



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.

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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

model was defined as “hospital-based HTA”. An HTA program operating at both the regional and hospital levels was defined as “double-level HTA”. “No-HTA” indicates that no HTA programs were implemented at either the regional or local level.

Confounding variables have been selected consistent with the covariates used in the empirical literature investigating the determinants of the diffusion of new medical technologies (Fleuren et al., 2004; Robert et al., 2010; Rye and Kimberly, 2007). They are the following: (1) hospital institutional arrangements (in Italy, public hospitals can be classified as independent trusts (ITs), hospitals directly managed by Local Health Authorities (LHAs), and research institutes (RIs)); (2) specialty hospitals (e.g., orthopedic hospitals) vs. general hospitals; (3) teaching status; (4) the existence of regional turnaround plans (TPs) (Italian regions are accountable for any healthcare deficit they incur and may be required to negotiate a TP with the central government if the deficit is high Jommi et al., 2013); (5) per capita regional deficit; and (6) the percentage of elderly people. Table 1 provides a list of the variables included in the dataset and the corresponding sources.

2.2. Statistical analysis

The first research question relates to whether different HTA governance models and procurement practices affected the selection of MDs in different ways. The analysis was conducted within homogeneous classes of products (e.g., bare-metal stent *a* vs. bare-metal stent *b*, drug-eluting stent *c* vs. drug-eluting stent *d*) and not between different classes of products (e.g., bare-metal stents vs. drug-eluting stents). Therefore, our analysis focused on the first-level decision to purchase devices with different unit prices within each class of products. A product was labelled “costly” if its average price among purchasers was higher than the mean price of its class according to the Italian National Classification of MDs. Therefore, the dependent variable *costly_{ijk}* was a dummy equal to 1 if the average price of device *i* across the *j* hospitals that purchased the device was higher than the average price of its product class *k*. Note that the definition of costly products does not refer to an external benchmark (such as reference prices, which did not exist in Italy at the time of the study) but rather depends on the actual unit price paid by the hospitals in the sample. This variable was coded in three steps. First, we calculated the MD product class *k* average price (i.e., the average price for all devices belonging to class *k* across all hospitals) as follows:

$$average\ class\ price_k = \frac{\sum_{j=1}^M \sum_{i=1}^N expenditure_{ijk}}{\sum_{j=1}^M \sum_{i=1}^N number\ of\ items_{ijk}} \tag{1}$$

Then, we computed the average price for device *i* in class *k* across all hospitals as follows:

$$average\ device\ price_{ik} = \frac{\sum_{j=1}^M expenditure_{ijk}}{\sum_{j=1}^M number\ of\ items_{ijk}} \tag{2}$$

Finally, we coded the variable *costly* as follows:

$$costly_{ik} = \begin{cases} 1 & \text{if } average\ device\ price_{ik} > average\ class\ price_k, \\ 0 & \text{otherwise} \end{cases} \tag{3}$$

To test the first research question, we used a logit model:

$$Pr(costly_{ik} = 1) = \frac{e^{x'_{ijk}\beta}}{1 + e^{x'_{ijk}\beta}}, \text{ where } x'_{ijk}\beta \tag{4}$$

$$x'_{ijk}\beta = \beta_0 + Regional\ HTA_t\beta_1 + Hospital_{i,ased}\ HTA_t\beta_2 + Regional\ Procurement_t\beta_3 + (k'\beta_4) + \beta_5t + Controls_t\beta_6 \tag{5}$$

The control variables included the type of hospital (i.e., IT, LHA, RI); mono-specialty status; teaching status; the presence of TP; regional per capita deficit; the share of the elderly population; and a time dummy, where *k'β₄* represents the set of class dummies. The regressions were run under two different baseline assumptions, i.e., no HTA in Model 1 and double-level HTA in Model 2.

The second research question investigated whether different HTA governance models and procurement practices affected MD unit prices differently. The hypothesis was tested at the single product level (e.g., TAXUS™ Express2™ Paclitaxel-Eluting Coronary Stent) using product fixed effects. The dependent variable was the unit price paid for device *i* by hospital *j* at time *t*. The aim of this analysis was to investigate the variables that influenced the unit price paid by the hospitals in each year. Because unit price is a positive and continuous variable, we used its logarithmic transformation to facilitate coefficient interpretation. We used a multi-level linear regression model with product and time fixed effects and robust standard errors:

$$\ln(unit\ expenditure_{ijk}) = \beta_0 + Regional\ HTA_t\beta_1 + Hospital_{i,ased}\ HTA_t\beta_2 + Regional\ procurement_t\beta_3 + i'\beta_4 + \beta_5t + \beta_6 Controls_t + \beta_7n + \beta_8n^2 + \epsilon_{ijk} \tag{6}$$

where *i'β₄* represents the set of product dummies and *n* is the number of units of device *i* purchased by hospital *j* in each year. The latter variable and its squared term were added to control for possible economies (or diseconomies) of scale. We ran three models: Model 3 included the entire sample, Model 4 included only the most expensive quartile of devices, and Model 5 included only the least expensive quartile of devices. Quartiles were defined over the entire sample, rather than within each class, to analyze the impact of the independent variables on the most and least costly devices overall.

3. Results

3.1. Sample description

Forty-four public hospitals agreed to take part in the survey. The hospitals were located in 15 Italian regions (out of a total of 21) where more than 90% of the total population lives. The overall representativeness of our sample with respect to hospitals active in Italy in 2008–2009 is 17.7%, as shown in Table 2. ITs (20.7%) are the most represented hospitals in the sample.

In 2008, seven regions (representing 47% of the regions in the sample) had implemented regional HTA policies, and six regions (40%) had developed centralized procurement programs (Fig. 1A). In four cases (27%), both policies were in place. In 2009, two additional regions implemented HTA, and one implemented a centralized procurement program (Fig. 1B).

We observed 1187 MDs that were grouped into 37 classes and belonged to the four analyzed sectors (interventional cardiology, interventional neurology, neurosurgery and orthopedics) for two years (2008 and 2009). Our sample is a balanced panel comprising

Table 1
Variables.

Variable	Description	Source
Regional HTA	1 if HTA program is active only at the regional level, 0 otherwise	Regional authorities
Hospital-based HTA	1 if HTA program is active only at the hospital level (i.e., the hospital has a technology evaluation commission), 0 otherwise	CERGAS Survey
Double-level HTA	1 if both regional and hospital-based HTA programs are active, 0 otherwise	National/regional authorities and CERGAS Survey
No HTA	1 if no HTA program is active at either the regional level or the hospital level, 0 otherwise	National/regional authorities and CERGAS Survey
Regional procurement	1 if centralized regional procurement program is active, 0 otherwise	Regional authorities/OASI
TP	1 if TP is active, 0 otherwise	MoH
LHA vs. IT	Compares LHA-managed hospitals to ITs	MoH
RI vs. IT	Compares RIs to ITs	MoH
Mono-specialty	1 if specialty hospital, 0 if general hospital	MoH
Teaching	1 if teaching, 0 otherwise	MoH
Per capita regional deficit	Per capita regional deficit	OASI
% Elderly	% of regional population aged 65 or older	ISTAT
T	Dummy for year (2009 vs. 2008)	

LHA = local health authority, IT = independent trust, RI = research institute, TP = turnaround plan, MoH = Ministry of Health, OASI = Observatory on Italian Healthcare Management.

all products that were purchased by each hospital in at least one year and includes 5064 observations (Table 3).

Research question #1: Do different HTA governance models and centralized procurement practices have different impacts on the selection of devices within each class?

The results for the first research question are presented in Table 4. The coefficients are reported as odds ratios. The two models differ with respect to the baseline HTA model (i.e., no HTA is considered in Model 1, whereas double-level HTA is considered in Model 2). The presence of HTA has an impact on the probability of choosing the costliest segment of products within a product class, and this impact varies according to the governance model. In particular, whereas regional HTA increases the probability of purchasing the costliest devices, the other models do not show significant differences relative to either the no-HTA case (Model 1) or the double-level HTA (Model 2). Between the hospital-based HTA and the double-level HTA, the presence of hospital-based HTA is associated with a lower probability of purchasing costly devices. The existence of a centralized regional procurement program does not significantly affect the selection of the specific device to be purchased. Regarding control variables, ITs are significantly more likely than LHA-managed hospitals and RIs to purchase costly devices. The same is true for mono-specialty hospitals, whereas hospitals located in regions with a high deficit per capita and a higher incidence of elderly residents have a significantly lower propensity to purchase costly devices.

Research Question #2: Do different HTA governance models and centralized procurement practices have different impacts on unit prices?

As shown in Table 5, the results for the second research question show that the presence of centralized regional procurement is associated with a reduction in unit prices. On average, hospitals located in regions with centralized procurement pay 10.1% less for the same products. Savings on the most expensive products (MDs in the fourth quartile) averaged 13.4%, whereas savings on the least

expensive devices (products in the first quartile) averaged 24%. Hospitals with internal HTA programs pay 8.3% more on average for the same products. The premium is slightly higher for costly devices (9.8%) and much higher for inexpensive products (20%). Compared with the absence of HTA, the presence of regional HTA programs is associated with higher prices paid for the least expensive products (23.2%). The simultaneous presence of regional and hospital-based HTAs translates into unit prices that are 10.2% higher on average and 30.3% higher for inexpensive products. Hospitals managed by LHAs pay a higher unit price (on average, +8.1%) than ITs do. Teaching hospitals pay higher unit prices than non-teaching hospitals, both in general (13.7%) and for costly products (34.3%). Compared with ITs, RIs pay 18.1% less on average for costly devices. The consumption of mono-specialty hospitals is oriented toward costly devices, and these hospitals pay an average of 97.2% more than general hospitals do. The presence of a TP does not significantly impact the average unit price, indicating rather poor attention to possible efficiency gains derived from procurement policies. Hospitals located in regions with a higher per capita deficit or with a higher share of the elderly population are characterized by better procurement capacity. A time dummy confirms the declining trend in unit prices (−2.1%), particularly for expensive devices (−3%). We included two control variables related to quantity in the analysis to capture possible economies of scale (i.e., linear and squared terms). Economies of scale imply a negative slope between quantity and price. Because we have a negative linear coefficient but a positive squared coefficient, the graph obtained is a parabola. Therefore, we conducted a within-sample simulation to determine whether our evidence was concentrated in the decreasing or increasing part of the parabola. The simulations confirmed that our data were consistent with economies of scale, which are evident for the entire sample (Model 3) and for inexpensive products (Model 5) but are not significant for the most expensive products (Model 4). This particular result is not surprising: scale effects might be modest for costly products because their impact might be captured by regional procurement.

Table 2
Representativeness of the sample.

Hospital type	Accepted	Invited	Representativeness
IT	19	92	20.7%
LHA	22	133	16.5%
RI	3	24	12.5%
Total	44	249	17.7%

4. Discussion

HTA aims to assess health technologies to provide recommendations to identify those with the most cost-effective profiles. When resources are scarce, HTA is a useful approach for fostering innovation while considering economic sustainability. If an HTA report issues a positive recommendation, the new technology is

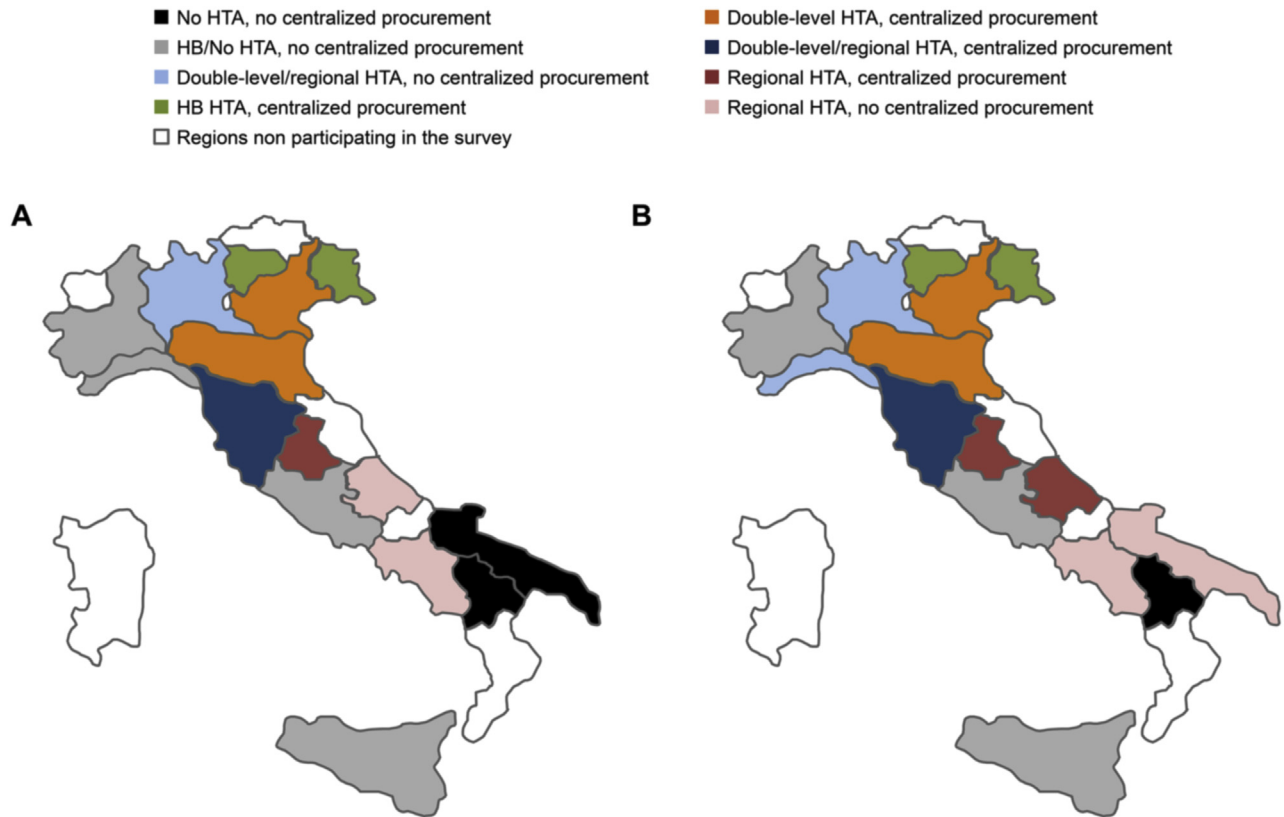


Fig. 1. HTA governance models and procurement practices implemented in Italy in 2008–2009. Combination of HTA governance models (regional, hospital-based, double-level, and no HTA) and centralized procurement in the hospitals participating in the survey in 2008 (1a) and 2009 (1b).

Table 3
Number of observations by sector and year.

Sector	Year 2008	Year 2009	Total
Interventional cardiology	273	273	546
Interventional neurology	244	244	488
Neurosurgery	230	230	460
Orthopedics	1785	1785	3570
<i>Total</i>	<i>2532</i>	<i>2532</i>	<i>5064</i>

Table 4
Results on the selection of costly devices.

Variables	(1) Odds ratio (Baseline = no HTA)	(2) Odds ratio (Baseline = double-level HTA)
No HTA		0.969
Hospital-based HTA	0.941	0.912
Regional HTA	1.421**	1.377***
Double-level HTA	1.032	–
Regional procurement	1.123	1.123
LHA vs. IT	0.669***	0.669***
RI vs. IT	0.616***	0.616***
Mono-specialty	8.904**	8.904**
Teaching	1.000	1.000
TP	0.925	0.925
Per capita deficit	0.997***	0.997***
% Elderly	0.000***	0.000***
Year = 2009	1.635***	1.635***
Observations	5062	5062
Number of MD classes	37	37
Log-likelihood	–2796	–2796

Dependent variable: probability of choosing a high-cost device in the same class;
***p < 0.01, **p < 0.05, *p < 0.10.

Table 5
Results on average unit price.

Variables	(3) All devices	(4) Costly devices	(5) Inexpensive devices
Hospital-based HTA	0.083***	0.098***	0.200***
Regional HTA	0.069*	0.032	0.232**
Double-level HTA	0.102***	0.098*	0.303***
Regional procurement	–0.101***	–0.134***	–0.240**
LHA vs. IT	0.081**	0.051*	0.245*
RI vs. IT	–0.082*	–0.181**	0.105
Mono-specialty	0.964***	0.972***	
Teaching	0.137***	0.052	0.343**
TP	0.035	–0.071	0.060
Per capita deficit	–0.001***	–0.001***	–0.001
% elderly	–2.674***	–1.835***	–2.580**
Quantity	–0.000**	–0.000	–0.000**
Quantity (squared)	0.000*	0.000	0.000*
Year = 2009	–0.021***	–0.030***	0.019
Constant	6.863***	7.718***	5.481***
Observations	3730	951	906
R-squared	0.128	0.181	0.127
Number of products	1183	272	310
Log-likelihood	–319.7	280	–415.2

Dependent variable: average unitary price (ln); ***p < 0.01, **p < 0.05, *p < 0.1.

generally introduced into the health system and purchased by health providers. Unlike pharmaceuticals, whose unit price is normally negotiated at a central level, MD prices are typically negotiated between individual manufacturers and purchasers, which may cause significant variations in price even within the same jurisdiction. Centralized procurement is widely recognized as an effective cost-containment approach for healthcare systems mainly because it allows hospitals to bargain for lower prices. Although

centralized procurement was traditionally used for low-tech goods and services (e.g., maintenance, utilities, commodities), it is also currently used for high-tech products, including MDs.

Although HTA and centralized procurement are becoming more common in the majority of industrialized economies and different governance models have emerged, research on the impact of these programs on healthcare expenditures remains scarce. This study is the first study that empirically investigates the influence of different HTA models (regional, hospital-based, double-level and no HTA) and centralized procurement practices on public expenditure for MDs and thus contributes to formulating evidence-based health policies.

Italy is a valuable case study because it is highly decentralized and because each region has adopted a different governance model for HTA and procurement, which makes our results interesting to consider for many other jurisdictions.

Our results clearly show that regional HTA programs play a role in the selection of MDs and that within each class of devices, the costliest products are recommended. An example of this impact in the orthopedic sector is provided by ceramic femoral heads. Specifically, the share of costly ceramic femoral heads purchased by hospitals when regional HTA programs are active is 96%, compared to 52% when hospital-based HTA models are in place. One interpretation of this result is that regional-level HTA favors more innovative devices, assuming that the costliest devices are also the most innovative. In other words, regional HTA does not appear to be a barrier to innovative products. The opposite phenomenon is observed in regions with hospital-based HTA but no regional-level HTA programs; when HTA is performed at the hospital level only, costly devices are less likely to be selected and purchased, which suggests that hospital-based HTA acts as a cost-containment tool. This result empirically confirms the widely held experts' opinion reported by Gagnon et al. (2014). Interestingly, however, once a hospital has selected the least expensive devices within each class, the unit price paid for them is significantly higher than that paid by hospitals with no form of HTA. In summary, hospital-based HTA does not seem to accomplish any of its main goals but rather seems to hinder access to innovative devices. Moreover, hospital-based HTA does work as a cost-containment tool. This result is quite relevant, especially given the recent changes to HTA for MDs in Italy. The MoH has launched a new national HTA program that aims to centralize this function at a central level. Although this program is still at a very preliminary design stage, it appears that regions would be invited to network with the MoH by leveraging their experience and contributing to HTA reports. Hospital-based HTA programs would be eliminated or possibly transformed into budget impact analysis programs that could be used by hospitals to secure appropriate budgets for MDs recommended by the MoH.

Our results indicate that centralized procurement does not influence the selection of MDs but does affect their unit prices once they have been selected, which is what we would expect from such a program. However, consistently with Burns and Lee (2008), the effectiveness of centralization is less evident for very costly devices. If we assume that costly devices are also likely to be the most innovative, we can explain this result. Specifically, in the case of high-tech, innovative MDs, it is more difficult to standardize the procurement process and to generate large purchase volumes because such devices are often indicated for specific categories of patients with specific clinical characteristics. Moreover, as also stated by Montgomery and Schneller (2007), these devices often depend on end-user preference, which tends to reduce the benefits of standardization. This result might be highly relevant to the Italian government, which has recently decided to centralize, starting in 2016, the procurement of several categories of MDs, including high-tech and costly devices (e.g., stents, hip prostheses,

defibrillators, pacemakers), at the regional level or even the national level through regional/national tenders.

4.1. Strengths and weaknesses

This paper evaluates the combined effect of different HTA governance models and procurement practices on the selection and unit prices of MDs. The work expands upon prior knowledge in several respects. First, it considers the coexistence of different HTA governance models, whereas the majority of HTA impact evaluations focus on either national or hospital-based HTA. Second, this study estimates the combined effect of HTA and procurement policies. Third, the study is based on a large sample of primary data collected through a national survey of public hospitals, which is complemented by data from several additional sources. Fourth, the empirical analyses consider several confounding factors in addition to HTA and procurement that have generally been disregarded in the literature. Fifth, the availability of a two-year period allowed us to perform panel data analyses, which have never previously been published.

The study has several limitations. In particular, MDs are neither costly nor inexpensive *per se* because the definition relies not on a reference price but rather on the actual unit price paid by the hospitals in the sample. Because the unit price and the sample are not independent, the classification itself might change if the sample changes. Another limitation of this study is that our sample represents 18% of Italian hospitals, which means that our conclusions should be interpreted cautiously. Finally, we assumed that the costliest devices are also the most innovative and that price erosion occurs as long as new MDs enter the market (Smith et al., 2013). This erosion is generally observed with high-tech products (e.g., iPhones), and health technologies are no exception. However, it must be noted that what defines a new health product as innovative is controversial, and no general agreements currently exist on this issue (Ciani et al., 2015).

5. Conclusions

Evidence-based policies are crucial if governments aim to achieve concrete and measurable results from their decisions. This paper aims to contribute to the consolidation of empirical evidence concerning the impact of HTA and centralized procurement on the selection of MDs and acquisition costs. Although further research is needed to confirm our results on a larger scale, our findings clearly indicate that hospital-based HTA programs currently work as cost-containment tools rather than as policy instruments to best allocate scarce resources and that centralized procurement is highly effective when the products to be purchased respond to standardized needs expressed by large shares of the population.

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