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The impact of HTA and procurement practices on the selection and prices of medical devices**Author names and affiliations**

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

2

3 **Abstract**

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

25

26

27 **Keywords**

28 Health Technology Assessment, Centralized procurement, Medical Devices, Selection, Price, Italy

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31 Introduction

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

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

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

54 Centralized procurement is a form of cooperation between “two or more independent
55 organizations that join together, either formally or informally, or through an independent third party, for
56 the purpose of combining their individual requirements for purchased materials, services, and capital
57 goods to leverage more value-added pricing, service, and technology from their external suppliers
58 than could be obtained if each firm purchased goods and services alone” (Hendrick, 1997). It is also
59 known as hospital purchasing alliances, group purchasing or collaborative purchasing (Gobbi &
60 Hsuan, 2015; Lega, Marsilio, & Villa, 2013). The expected benefits derive from economies of scale,

61 process and information (Johnsons, 1999; Nollet & Beaulieu, 2005; Tella & Virolainen, 2005).
62 Economies of scale refer to the ability to obtain lower prices through volume bundling and
63 standardization of categories. Economies of process refer to the reduction of duplicated effort and
64 resources in the purchasing process (e.g., workforce, tendering). Economies of information and
65 learning refer to the capacity of personnel to develop category-specific or process knowledge.

66 Although these two practices can support health care decision makers to select the most
67 cost-effective devices (HTA) at the lowest possible price (centralized procurement), there is scant
68 empirical evidence regarding the actual impact of HTA on MD selection and of centralized
69 procurement on MD unit prices. Some studies have demonstrated that national HTA has incentivized
70 the selection of cost-effective devices (Zechmeister and Schumacher, 2012) and enhanced a
71 reduction in the unit price of innovative devices (Scottish Health Technology Group, 2008), whereas
72 hospital-based HTA programs have been perceived, especially among clinicians, as instruments
73 primarily used to curb device expenditure (Gagnon et al., 2014). To the best of our knowledge, the
74 current available literature contains no evidence regarding the coexistence of different HTA models or
75 the impact of meso-level (i.e., regional) HTA on MD selection. Existing studies have referred to
76 individual technologies (Scottish Health Technology Group, 2008) rather than to HTA programs as a
77 whole. Moreover, they relied on expert interviews and case studies (papers reviewed by Gagnon et
78 al., 2014), mixed methods (interviews and administrative databases in Zechmeister and Schumacher,
79 2012), or pre-post analyses (Scottish Health Technology Group, 2008). These methods may
80 disregard confounding factors. As for the impact of centralized procurement on MD unit prices, some
81 scholars have confirmed that it leads to economic efficiency, i.e., reductions in MD unit prices
82 (Kastanioti, Kontodimopoulos, Stasinopoulos, Kapetaneas, & Polyzos, 2013; Kruetten, Rautenberg, &
83 Liefner, 2005). By contrast, Burns and Lee (2008) found that purchasing groups are less successful at
84 reducing the prices of devices compared to commodities. This finding was especially true for the most
85 expensive physician preferred items (PPIs, e.g., hip and knee implants, cardiac stents, MDs used in
86 spinal surgery), whose selection is strongly influenced by physician expectations of the clinical
87 outcome and physician experience with the specific product or brand (Montgomery & Schneller,
88 2007). However, these findings relied on secondary data reported in official government/institutional
89 documents (Kastanioti et al., 2013) or on the opinions of procurement experts (Kruetten et al., 2005).
90 Large samples of primary data have rarely been used in empirical analyses of this issue (Burns &

91 Lee, 2008). Finally, no evidence exists regarding the combined impact of HTA and centralized
92 procurement.

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

100 Italy represents an ideal case study to achieve the above goals because the Italian National
101 Health Care System (NHS) is highly decentralized at the regional level (Tediosi, Gabriele, & Longo,
102 2009). Regions have adopted different HTA governance models (regional, hospital-based, double-
103 level or no HTA) (Boscolo, Ciani, & Torbica, 2012; Boscolo, Ciani, Tarricone, & Torbica, 2015; Ciani,
104 Tarricone, & Torbica, 2012), and purchasing has experienced an increasing trend toward centralized
105 regional procurement since the end of the 1990s (Brusoni & Marsilio, 2007; Di Pietro, Marsilio, &
106 Sartirana, 2014; Marsilio, Amatucci, & Callea, 2016). Hence, the Italian case allows us to test the
107 impact of different combinations of HTA models and procurement practices in different regions.

108

109 **Data and methods**

110 *Data*

111 This study relied on data from multiple sources. The main data source was a national survey
112 of MD purchases by Italian public hospitals conducted by the Centre for Research on Health and
113 Social Care Management (CERGAS) in collaboration with the Italian Ministry of Health (MoH) (De
114 Luca & Tarricone, 2012). The survey focused on four therapeutic areas characterized by rapid
115 innovation, high levels of product differentiation in terms of technological content, high potential for
116 PPIs and significant expenditure growth rates: interventional cardiology, interventional neurology,
117 neurosurgery, and orthopedics. All Italian public hospitals that provided in-hospital services in these
118 four therapeutic areas in 2008 were identified in the National Hospital Discharge Records database
119 and were invited to participate in the survey. In total, 249 hospitals were invited. The selected
120 hospitals provided data on the quantities and total expenditure for the MDs purchased in the years

121 2008-2009. Data were requested at the product level (i.e., for each single item purchased) and were
122 subsequently aggregated into homogeneous product classes according to the Italian National
123 Classification System for MDs. Hospitals also provided information on the state of implementation of
124 hospital-based HTA practices, i.e., the existence of a technology assessment committee, and
125 information on whether HTA principles were employed in procurement decisions.

126 Regional HTA and procurement programs were identified through document review (i.e., a
127 review of legislative and administrative documents from national and regional authorities) and
128 interviews with key stakeholders, as described in previous publications (Brusoni & Marsilio, 2007;
129 Ciani et al., 2012; Di Pietro et al., 2014). If HTA was performed only at the regional level, the
130 governance model was defined as “regional HTA”. Similarly, if the technology assessment committee
131 existed within the hospital, the model was defined as “hospital-based HTA”. An HTA program
132 operating at both the regional and hospital levels was defined as “double-level HTA”. “No-HTA”
133 indicates that no HTA programs were implemented at either the regional or local level.

134 Confounding variables have been selected consistent with the covariates used in the
135 empirical literature investigating the determinants of the diffusion of new medical technologies
136 (Fleuren, Wiefferink, & Paulussen, 2004; Robert, Greenhalgh, MacFarlane, & Peacock, 2010; Rye &
137 Kimberly, 2007). They are the following: (1) hospital institutional arrangements (in Italy, public
138 hospitals can be classified as independent trusts (ITs), hospitals directly managed by Local Health
139 Authorities (LHAs), and research institutes (RIs); (2) specialty hospitals (e.g., orthopedic hospitals) vs.
140 general hospitals; (3) teaching status; (4) the existence of regional turnaround plans (TPs) (Italian
141 regions are accountable for any healthcare deficit they incur and may be required to negotiate a TP
142 with the central government if the deficit is high Jommi, Costa, Michelon, Pisacane, & Scroccaro,
143 2013); (5) per capita regional deficit; and (6) the percentage of elderly people. Table 1 provides a list
144 of the variables included in the dataset and the corresponding sources.

145

146 *Statistical analysis*

147 The first research question relates to whether different HTA governance models and
148 procurement practices affected the selection of MDs in different ways. The analysis was conducted
149 *within* homogeneous classes of products (e.g., bare-metal stent *a* vs. bare-metal stent *b*, drug-eluting
150 stent *c* vs. drug-eluting stent *d*) and not *between* different classes of products (e.g., bare-metal stents

151 vs. drug-eluting stents). Therefore, our analysis focused on the first-level decision to purchase devices
 152 with different unit prices within each class of products. A product was labelled “costly” if its average
 153 price among purchasers was higher than the mean price of its class according to the Italian National
 154 Classification of MDs. Therefore, the dependent variable $costly_{ik}$ was a dummy equal to 1 if the
 155 average price of device i across the j hospitals that purchased the device was higher than the
 156 average price of its product class k . Note that the definition of costly products does not refer to an
 157 external benchmark (such as reference prices, which did not exist in Italy at the time of the study) but
 158 rather depends on the actual unit price paid by the hospitals in the sample. This variable was coded in
 159 three steps. First, we calculated the MD product class k average price (i.e., the average price for all
 160 devices belonging to class k across all hospitals) as follows:

$$161 \quad (1) \text{ average class price}_k = \frac{\sum_{j=1}^M \sum_{i=1}^N \text{expenditure}_{ijk}}{\sum_{j=1}^M \sum_{i=1}^N \text{number of items}_{ijk}}.$$

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

$$163 \quad (2) \text{ average device price}_{ik} = \frac{\sum_{j=1}^M \text{expenditure}_{ijk}}{\sum_{j=1}^M \text{number of items}_{ijk}}.$$

164 Finally, we coded the variable $costly$ as follows:

$$165 \quad (3) \text{ costly}_{ik} = 1 \text{ if average device price}_{ik} > \text{average class price}_k, 0 \text{ otherwise.}$$

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

$$167 \quad (4) \text{ Pr}(\text{costly}_{ik} = 1) = \frac{e^{x'_{ijk}\beta}}{1 + e^{x'_{ijk}\beta}}, \text{ where } x'_{ijk}\beta \text{ is}$$

$$168 \quad (5) x'_{ijk}\beta = \beta_0 + \text{Regional HTA}'_j \beta_1 + \text{Hospital_based HTA}'_j \beta_2 + \text{Regional Procurement}'_j \beta_3 +$$

$$169 \quad (k' \beta_4) + \beta_5 t + \text{Controls}' \beta_6.$$

170 The control variables included the type of hospital (i.e., IT, LHA, RI); mono-specialty status;
 171 teaching status; the presence of TP; regional per capita deficit; the share of the elderly population;
 172 and a time dummy, where $k' \beta_4$ represents the set of class dummies. The regressions were run under
 173 two different baseline assumptions, i.e., no HTA in Model 1 and double-level HTA in Model 2.

174 The second research question investigated whether different HTA governance models and
 175 procurement practices affected MD unit prices differently. The hypothesis was tested at the single
 176 product level (e.g., TAXUS™ Express2™ Paclitaxel-Eluting Coronary Stent) using product fixed
 177 effects. The dependent variable was the unit price paid for device i by hospital j at time t . The aim of
 178 this analysis was to investigate the variables that influenced the unit price paid by the hospitals in

179 each year. Because unit price is a positive and continuous variable, we used its logarithmic
 180 transformation to facilitate coefficient interpretation. We used a multi-level linear regression model
 181 with product and time fixed effects and robust standard errors:

$$\begin{aligned}
 182 \quad (6) \quad \ln(\text{unit expenditure}_{ijk}) = \\
 183 \quad \beta_0 + \text{Regional HTA}'_j \beta_1 + \text{Hospital_based HTA}'_j \beta_2 + \text{Regional procurement}'_j \beta_3 + i' \beta_4 + \beta_5 t + \\
 184 \quad \beta_6 \text{Controls}' + \beta_7 n + \beta_8 n^2 + \varepsilon_{ijk}
 \end{aligned}$$

185 where $i' \beta_4$ represents the set of product dummies and n is the number of units of device i purchased
 186 by hospital j in each year. The latter variable and its squared term were added to control for possible
 187 economies (or diseconomies) of scale. We ran three models: Model 3 included the entire sample,
 188 Model 4 included only the most expensive quartile of devices, and Model 5 included only the least
 189 expensive quartile of devices. Quartiles were defined over the entire sample, rather than within each
 190 class, to analyze the impact of the independent variables on the most and least costly devices overall.

191

192 **Results**

193 *Sample description*

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

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

202 We observed 1,187 MDs that were grouped into 37 classes and belonged to the four
 203 analyzed sectors (interventional cardiology, interventional neurology, neurosurgery and orthopedics)
 204 for two years (2008 and 2009). Our sample is a balanced panel comprising all products that were
 205 purchased by each hospital in at least one year and includes 5,064 observations (Table 3).

206

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

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

223

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

226 As shown in Table 5, the results for the second research question show that the presence of
227 centralized regional procurement is associated with a reduction in unit prices. On average, hospitals
228 located in regions with centralized procurement pay 10.1% less for the same products. Savings on the
229 most expensive products (MDs in the fourth quartile) averaged 13.4%, whereas savings on the least
230 expensive devices (products in the first quartile) averaged 24%. Hospitals with internal HTA programs
231 pay 8.3% more on average for the same products. The premium is slightly higher for costly devices
232 (9.8%) and much higher for inexpensive products (20%). Compared with the absence of HTA, the
233 presence of regional HTA programs is associated with higher prices paid for the least expensive
234 products (23.2%). The simultaneous presence of regional and hospital-based HTAs translates into
235 unit prices that are 10.2% higher on average and 30.3% higher for inexpensive products. Hospitals
236 managed by LHAs pay a higher unit price (on average, +8.1%) than ITs do. Teaching hospitals pay
237 higher unit prices than non-teaching hospitals, both in general (13.7%) and for costly products
238 (34.3%). Compared with ITs, RIs pay 18.1% less on average for costly devices. The consumption of

239 mono-specialty hospitals is oriented toward costly devices, and these hospitals pay an average of
240 97.2% more than general hospitals do. The presence of a TP does not significantly impact the
241 average unit price, indicating rather poor attention to possible efficiency gains derived from
242 procurement policies. Hospitals located in regions with a higher per capita deficit or with a higher
243 share of the elderly population are characterized by better procurement capacity. A time dummy
244 confirms the declining trend in unit prices (-2.1%), particularly for expensive devices (-3%). We
245 included two control variables related to quantity in the analysis to capture possible economies of
246 scale (i.e., linear and squared terms). Economies of scale imply a negative slope between quantity
247 and price. Because we have a negative linear coefficient but a positive squared coefficient, the graph
248 obtained is a parabola. Therefore, we conducted a within-sample simulation to determine whether our
249 evidence was concentrated in the decreasing or increasing part of the parabola. The simulations
250 confirmed that our data were consistent with economies of scale, which are evident for the entire
251 sample (Model 3) and for inexpensive products (Model 5) but are not significant for the most
252 expensive products (Model 4). This particular result is not surprising: scale effects might be modest
253 for costly products because their impact might be captured by regional procurement.

254

255 **Discussion**

256 HTA aims to assess health technologies to provide recommendations to identify those with
257 the most cost-effective profiles. When resources are scarce, HTA is a useful approach for fostering
258 innovation while considering economic sustainability. If an HTA report issues a positive
259 recommendation, the new technology is generally introduced into the health system and purchased
260 by health providers. Unlike pharmaceuticals, whose unit price is normally negotiated at a central level,
261 MD prices are typically negotiated between individual manufacturers and purchasers, which may
262 cause significant variations in price even within the same jurisdiction. Centralized procurement is
263 widely recognized as an effective cost-containment approach for healthcare systems mainly because
264 it allows hospitals to bargain for lower prices. Although centralized procurement was traditionally used
265 for low-tech goods and services (e.g., maintenance, utilities, commodities), it is also currently used for
266 high-tech products, including MDs.

267 Although HTA and centralized procurement are becoming more common in the majority of
268 industrialized economies and different governance models have emerged, research on the impact of

269 these programs on healthcare expenditures remains scarce. This study is the first study that
270 empirically investigates the influence of different HTA models (regional, hospital-based, double-level
271 and no HTA) and centralized procurement practices on public expenditure for MDs and thus
272 contributes to formulating evidence-based health policies.

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

276 Our results clearly show that regional HTA programs play a role in the selection of MDs and
277 that within each class of devices, the costliest products are recommended. An example of this impact
278 in the orthopedic sector is provided by ceramic femoral heads. Specifically, the share of costly
279 ceramic femoral heads purchased by hospitals when regional HTA programs are active is 96%,
280 compared to 52% when hospital-based HTA models are in place. One interpretation of this result is
281 that regional-level HTA favors more innovative devices, assuming that the costliest devices are also
282 the most innovative. In other words, regional HTA does not appear to be a barrier to innovative
283 products. The opposite phenomenon is observed in regions with hospital-based HTA but no regional-
284 level HTA programs; when HTA is performed at the hospital level only, costly devices are less likely to
285 be selected and purchased, which suggests that hospital-based HTA acts as a cost-containment tool.
286 This result empirically confirms the widely held experts' opinion reported by Gagnon and colleagues
287 (2014). Interestingly, however, once a hospital has selected the least expensive devices within each
288 class, the unit price paid for them is significantly higher than that paid by hospitals with no form of
289 HTA. In summary, hospital-based HTA does not seem to accomplish any of its main goals but rather
290 seems to hinder access to innovative devices. Moreover, hospital-based HTA does work as a cost-
291 containment tool. This result is quite relevant, especially given the recent changes to HTA for MDs in
292 Italy. The MoH has launched a new national HTA program that aims to centralize this function at a
293 central level. Although this program is still at a very preliminary design stage, it appears that regions
294 would be invited to network with the MoH by leveraging their experience and contributing to HTA
295 reports. Hospital-based HTA programs would be eliminated or possibly transformed into budget
296 impact analysis programs that could be used by hospitals to secure appropriate budgets for MDs
297 recommended by the MoH.

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

311

312 *Strengths and weaknesses*

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

323 The study has several limitations. In particular, MDs are neither costly nor inexpensive *per se*
324 because the definition relies not on a reference price but rather on the actual unit price paid by the
325 hospitals in the sample. Because the unit price and the sample are not independent, the classification
326 itself might change if the sample changes. Another limitation of this study is that our sample
327 represents 18% of Italian hospitals, which means that our conclusions should be interpreted

328 cautiously. Finally, we assumed that the costliest devices are also the most innovative and that price
329 erosion occurs as long as new MDs enter the market (Smith, Tarricone, & Vella, 2013). This erosion is
330 generally observed with high-tech products (e.g., iPhones), and health technologies are no exception.
331 However, it must be noted that what defines a new health product as innovative is controversial, and
332 no general agreements currently exists on this issue (Ciani et al., 2015).

333

334 **Conclusions**

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

343

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Figure captions**Figure 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)

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Table 1 Variables

Variable	Description	Source
Regional HTA	1 if HTA program is active only at the regional level, 0 otherwise	National/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.

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%
<i>Total</i>	44	249	17.7%

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	1,785	1,785	3,570
<i>Total</i>	<i>2,532</i>	<i>2,532</i>	<i>5,064</i>

Table 4 Results on the selection of costly devices

Variables	(1)	(2)
	Odds ratio (Baseline = no HTA)	Odds ratio (Baseline = double-level HTA)
No HTA		.969
Hospital-based HTA	.941	.912
Regional HTA	1.421**	1.377***
Double-level HTA	1.032	-
Regional procurement	1.123	1.123
LHA vs. IT	.669***	.669***
RI vs. IT	.616***	.616***
Mono-specialty	8.904**	8.904**
Teaching	1.000	1.000
TP	.925	.925
Per capita deficit	.997***	.997***
% Elderly	.000***	.000***
Year = 2009	1.635***	1.635***
Observations	5,062	5,062
Number of MD classes	37	37
Log-likelihood	-2796	-2796

Dependent variable: probability of choosing a high-cost device in the same class;
 *** p<.01, ** p<.05, * p<.10.

Table 5 Results on average unit price

Variables	(3) All devices	(4) Costly devices	(5) Inexpensive devices
Hospital-based HTA	.083***	.098***	.200***
Regional HTA	.069*	.032	.232**
Double-level HTA	.102***	.098*	.303***
Regional procurement	-.101***	-.134***	-.240**
LHA vs. IT	.081**	.051*	.245*
RI vs. IT	-.082*	-.181**	.105
Mono-specialty	.964***	.972***	
Teaching	.137***	.052	.343**
TP	.035	-.071	.060
Per capita deficit	-.001***	-.001***	-.001
% elderly	-2.674***	-1.835***	-2.580**
Quantity	-.000**	-.000	-.000**
Quantity (squared)	.000*	.000	.000*
Year = 2009	-.021***	-.030***	.019
Constant	6.863***	7.718***	5.481***
Observations	3,730	951	906
R-squared	.128	.181	.127
Number of products	1,183	272	310
Log-likelihood	-319.7	280	-415.2

Dependent variable: average unitary price (ln); *** p<.01, ** p<.05, * p<.1.

- No HTA, no centralized procurement
- HB/No HTA, no centralized procurement
- Double-level/regional HTA, no centralized procurement
- HB HTA, centralized procurement
- Regions non participating in the survey
- Double-level HTA, centralized procurement
- Double-level/regional HTA, centralized procurement
- Regional HTA, centralized procurement
- Regional HTA, no centralized procurement

A



B



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Research highlights

- HTA and procurement are increasingly used to govern the uptake of new devices.
- Little empirical evidence exists regarding their impact on healthcare expenditure.
- We collected primary data through a national survey of Italian public hospitals.
- Regional HTA favors the adoption of costly devices, unlike hospital-based HTA.
- Centralized regional procurement yields lower medical device unit prices.