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The impact of HTA and procurement practices on the selection and prices of medical devices

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ABSTRACT

Technological innovation in healthcare yields better health outcomes but also drives healthcare expenditure, and governments are struggling to maintain an appropriate balance between patient access to modern care and the economic sustainability of healthcare systems. Health Technology Assessment (HTA) and centralized procurement are increasingly used to govern the introduction and diffusion of new technologies in an effort to make access to innovation financially sustainable. However, little empirical evidence is available to determine how they affect the selection of new technologies and unit prices. This paper focuses on medical devices (MDs) and investigates the combined effect of various HTA governance models and procurement practices on the two steps of the MD purchasing process (i.e., selecting the product and setting the unit price). Our analyses are based on primary data collected through a national survey of Italian public hospitals. The Italian National Health Service is an ideal case study because it is highly decentralized and because regions have adopted different HTA governance models (i.e., regional, hospital-based, double-level or no HTA), often in combination with centralized regional procurement programs. Hence, the Italian case allows us to test the impact of different combinations of HTA models and procurement programs in the various regions. The results show that regional HTA increases the probability of purchasing the costliest devices, whereas hospital-based HTA functions more like a cost-containment unit. Centralized regional procurement does not significantly affect MD selection and is associated with a reduction in the MD unit price: on average, hospitals located in regions with centralized procurement pay 10.1% less for the same product. Hospitals located in regions with active regional HTA programs pay higher prices for the same device (+23.2% for inexpensive products), whereas hospitals that have developed internal HTA programs pay 8.3% on average more for the same product.

1. Introduction

Technological innovation in healthcare is both a key determinant of better health outcomes and a driver of healthcare expenditure. Among health technologies, medical devices (MDs) represent a highly dynamic sector characterized by a rapid pace of innovation. A recent study evaluating worldwide patent application activity as an indicator of innovation across twelve sectors showed that MDs were the most active, having experienced the largest year-over-year increase (+27%) in the number of patents from 2014 to 2015 (Thomson Reuters, 2016).

As governments struggle to maintain an equitable balance between patient access to modern care and the economic sustainability of healthcare systems, they are endeavoring to select the most cost-effective devices at the lowest possible prices. Health Technology Assessment (HTA) and centralized procurement have clearly played an increasing role in managing the introduction and diffusion of MDs in an effort to find an appropriate balance between patient access to innovation and cost containment (Sorenson and Kanavos, 2011).

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HTA is defined by the International Network of Agencies for HTA (INAHTA) as "a multidisciplinary field of policy analysis [that] studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology". HTA is traditionally considered an effective approach to the decision-making process involved in the allocation of scarce resources. Indeed, it aims to promote allocative efficiency by providing recommendations on the adoption of new technologies and, more generally, on healthcare programs, which maximize health benefits given a limited budget. HTA can be performed at the national (macro), regional (meso) or hospital (local) level. This implies that different HTA governance models (i.e., models that differ in the involvement and integration of the various levels) may co-exist within a single jurisdiction to support decisions regarding technology adoption, reimbursement practices and pricing.

Centralized procurement is a form of cooperation between "two or more independent organizations that join together, either formally or informally, or through an independent third party, for the purpose of combining their individual requirements for purchased materials, services, and capital goods to leverage more value-added pricing, service, and technology from their external suppliers than could be obtained if each firm purchased goods and services alone" (Hendrick, 1997). It is also known as hospital purchasing alliances, group purchasing or collaborative purchasing (Gobbi and Hsuan, 2015; Lega et al., 2013). The expected benefits derive from economies of scale, process and information (Johnsons, 1999; Nollet and Beaulieu, 2005; Tella and Virolainen, 2005). Economies of scale refer to the ability to obtain lower prices through volume bundling and standardization of categories. Economies of process refer to the reduction of duplicated effort and resources in the purchasing process (e.g., workforce, tendering). Economies of information and learning refer to the capacity of personnel to develop category-specific or process knowledge.

Although these two practices can support health care decision makers to select the most cost-effective devices (HTA) at the lowest possible price (centralized procurement), there is scant empirical evidence regarding the actual impact of HTA on MD selection and of centralized procurement on MD unit prices. Some studies have demonstrated that national HTA has incentivized the selection of cost-effective devices (Zechmeister and Schumacher, 2012) and enhanced a reduction in the unit price of innovative devices (Scottish Health Technologies Group, 2008), whereas hospital-based HTA programs have been perceived, especially among clinicians, as instruments primarily used to curb device expenditure (Gagnon et al., 2014). To the best of our knowledge, the current available literature contains no evidence regarding the coexistence of different HTA models or the impact of meso-level (i.e., regional) HTA on MD selection. Existing studies have referred to individual technologies (Scottish Health Technologies Group, 2008) rather than to HTA programs as a whole. Moreover, they relied on expert interviews and case studies (papers reviewed by Gagnon et al., 2014), mixed methods (interviews and administrative databases in Zechmeister and Schumacher, 2012), or pre-post analyses (Scottish Health Technologies Group, 2008). These methods may disregard confounding factors. As for the impact of centralized procurement on MD unit prices, some scholars have confirmed that it leads to economic efficiency, i.e., reductions in MD unit prices (Kastanioti et al., 2013; Kruetten et al., 2005). By contrast, Burns and Lee (2008) found that purchasing groups are less successful at reducing the prices of devices compared to commodities. This finding was especially true for the most expensive physician preferred items (PPIs, e.g., hip and knee implants, cardiac stents, MDs used in spinal surgery), whose selection is strongly influenced by physician expectations of the clinical outcome and physician experience with the specific product or brand (Montgomery and Schneller, 2007). However, these findings relied on secondary data reported in official government/institutional documents (Kastanioti et al., 2013) or on the opinions of procurement experts (Kruetten et al., 2005). Large samples of primary data have rarely been used in empirical analyses of this issue (Burns and Lee, 2008). Finally, no evidence exists regarding the combined impact of HTA and centralized procurement.

This paper aims to fill the literature gaps by evaluating the combined effect of different HTA governance models and centralized procurement practices on MD selection and unit prices. More specifically, this paper answers the following two research questions: (1) Do different HTA governance models and procurement practices impact MD selection? (2) Do different HTA governance models and procurement practices impact the unit price of the selected device? The ultimate aim of this paper is to provide empirical evidence to contribute to the ongoing debate on how to ensure that access to modern care is timely and financially sustainable.

Italy represents an ideal case study to achieve the above goals because the Italian National Health Care System (NHS) is highly decentralized at the regional level (Tediosi et al., 2009). Regions have adopted different HTA governance models (regional, hospital-based, double-level or no HTA) (Boscolo et al., 2012; Boscolo et al., 2015; Ciani et al., 2012), and purchasing has experienced an increasing trend toward centralized regional procurement since the end of the 1990s (Brusoni and Marsilio, 2007; Di Pietro et al, 2014; Marsilio et al., 2016). Hence, the Italian case allows us to test the impact of different combinations of HTA models and procurement practices in different regions.

2. Data and methods

2.1. Data

This study relied on data from multiple sources. The main data source was a national survey of MD purchases by Italian public hospitals conducted by the Centre for Research on Health and Social Care Management (CERGAS) in collaboration with the Italian Ministry of Health (MoH) (De Luca and Tarricone, 2012). The survey focused on four therapeutic areas characterized by rapid innovation, high levels of product differentiation in terms of technological content, high potential for PPIs and significant expenditure growth rates: interventional cardiology, interventional neurology, neurosurgery, and orthopedics. All Italian public hospitals that provided in-hospital services in these four therapeutic areas in 2008 were identified in the National Hospital Discharge Records database and were invited to participate in the survey. In total, 249 hospitals were invited. The selected hospitals provided data on the quantities and total expenditure for the MDs purchased in the years 2008–2009. Data were requested at the product level (i.e., for each single item purchased) and were subsequently aggregated into homogeneous product classes according to the Italian National Classification System for MDs. Hospitals also provided information on the state of implementation of hospital-based HTA practices, i.e., the existence of a technology assessment committee, and information on whether HTA principles were employed in procurement decisions.

Regional HTA and procurement programs were identified through document review (i.e., a review of legislative and administrative documents from national and regional authorities) and interviews with key stakeholders, as described in previous publications (Brusoni and Marsilio, 2007; Ciani et al., 2012; Di Pietro et al., 2014). If HTA was performed only at the regional level, the governance model was defined as "regional HTA". Similarly, if the technology assessment committee existed within the hospital, the