Health Policy 105 (2012) 236–245

Contents lists available at SciVerse ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

Stakeholders involvement by HTA Organisations: Why is so different?

Marianna Cavazza [a,*], Claudio Jommi [b]

[a] CERGAS (Centre for Health and Social Care Management), Università Bocconi, Via Roengten 1, 20136 Milan, Italy
[b] Department of Pharmaceutical Sciences, Università del Piemonte Orientale, Novara, Italy

ARTICLE INFO

Article history:
Received 23 September 2011
Received in revised form 23 January 2012
Accepted 24 January 2012

JEL classification:
I180
O38

Keywords:
HTA
Healthcare system
Policy-making
Stakeholders
Administrative tradition

ABSTRACT

Objective: To investigate stakeholder involvement by Health Technology Assessment Organisations (HTAOs) in France, Spain, England and Wales, Germany, Sweden, and The Netherlands and to examine whether this involvement depends on (i) the administrative tradition and the relevant conception of the relationship between state and society (contractarian and corporative vs. organic), (ii) the general structure of the healthcare system (HCS) (Bismarckian vs. Beveridgian system), and (iii) the role of Health Technology Assessment (HTA) and HTAOs in the HCS.
Methods: Given the exploratory nature of the study, we considered interviews based on semi-structured questionnaires the most appropriate data-gathering technique. The interviews were administered to 16 key personnel in the HTAOs concerned. We have also carried out a literature review on HTAOs and stakeholders (1999–2011) using PubMed, Ebsco, JSTOR and Wiley Science.
Results: In contractarian and (to a lesser extent) Bismarckian models, stakeholders are more involved. The administrative tradition and the HCS appear less important when the HTA is binding and used for regulatory purposes. In such situations, stakeholders are more intensively involved because their participation provides an opportunity for HTAOs to achieve consensus and legitimacy in advance.
Conclusions: Despite the limitations of the research (we did not conduct multiple interviews for each HTAO, and key informants were not always available) and its exploratory nature, we can conclude that models of stakeholders involvement cannot easily be transferred from one country to another due to the importance of national administrative traditions and the characteristics of HCSs.

1. Introduction

The introduction of new technologies into a healthcare system is regulated by policy makers [1], who are expected to promote allocative efficiency and to control costs. Health Technology Assessment (HTA) provides policy makers with the technical support required for their regulatory action [2]. Policy makers might not manage HTAs on their own and could depend on the support of HTA organisations (HTAOs) [3,4]. Furthermore, the implementation of a HTA is a complex and multidimensional process [5]. Hence, unless HTAOs hold all the required competences and information internally, they require the technical support, information and expertise provided by stakeholders. The involvement of stakeholders could also guarantee the legitimacy of the final assessment and help prevent conflict after the technologies have entered the market [6,7].

The literature on HTAOs demonstrates (i) significant similarities among the HTAOs in the way they formally organise the assessment process and in the technical issues of decision making (e.g., the parameters used for setting priorities) and (ii) important differences among HTAOs in how the decision-making process is actually

* Corresponding author. Tel.: +39 02 5836 2664.
E-mail addresses: marianna.cavazza@unibocconi.it (M. Cavazza), claudio.jommi@pharm.unipmn.it (C. Jommi).

0168-8510/$ – see front matter © 2012 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.healthpol.2012.01.012

implemented [8–12]. Some recent contributions have investigated the identity of stakeholders involved in the assessment process, how they are engaged and for what purposes [6,7,13,14].

Our survey of the literature, however, has identified two gaps in understanding of the relationships between HTAOs and stakeholders. The first is the actual role played by all categories of stakeholders. The second implicates reasons for their different levels of involvement, i.e., whether the reasons are country-dependent or HTAO-dependent. Should the different engagements of stakeholders be country-dependent, the transferability of one model of relationships between HTAO and stakeholders from one country to another would be limited.

This research attempts to answer these two research questions. Section 2 analyses the theoretical framework used to compare the HTAOs. Section 3 describes the methodology used in this study. Section 4 describes the results, and Section 5 discusses policy implications and limits of the analysis.

2. Theoretical framework

As Nielsen et al. (2009) note, HTAOs usually do not hold decision-making power because they are not political or regulatory bodies, even though their status is very close to that of a political institution; they are often public bodies that are financed by taxes and engaged in an activity aimed at improving the healthcare system.

Referring to the literature on New Public Management [15,16], HTAOs can be defined as Quasi-autonomous non-governmental organisations (Quangos). A Quango is an "organisation in charge of [or involved in] the implementation of one or more policies, which is publicly funded but operates at arm's length from the central government without an immediate hierarchical relationship with a minister or a parent department" ([17] p. 176). Quangos may range from private organisations with which the state contracts to engage in the relevant activity to quasi-autonomous units of a public department [18,19]; this range includes the whole spectrum of HTAOs considered herein. Quangos are often required by governments to provide information or advice [20]. This is precisely the key role of HTAOs.

According to Bouckaert and Peters [21], the *modus operandi* of a Quango is mainly related to: (i) its intervention area and the related knowledge level of key players, (ii) its attributed role/function with respect to the public interest and (iii) the administrative tradition of the country [22]. This theoretical framework has been tested by the authors to explore whether it explains variations in stakeholder involvement by HTAOs.

This description encompasses the common background of all HTAOs with regard to the nature of their intervention area and the related highly specific management of knowledge involved.

With regard to the second point Bouckaert and Peters raise [21], the role of HTAOs is to provide HTA reports on new technologies. Policy makers may be (i) obliged to use HTA reports (binding HTA), (ii) obliged to consider them in their decision making (partially binding HTA), or (iii) free to use them or not (non-binding HTA). The requirement to use a binding HTA for regulatory purposes (prices and reimbursement) implies a greater need for legitimacy. Hence, stakeholders are expected to be more involved in such a situation.

As for administrative traditions, Peters [22] has distinguished between a *contractarian* and an *organic* approach to the management of the relationship between state and society. The contractarian view is based on a contract between the members of society and the state in which the terms of agreement can be changed by either party and the residual rights tend to lie with the citizens. In such a context, social actors are expected to be intimately involved in the policy-making process. The *contractarian* model may evolve into (i) a *consociative* approach, in which the state collects and coordinates the points of view of the stakeholders and manages the final consensual decision-making process [23], or (ii) a *corporative* system, in which corporate bodies manage some specific public policies in their role as guardians of the interests of society [19]. In the *organic* conception, the state represents and summarises the interests of society, and stakeholder involvement in decision-making is considered illegitimate. However, given the increasing complexity of society, states that have an *organic* tradition have strengthened the role of stakeholders and now tend to select those interest groups that accept their authority within a network of governance [24].

In our analysis, the difference between the *contractarian* and the *organic* approach has been marked by the identification of the entities entitled to submit proposals of assessment. The state is expected to be the main commissioner of HTAs if the *organic* approach is used. A *contractarian* model is more consistent with a system in which a wide range of internal and external (mentioned below) stakeholders can submit proposals to HTAOs. In a *corporative* system, internal stakeholders are expected to be the main proposers of HTAs.

This theoretical framework has been completed, including the healthcare system model (HCS) implemented in each country. Because assessment is focused on healthcare technologies to be introduced in HCS, these systems have been classified into (i) a Bismarck model, in which regulators (the state) and third party payers (social insurance) are separated, and (ii) a Beveridge model, where the state both regulates and funds the system. In a Bismarckian model, in which regulators and third-party payers are separated, HTAs may strengthen the relationships between internal stakeholders (and third-party payers in particular) and the government. As a consequence, internal stakeholders are expected to be at least formally engaged.

Stakeholders have been classified as internal to the healthcare system (third-party payers, policy-makers, healthcare managers and organisations, and research centres), internal but with objectives that possibly conflict with HTAOs (clinicians) and external (healthcare industry and citizens, or patient associations). The intensity of stakeholder involvement ranges from acting as (i) spot informants, (ii) structured informants, and (iii) advisers to being (iv) participants deeply involved in the process who hold voting rights [6,14].