure timely coverage decision-making and provided grants to support the European Network of Health Technology Assessment (EUnetHTA), which recently implemented the EUnetHTA Joint Action project 2 (EUnetHTA JA2) to establish sustainable cross-border HTA collaboration in Europe with the development of a core HTA model [20,21].

The aims of this study were (1) to provide a high-level overview and characterise the regulatory, HTA and decision-making systems for new pharmaceuticals throughout Europe through the development of standardised process maps and to categorise these according to a standard taxonomy; (2) to categorise the diversity of the different HTA systems by identifying sub-groups with common elements of process (i.e., archetypes) that could be used to describe general characteristics common to the different systems within each archetype.

Resources are currently available that offer flow diagrams and pictorial representations of coverage systems [22–24]. However, this study aimed to provide additional value to the currently available resources through the application of a novel mapping process that ensures all maps conform to a uniform methodology, a common graphical representation and standardised descriptors focused on reimbursement.

2. Methods

This research chose to focus on 33 jurisdictions from the European Economic Area, this includes the English, Scottish and Welsh systems as individual jurisdictions. The national HTA agencies or committees were identified using HTA methodologies from official agency or ministry of health websites. These agencies or committees were used to create process maps representing the pathways for regulatory, HTA and coverage decisions were created for new active substances (NASs). For the purpose of this study a NAS is defined as any chemical, biological or radiopharmaceutical substance that has not been previously available for therapeutic use in humans and which is intended for use to cure, alleviate, treat, and prevent or as an in vitro diagnostic of human disease.

A previously developed mapping methodology was used to create a visual aid to graphically illustrate and facilitate the comparison of national regulatory, HTA and coverage systems for 33 European nations (Figs. 1 and 2) [25–28]. Key agencies (Table 1), with an indication of their independence from or integration into the governmental structure and order within the coverage system, were identified and graphically represented to produce the first information tier of the process maps. The second tier of information indicated whether the agencies served in 1 or more of the 7 core functions: decision maker; HTA; marketing authorisation; pricing authority; provider; recommender; and regulator (Fig. 1) [25–29]. For the final tier, agencies participation in 6 key HTA activities was mapped: scientific advice; therapeutic value; economic value; reimbursement rate; public consultation; and coverage with evidence development (Fig. 1) [25–29]. These tasks, identified graphically in a task bar, were the focus of the process maps, thereby providing unique detail while remaining visually concise for efficient comparison. These process maps are now being consolidated into an electronic atlas.

Following the completion of the process maps, common similarities and differences were identified and used to create 2 groups of taxonomies for the healthcare systems (Fig. 3). The first taxonomic grouping is based on the position of a national HTA agency, if present, in relation