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Funding health technologies in decentralized systems: A comparison between Italy and Spain

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ABSTRACT

Although cost-containment policies in Europe are focusing increasingly on medical devices, the impact of these policies has yet to be fully investigated, particularly in cross-country settings. This paper analyses coverage, procurement, and reimbursement of three inpatient medical devices (coronary stent, knee endoprosthesis and implantable cardioverter defibrillator) in the Italian and Spanish healthcare systems. The research was carried out by reviewing published and grey literature, as well as national and regional legislation; in addition, 19 experts from hospitals and the industry were interviewed.

In both countries, there has been a shift in political power from the national to the regional level. At the same time, the content of public coverage has become more explicit. A major issue in both systems is reimbursement, i.e. the rules about funding the delivery of services included in the benefit baskets. The differences in procurement and funding mechanisms create different incentives that may have an impact on the uptake and diffusion of technologies. These mechanisms, however, can only partially explain organizational and professional behaviour, as the use of technologies in both countries is mainly left to professionals who are exposed to a variety of incentives. There is limited direct and indirect guidance of national and regional authorities over the use of technologies in both countries. It is likely that the difficult search for a balance between introducing innovations, containing costs and assuring equity will require stronger regulatory action in the next future.

1. Introduction

There are considerable similarities between Italy and Spain in terms of historical development, economic structure and institutional arrangements concerning healthcare. In both countries, the constitution grants a large degree of autonomy to regions or autonomous communities (ACs) with unique linguistic, cultural, geographic, or other characteristics. Decentralization has also been extended to all regions or ACs and increasingly encompasses the collection and distribution of tax revenues [1,2].

Italy and Spain have important similarities from an economic perspective as well. Both are affluent countries whose main economic sectors (i.e. services, manufacturing, and agriculture) make similar relative contributions to country's GDP, but with large regional variations. In Italy, economic disparities are associated primarily with the underdeveloped southern regions, which have weak economies and depend largely on the transfer of resources from the central government. In Spain, the different levels and rates of economic development are due to a variety of factors, with Basque Country, Catalonia, and Navarra having much stronger economies than other ACs in the country. While the ACs in Spain are based on historical and cultural characteristics, Italian regions are entities that were created after the Second World

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Table 1
Public per-capita health care expenditure in Italian regions and Spanish ACs in 2005.

Italy			Spain		
Region	Resident population	Current public per-capita expenditure (€)	Autonomous community	Resident population	Public per-capita expenditure (€)
Piemonte	4,330,172	1,664	Andalucìa	7,372,398	1,020
Valle d'Aosta	122,868	1,974	Aragòn	1,193,252	1,209
Lombardia	9,393,092	1,528	Asturias (Principato de)	1,041,621	1,205
Bolzano (Autonomous Province of)	477,067	2,046	Baleares (Islas)	945,823	1,121
Trento (Autonomous Province of)	497,546	1,754	Canarias	1,877,169	1,147
Veneto	4,699,950	1,584	Cantabrias	539,710	1,331
Friuli Venezia Giulia	1,204,718	1,638	Castilla y Leon	2,340,502	1,177
Liguria	1,592,309	1,847	Castilla La-Mancha	1,801,002	1,157
Emilia Romagna	4,151,369	1,629	Catalunia	6,818,468	1,058
Toscana	3,598,269	1,618	Comunidad Valenciana	4,506,448	1,029
Umbria	858,938	1,607	Extremadura	1,013,125	1,199
Marche	1,518,780	1,573	Galicia	2,613,836	1,122
Lazio	5,269,972	1,906	Madrid (Comunidad de)	5,555,935	1,026
Abruzzo	1,299,272	1,718	Murcia (Regiòn de)	1,254,811	1,114
Molise	321,953	2,012	Navarra (Comunidad Foral de)	578,130	1,204
Campania	5,788,986	1,716	Paìs Vasco	2,077,143	1,195
Puglia	4,068,167	1,557	Rioja (La)	287,468	1,228
Basilicata	596,546	1,586	Ceuta	60,189	1,182
Calabria	2,009,268	1,528	Melilla	51,198	1,465
Sicilia	5,013,081	1,600			
Sardegna	1,650,052	1,658			
Minimum		1,528	Minimum		1,020
Maximum		2,046	Maximum		1,465
Variation coefficient		9.5%	Variation coefficient		6.87%

War and the call for autonomy in Italy appears strongly motivated by economic arguments raised by northern regions.

The constitutions of both countries, as well as major pieces of legislation, grant substantial powers to the regions, but at the same time clearly identify national rights, including that of access to healthcare. In both countries devolution of powers to regions is associated with measures to ensure that citizens are granted the same rights across regional jurisdictions. In this respect, the Italian and the Spanish healthcare systems are very similar, because although they are managed at the regional level, they are subject to national rules concerning coverage and, to a large extent, financing.

The two countries, on the other hand, are characterised by substantial differences with regard to the public expenditure on health care. In 2005 public per capita health expenditure was 1675 euro in Italy and 1224 in Spain [3], with high variability across regions (Table 1).

2. Definition of benefit baskets and hospital funding

In Italy and Spain, the issue of how to define health benefit baskets (i.e. the overall set of healthcare goods and services guaranteed to citizens under public coverage) is deeply intertwined with the history of the two national healthcare systems and their reforms over the past few decades. The benefit baskets in both countries have changed throughout the years in terms of form, content, and objectives. The distribution of powers between the central and regional levels, as well as the respective roles of these levels in funding and the provision of healthcare services is currently the most critical issue in both systems [4,5].

In Italy, central government has the role of ensuring and monitoring adequate funding for the provision of the essential levels of care (LEA), whereas regions are held accountable for the organization of healthcare facilities and the provision of services. Healthcare system financing is mainly based on regional and central taxes. The incidence of regional taxes on the total regional revenues is marked by a high variability (from 10% in Calabria to 60% in Lombardy).

Since 2003 health planning, public health and provision of care are the foremost policy responsibilities of the ACs in Spain. Central Government retains competences on the basic principles and on coordination of health strategies and drug policies, whereas Inter-Territorial Council of the NHS – an advisory committee composed by representatives of both central and regional governments -is in charge for ensuring the cohesion of the health system. Healthcare systems of the ACs are financed by both tax-related resources and transfers from the general state budgets, mainly through the Sufficiency Fund and the Interterritorial Compensation Fund. ACs are given the authority to retain part of tax revenues raised within their territories; as in the Italian case, fiscal capacity of ACs varies greatly.

Given the common decentralization process, in both countries a clear definition of the guarantees provided by the central government is a key element of intergovernmental relations. National baskets are seen as the means to keep management and policy powers at the regional level while maintaining national guarantees. In practice, however, two main obstacles have been encountered while implementing this system. A major problem is

how to make regions and autonomous communities fully accountable for the provision of benefit baskets. In both countries, the benefit package definition is accompanied by the allocation or re-allocation of resources that should ensure the actual provision of services included in the benefit package. However, it has proved difficult to make regions and ACs financially accountable for inefficiencies and overspending. Despite decentralization, the ultimate financial responsibility rests with the central government. There are also practical difficulties in defining the benefit packages operationally, even though both healthcare systems are making clear efforts to spell out the content of public system coverage in greater detail. In Italy, criteria for determining the minimum package were legislated in 1999, and an overall catalogue was released in 2001 (the LEA Decree) that also includes a list of Diagnosis Related Groups (DRGs) deemed at risk of inappropriateness [5]. In 2004 a new technical body – the National LEA Commission – was established with the aim of updating the national health basket on the basis of scientific, technological and economic evidence. Similarly, the pivotal document related to the current Spanish health basket (Real Decreto 1030/06), which substituted a series of previous acts, brought about significant changes, mainly in the degree of explicitness with which the healthcare services and goods included were described.

One of the main differences between the benefit baskets in the two countries concerns the definition of services and goods provided in the hospital setting. Traditionally, these services have never been defined explicitly in the Italian NHS. Rather, the implicit assumption has been that all interventions (including medical technologies) considered to be appropriate at the hospital level would be covered by the public system. In the Spanish health basket, conversely, the services and medical technologies to be provided in hospital settings are, in most cases, defined in an explicit manner.

Italy and Spain have two very different systems for funding hospitals and thus differ substantially in the way the costs of inpatient medical technologies are covered. In Italy, all goods and services delivered by public or private accredited hospitals since 1995 have been mainly funded on a per-case basis, as classified according to US Medicare DRGs [6]. The DRG tariffs are intended to cover all hospital operating costs, including administrative costs and overheads, but excluding most capital costs. Since the adoption of this legislation at the central level, the regions have reacted in different ways and great variability in regional funding arrangements has been observed [7]. At present, setting tariffs to fund providers is mainly a regional matter. Across regions there are differences with regard to the version of the DRG classification adopted, the methodology employed to calculate tariffs, the frequency of updates, and the criteria used to differentiate tariffs across providers. The extent to which tariffs cover production costs, and therefore the costs of specific medical technologies, varies across regions and within regions [8]. In order to increase inter-regional comparability, the central government mandated in 2006 that a single DRG classification (Grouper no. 19) be adopted throughout Italy.

Although Spain was one of the first European countries to introduce DRGs as a system of classification for hospital output, DRGs are not used in the reimbursement of public providers. Instead, hospitals in Spain are funded primarily through a global budget [9]. Before the devolution of competencies to the ACs, hospital budget allocation was based on a contractual relationship between the financing body at the national level (INSALUD) and healthcare providers. After 2002 the responsibility for hospital budget allocation was transferred to the ACs. Hospital funding in the public sector is now generally carried out prospectively by negotiating a *contract programme* between the hospital and the regional authority/third-party payer. The contract annually sets out the objectives to be achieved by the hospital (type, volume, and quality of services) and defines a budget for achieving these goals. Capital investment in the public sector is generally funded from global budgets and is monitored by the respective regional funding authority [10]. Even though the system was initially designed to separate functions between purchasers and providers and to introduce contractual parameters into the relationship between these two parties, global budgets have continued to be defined mainly on the basis of historical patterns, therefore maintaining *de facto* the retrospective nature of the funding mechanism [9].

Given their decentralized character, Italy and Spain have been facing a common challenge in the recent years: to maintain the financial sustainability of their national healthcare systems while ensuring equitable access to care throughout the jurisdictions. Regulation and funding of innovative medical technologies play an important role in this regard. The policies affecting medical technologies in the two countries have not been fully investigated, particularly in cross-country studies. Thus, it is innovative and promising to examine more closely and specifically how medical technologies are governed in two countries that are similar in many respects. Comparing alike situations may provide relevant insights on specific measures.

The primary aim of the present study was to conduct an in-depth investigation of the current regulation and funding arrangements for selected medical devices across three different dimensions: coverage status, procurement and reimbursement mechanisms. The methods applied are described in the next section, which is followed by a presentation of the results for each of the three technologies. The differences between the two countries, policy implications and possible impact on the uptake and diffusion of technologies are discussed.

3. Methods

We selected three technologies for our analysis: implantable cardioverter defibrillators (ICDs), coronary stents, and knee endoprostheses. They are major examples of artificial body parts implanted in the hospital setting; when specified according to medical-technology categories, they can be defined as technologies that (a) provide life-saving treatments (ICDs), (b) prevent major adverse cardiac events (coronary stents), and (c) improve patients' quality of life (knee endoprostheses). For each of the three technologies in the last years relevant technological changes took place and their impact on health care expenditure has been debated [11–14]. They well

represent relevant and common examples of new costly and effective medical technologies posing challenges to health care systems.

A mixed methodology approach was developed to gather data about the regulation and funding of medical devices in general, as well as about these three technologies in particular. First, we performed a systematic search of the literature using MEDLINE and EMBASE to collect all relevant publications. To select abstracts we used the following keywords: economics, costs, financing, funding, procurement, reimbursement, DRG, financial arrangements (alone or combined), knee prostheses, coronary stents, and implantable cardioverter defibrillators. The search was limited to studies published within the past 10 years in English, Italian, or Spanish. Papers whose abstracts appeared relevant were reviewed in full. Second, we visited governmental and industry websites to gather additional information and we also analysed legislative and other relevant documents.

Finally, we carried out nineteen semi-structured interviews, on the basis of a predefined interview protocol, to health professionals and industry representatives operating in the field of the technologies investigated in our study. The sample was created with the support of the National Medical Devices Industry Associations operating in Spain and Italy, i.e. Fenin and Assobiomedica. Interviews in both countries were conducted in person [15] or by telephone [4], lasted approximately one hour on average, and were recorded and transcribed to facilitate full analysis. The interviews were conducted as a way to verify and complement the information gathered from the literature review, websites, and official documents. Both the choice of the sample and the content of the interviews aimed at collecting information concerning the variety of elements experienced by regions and ACs.

4. Results

4.1. Coronary stents

4.1.1. Coverage and diffusion

A coronary stent is an implantable device placed in the patient's coronary artery during a percutaneous coronary intervention (PCI). In both Spain and Italy, the device is included in the national basket of services available to citizens. While coronary stents are not mentioned in the 2001 LEA decree in Italy, the Real Decreto 1030/06 in Spain defines the category of 'Coronary Endovascular Implants' and thus explicitly includes stents in the health benefit basket (Appendix VI, which regulates the national catalogue for orthoprosthetic services).

Data from the national registries show a substantial increase in the use of coronary stents in both countries since the introduction of this technology. In Italy, the number of coronary stents implanted per centre in the period from 2003 through 2006 increased by more than 40% (524 in 2003 vs. 750 in 2006) [15]. A significant increase was also observed in Spain: according to the national registry that covers 97% of all centres, the number of coronary stents per centre increased by approximately 30.7% (516 in 2003 vs. 674 in 2006). In the same period, the total number of devices implanted in Italy increased by 68% (i.e. from 106,948 to 179,932) and by 58% in Spain (i.e. from 57,778 to 91,006) [15–17].

In both countries, this sharp increase in the number of coronary stents in 2003–2006 period is associated with: (i) a general increase in the number of PCIs performed per centre (i.e. by 20.3% in Italy and 16.5% in Spain), (ii) a greater proportion of PCIs with stents (i.e. in 2006 96.1% of all PCIs in Spain and 92.5% of all PCIs in Italy were performed with at least one stent), and (iii) an increase in the average number of stents implanted per procedure (i.e. from 1.53 to 1.59 in Spain and from 1.22 to 1.45 in Italy) [15–17].

The differences in the number of stents implanted between the two countries mainly reflect the differences in the number of catheter laboratories and their case volumes. In 2006, a total of 2112 PCI procedures per million population were performed in 240 catheter laboratories in Italy, compared to 1276 PCI procedures per million population in 135 catheter laboratories in Spain.

Regarding the type of implant, the proportion of drug-eluting stents (DES) showed a similar trend in both countries, rising from 20% in 2003 to 59% in 2006 in Spain and from 18% to 55% during the same period in Italy. However, the national figures mask significant regional differences: in 2006 in Italy, the proportion of DES ranged from 23% in Umbria to 78% in Abruzzo; similarly, but less markedly, in Spain the proportion of DES ranged from 40% in Asturias to 78% in Basque Country [15–17].

4.1.2. Reimbursement

There are also differences between Italy and Spain with regard to reimbursement mechanisms. As with all resources used during hospital treatment in the Spanish system, coronary stents are funded through a mixed payment system assigned to the hospital as a whole. The approximate number of procedures expected to be performed during a given year are negotiated as part of an annual programme contract between the hospital and the Health Services Department of the ACs. According to some of the interviewees, however, these volume caps are not strictly binding, as clinicians can sometimes overshoot the target and ask for compensation the following year.

In Italy, on the other hand, coronary stents are reimbursed prospectively through DRG tariffs. Traditionally, reimbursement for the devices was included in DRG 112, which referred generally to all PCIs; the updated version of the classification, adopted nationwide in 2006, introduced a new, specific DRG (i.e. DRG 517 – percutaneous coronary interventions with stent implant in the coronary artery without acute myocardial infarction). The actual amount reimbursed is, nevertheless, variable among and within regions. Variations in the actual amount given to providers can be due (a) to different fee schedules, with specific reference to DRG 517, (b) to different tariffs applied to DRG 517 on the basis of stent type (e.g. the Piedmont region pays a different tariff based on whether a bare-metal stent (BMS) or DES is used), or (c) to add-on payments calculated as a percentage of the total cost of the device (e.g. Lombardy reimburses 30% of the average regional weighted cost of BMS and 50% of DES) or as a fixed amount on the top of the tariffs (e.g. €300 for DES in Campania).

4.1.3. Procurement

Italy and Spain appear similar in the procurement mechanisms that have been adopted: in both countries, coronary stents and other technologies are purchased by hospitals and/or local health organizations that engage directly in negotiations with producers. Nevertheless, in recent years differences have emerged in the procurement policies adopted by the two countries for this technology. The first difference involves the introduction of national price regulation. In Italy, coronary stents are explicitly included in the first "reference price" list of medical devices. A recent ministerial decree lists four categories of coronary stents on the basis of technical specifications, and indicates the maximum reimbursement for each of them. The decree was issued in October 2007; it is therefore too recent to evaluate its impact using empirical data [18]. Spain has not implemented this type of regulation, and there is no indication that it plans to introduce reference pricing for medical technologies at the national level.

The second difference involves the role of regional authorities in the purchasing process. In Italy, some regions have adopted explicit measures to regulate the use of DES in clinical practice. The Emilia Romagna region, for instance, purchased DES centrally when they were first introduced to the market in April 2002, negotiating a 40% reduction in the selling price. Furthermore, it established a Regional Registry for Coronary Angioplasties (REAL) to monitor the diffusion of stents in the region and created a Regional Cardiology/Cardiosurgery Committee, which developed clinical guidelines for DES based on the results documented by REAL [19]. A centralization of purchasing procedures has taken place in other regions as well. For example, *Centro Servizi Condivisi* in Friuli Venezia Giulia and *Estav* in Toscana purchase various devices products, including stents, for all the public providers within their jurisdiction. In Spain, some ACs, such as Madrid, Valencia, and Galicia, are developing regional registries similar to REAL as a way to evaluate new technologies. However, to our knowledge, ACs in Spain are not involved in purchasing coronary stents as direct partners in a contractual relationship.

The third difference involves the way in which coronary stents are introduced into clinical practice at the hospital level. Whereas in Italy the process still appears to be based mainly on an individual relationship between clinicians and hospital managers, in Spain the process is more formalized. In order to add a new technology to the hospital formulary, clinicians are required to provide scientific evidence of its therapeutic value. This evidence is evaluated by an internal commission that includes managers and clinicians. In some ACs, health technology assessment activities have been introduced in hospitals and are increasingly contributing to decision-making processes related to the purchase of new devices, including coronary stents.

4.2. Knee endoprostheses

4.2.1. Coverage

The Spanish benefit basket explicitly mentions the different types of knee endoprostheses (i.e. cemented, cementless, and hybrid) to be used in various procedures (i.e. primary, revision and tumoral). Consequently, the ACs are mandated to ensure the availability of a device within their jurisdiction. In Italy, adding a technology to the national benefit basket is more implicit, because legislation does not specify which services are to be provided, but rather refers to appropriateness as a major criterion to be followed by regions and providers in the delivery of care.

4.2.2. Reimbursement

In the vast majority of cases in Italy, the cost of knee endoprostheses is supposed to be covered by DRG 209 ("major joint and limb reattachment procedures of the lower extremities"). The assigned DRG code does not, however, distinguish between devices used for different parts of the lower extremities; the same DRG is used for reimbursing hip and knee endoprostheses. Moreover, the tariff does not distinguish between different types of knee endoprostheses (i.e. monocompartmental and total). The specific procedure is identified using two ICD-9-CM codes 2002: 81.54 (total knee replacement) and 81.55 (revision of knee replacement).

Substantial variations across regions can be observed both in terms of the DRG 209 tariff and specific add-on payments related to it. The DRG 209 tariff ranges from €7919 in Lombardy to €10,079 in Emilia Romagna. In addition, several regions have introduced add-on payments to help cover the costs of the device. These payments are defined either as a specific amount (e.g. €1300 in Veneto) or as a percentage of the total cost of the prosthesis (e.g. Lombardy reimburses 45% of the average regional weighted cost of the prosthesis). In the majority of regions, these payments are meant to cover the costs of revision procedures, which are more resource intensive, rather than those of primary procedures. In contrast, knee endoprostheses in Spain are reimbursed within global budgets assigned to hospitals on an annual basis, as described above.

During the interviews, a variety of critical issues related to the two systems emerged. In Italy, the use of the same DRG tariff to reimburse the different types of knee endoprostheses has been perceived as a potential way to influence the behaviour of providers. More specifically, one informant specified that the system in place introduces incentive mechanisms that may lead to patient selection by private providers:

> "Private operators, for instance, may select a higher number of monocompartmental rather than total interventions, because – given the same amount of DRG reimbursement – the cost of prostheses is thus lower" (industry representative, Italy).

In the Spanish system, the most critical issue appears to be the question of access to the technology. Even though universal access is officially guaranteed by law, several disparities emerge in real practice due to long waiting lists. The standard defined by law – 6 months for a knee replacement – is rarely observed in practice, and the professionals interviewed as part of this study provided examples of hospitals with waiting times longer than 2 years. In Spain, the search for ways to reduce waiting times for surgical treatments remains at the top of the political and managerial agenda; nevertheless, for the time being, few concrete measures have been adopted to address the problem.

> "In theory, there are no access restrictions to knee endoprosthesis interventions in Spain. Nevertheless, differences in the length of service providers' waiting lists lead indirectly to inequalities between different geographical areas. Promising shorter waiting times is thus a popular strategy among policy makers, especially when elections are close; nevertheless we still urge them to find a concrete solution to the problem" (professional, Spain).

4.2.3. Procurement

Procurement mechanisms in Italy and Spain are similar in several respects. Public tenders for knee endoprostheses are usually structured in lots, while making explicit reference to the components (i.e. patellar, femoral, tibial) to be implanted. In both countries, the payments made to manufacturers by local hospitals can vary depending not only on the volume of the lots, but also on complementary services, such as the provision of technical assistance in the operating theatre or of surgical instruments. As for price setting, in the Italian system knee endoprostheses are included in the list of devices that will be subject to national reference prices; nevertheless, at present, no ministerial decree has been issued to set categories or related prices for these devices; in fact, the recent MD 10/11/07 refers exclusively to hip components. In Spain, the central government has not implemented an analogous regulatory system at the national level. However, Andalusia has introduced a process of registration for knee endoprostheses, among other medical devices, purchased within regional borders. Other ACs work with hospitals to improve procurement specifications and streamline tendering procedures.

4.3. Implantable cardioverter defibrillators

4.3.1. Coverage and diffusion

Italy and Spain have different regulations pertaining to how implantable cardioverter defibrillators (ICDs) are included in the benefit basket. In Spain, the benefit basket (Appendix VI of the RD 1030/06) refers to eight different types of ICDs belonging to three major categories: single-chamber ICDs, double-chamber ICDs, and ICDs with cardiac resynchronization therapy (CRT-D). In Italy, the inclusion of ICDs in the benefit basket is implicit (see above).

The diffusion of technology is monitored through national ICD registries, which in both countries currently cover approximately 90% of centres. Data suggest that there are relevant differences in utilization patterns in the two countries. Italy and Spain show different ICD implantation rates, with the former reporting 189 implants and the latter 60 implants per million population in 2006 [20,21]. Both countries are characterized by significant variability across regions or ACs. In Italy, implantation rates range from 39 in Sardinia, which has 1.6 million inhabitants, to 285 implants per million population in Lombardy, which has 9.5 million inhabitants. In Spain, the majority of ACs reported less than 50 implants per million population; the highest rate is found in Navarra (116 implants), the lowest in Extremadura (24 implants), whereas in one ACs (La Rioja) and two autonomous cities (Ceuta and Melilla) no ICDs implants were reported.

Relevant differences between the two countries can also be found regarding the type of defibrillator being implanted. In Spain, the most frequently used defibrillators are single-chamber ICDs (53.4%), followed by triple-chamber (26.7%) and dual-chamber (19.9%) devices [21]. In Italy, on the other hand, triple-chamber devices account for the highest percentage (38%) of total implants, whereas dual-chamber and single-chamber ICDs account for 31.6% and 30.4% of total implants, respectively [20].

4.3.2. Reimbursement

In Italy, the cost of ICDs is meant to be covered by DRG tariffs. In the first DRG list (Grouper version 10), the ICD implant procedure was not identified specifically, but rather included in the DRGs that provided reimbursement for general cardiac valve and other major cardiothoracic procedures (DRGs 104 and 105). The updated Grouper defined two new specific DRGs for the device ("cardiac defibrillator implant with -DRG 514- and without -DRG 515- cardiac catheterization"). In case of partial replacement of an ICD (i.e. either the generator or the leads), DRG 115 applies ("other permanent cardiac pacemaker implant procedure with acute myocardial infarction/heart failure/shock or AICD lead or generator procedure").

Regional variations are related primarily to the different fee schedules that have been adopted; for instance, the DRG 515 tariff ranges from €10,271 in Campania to €28,498 in Trento. Add-on payments are less frequent for ICDs than for the two other technologies investigated in this study. After adopting the new Grouper (version 19), several regions (e.g. Piedmont) removed the add-on payments from their fee schedule. Only some regions still pay an additional fee that specifically covers a portion of prosthesis costs (e.g. Lombardy reimburses 30% of the regional average weighted cost of the device).

In Spain, ICDs are reimbursed within global budgets assigned to hospitals on an annual basis (see above).

The interviews and the documents reviewed as part of our study revealed several critical features of the two systems of reimbursement. In Italy, undifferentiated payment for all three types of devices (i.e. the same DRGs for reimbursement of single, double and triple-chamber ICDs) might create a financial incentive to use the cheapest device (i.e. single-chamber ICDs). However, data from the national ICD registry show that the triple-chamber ICDs are the devices used most frequently in practice. In this case, financial incentives have not prevented the use of triple-chamber ICDs, as was also confirmed in the interviews.

A similar situation was found in Spain, where reimbursement mechanisms appear to influence marginally the diffusion and uptake of the technology. More specifically, one informant argued that regional variability in ICD implants was related to the cultural background and education of the professionals rather than to any economic incentives or constraints.

> "I would say that reimbursement mechanisms affect diffusion in no more than 10% to 12% of cases. Variations in ICD implants between ACs are more strongly related to different professionals' beliefs about the usefulness of these devices for primary prevention; moreover, in

some secondary hospitals, sending patients to other ACs hospitals for an implant procedure is often perceived by professionals as too invasive for some groups of individuals (e.g. those over 75) and too cumbersome in terms of red tape" (professional, Spain).

4.3.3. Procurement

Similarly to the other technologies, procurement mechanisms for ICDs in Italy and Spain follow common rationales. As far as price regulation is concerned, ICDs in Italy are, like knee endoprostheses, expected to be subject to national reference prices in the near future. In the Spanish system, one AC (i.e. Castilla y Leon) introduced an analogous mechanism, labelled "two-round negotiation", by which regional health authorities establish minimum requirements and maximum prices for each device type. Manufacturers apply to the AC to have their devices classified, after which they may participate in all tenders issued by the hospitals within that AC, negotiating the adjudication price as a reduction in the maximum price that was established by the regional health authority.

Last but not least, differences between Italy and Spain can also be found at the level of negotiation. In Italy, some regions have included ICDs among the devices to be purchased at the national or inter-provincial level, as in the case of *Estav Centro* in Tuscany. In Spain, we were unable to find evidence of formally established agencies for centralized procurement at the AC level; there are, nevertheless, examples of consortia between hospitals (e.g. in Catalunia).

5. Discussion and conclusions

This paper reports on the first comparative study analysing the regulation and funding of medical devices in two major Southern European countries. We investigated whether and how medical devices are included in the national health benefit baskets (i.e. coverage); how these devices are funded through public resources (i.e. reimbursement); and what purchasing mechanisms are in place (i.e. procurement). As such, the study represents an original contribution to the understanding of policy measures adopted in the two countries to manage new technologies. In addition, this study adds to the evidence base needed to evaluate the impact of these policy measures on the diffusion and uptake of medical devices. Looking into the three dimensions investigated (i.e. coverage, procurement, and reimbursement), there are several similarities, but also prominent differences in the two countries (Table 2).

As far as coverage is concerned, both Italy and Spain include the three technologies in their benefit basket. The fact that the Italian basket is more vague does not appear to have an impact on the uptake of these technologies. However, if the current shortage of public funding becomes more acute, we cannot exclude that explicitness will become increasingly important for the appropriate and homogenous diffusion of health technologies across regions or ACs.

There are some important differences in the procurement mechanisms adopted in the two countries. First, there is a clear tendency in both countries to centralize purchasing as a way to strengthen market power and reduce the administrative costs of hospitals. However, whereas in Spain these initiatives most often take the form of consortia between service providers, several Italian regions have also established organizations that centralize technical and administrative activities, including purchasing. Although this centralization has proved to leverage economies of scale and specialization, the long-term impacts of this kind of standardization process are still debated [22]. The trade-off between costs and quality might become more evident in the near future when the reference pricing

Table 2
Cross-country comparison on implantable medical devices (coronary stents, knee endoprostheses, ICDs).

	Italy	Spain
Coverage	• Implantable devices are not explicitly mentioned in the national benefit basket (LEA Decree) in the list of services available under public coverage • Implicit recognition that all services deemed appropriate to provide hospital care must be available to citizens • The DRG classification provides an implicit catalogue of hospital-based services	• ICDs and knee endoprostheses are explicitly mentioned in the benefit catalogue with the list of models (RD 1030/2006 – Annex VI for Orthoprosthetic Services) • Coronary stents are not mentioned, but implicitly included in the benefit catalogue in the category of Coronary Endovascular Implants (RD 1030/2006 – Annex VI for Orthoprosthetic Services)
Procurement	• Devices purchased through open public tender procedures • Negotiations take place at local level between health providers and manufacturers/wholesalers • Various types of voluntary and compulsory consortia between health providers • Reference prices at national level for a selected list of medical devices	• Devices purchased through open public tender procedures • Negotiations take place at local level between health providers and manufacturers/wholesalers • Various types of voluntary consortia between health providers
Reimbursement	• Implantable devices are prospectively reimbursed through DRG tariffs • Tariffs vary across regions and even within regions • In some regions: add-on payments, differentiation according to types of devices	• Implantable devices are reimbursed through hospital's global budget • Global budgets are agreed between hospital providers and regional authorities on an annual basis according to the program-contract • Program contract might contain the catalogue of services to be supplied and the volume of activities agreed • Global budget is partly based upon a blended-DRG system • DRG is not generally used for reimbursement of hospital care.

policy introduced by the Italian government will come into full effect. Both reference pricing and centralized procurement initiatives are signals that central and regional governments are increasingly active on purchasing activities. The Italian government appears to be more active than its Spanish counterpart in expanding regulation, especially in cases where this can contribute to cost-containment. The extent to which these initiatives will affect the medical device market, however, remains to be seen.

The main differences between Italy and Spain are to be found in the third dimension: reimbursement. Negotiated global budgets in Spain and DRG-based prospective payments in Italy are major elements of different approaches to influencing hospitals and producing incentives to organizations and professionals in the use of medical technologies.

At first glance, Spain may appear to be a more amenable setting for adopting these technologies, because organizations there have, in theory, only a "macro" constraint thanks to global budgets. However, these budgets are the result of incremental changes and such an approach can deter the introduction of new technologies. In contrast, the use of technology in Italy is determined less by overall hospital constraints, because the relevant funding mechanisms tend to apply at a lower organizational level, where heads of divisions and departments are most easily held accountable for their decisions and actions. In other words, the DRG system in Italy leads to revenue measures that can be easily assigned to organizational units (e.g. departments) and used to ensure that professionals remain accountable for the margin between revenues and costs. This implies that professionals naturally look at specific DRG tariffs and direct costs for the interventions to understand the financial impact of their treatment decisions. As a result, specific choices concerning whether a given DRG will cover the costs of a new technology or how well a DRG system can adjust to technological change are very relevant in the Italian setting. Phrased differently, the relationship between tariffs and costs and the frequency with which tariffs are revised are two key elements for understanding the economic rationale behind the use of healthcare technologies in Italy.

In short, the systems for regulating and funding medical devices in Italy and Spain operate according to two different principles. In the Spanish case, funding arrangements follow decisions taken at the hospital level about the use of a given technology, whereas in the Italian case there is less organizational control over the use of technologies due to the existence of more decentralized systems of accountability.

A major issue in both countries concerns the actual impact of funding rules on organizations. In normal market conditions, funding mechanisms determine, at least in the long run, the ceiling for expenses, including those for medical devices and technologies. In public systems, however, budgets can be "soft" in the sense that they can be renegotiated or even exceeded with only limited consequences for the organizations in question [23]. In both countries, data from interviews and other sources confirm that budgets are often soft and thus that funding rules do not automatically translate into actual constraints. With regard to funding technologies, this has two major consequences. First, decision making is driven only in part by cost–revenue considerations and depends to no small degree on other issues such as professional status, prestige, the distribution of power within the organization, and the professional and political relationships between decision makers. Hospitals are organizations so embedded within their social and political environment that factors other than financial incentives may be of paramount importance. Second, financial constraints have a greater impact on private organizations, especially those seeking profit. For organizations like these, the funding mechanism in place defines what can be done for patients and whether the use of new technologies needs to be justified from an economic perspective. This means that the same funding rules can influence professional and organizational behaviour in different ways; in general, private for-profit hospitals to react more quickly and more radically to financial incentives than public hospitals.

It is worth reminding that for these three technologies physicians are the key decision makers and that hospital financial constraints and incentives affect (but do not mechanically determine) decisions, as they mainly remain the territory of autonomous professional behaviours. Organizational procedures and rules provide the context in which physicians act. In both countries physicians are employed by public hospitals and are accountable to their top management. Depending on the local context, they may have specific incentives to follow the objectives of the organizations for which they work. However, they have also substantial professional autonomy and their professional and financial interests are generally not completely aligned to those of their organizations. Probably, it is at this level that further explanation of the variability of technology uptake should be searched. From one side, the alignment of professionals to organizational rules and objectives strongly depends on management systems and their effectiveness. Whether physicians pursue their organizations financial objectives depend on how effectively they are managed to do so. Consequently, part of the variability that we have observed may be explained by differences in terms of management systems between and within the two countries. On the other side, how much professionals want to be aligned to the objectives of their hospitals depends on their own objectives. Professional values, scientific prestige as well as reputation effects may motivate physicians to act in contrast to the financial incentives of the organizations for which they work. In sum, reimbursement systems influence professional behaviour but only partly. The extent of such influence depends on the nature of management systems and the array of factors that motivate professional behaviour. Our study suggests that professional behaviour and local management systems may be important explanatory variables of the variation in technology uptake.

Our results have relevant health policy implications. For two of the three technologies investigated we have clear evidence that the utilization rates differ between the two countries. For such different utilisation rates cannot be explained by epidemiological factors, the access to the technologies varies across regions and, *de facto*, is not guaranteed nationally. For decentralized systems that operate according to a national coverage framework monitoring

access to innovative technologies is pivotal and it is a prerequisite to maintain territorial equity to health care. The issue of postcode rationing is common to most systems, but in decentralized ones is more relevant because policy diversity may favour heterogeneity in service provision. In decentralized NHS type of systems monitoring and managing equity across jurisdictions is a major challenge, likely to gain importance due to the tension between technological advances and fiscal constraints. If in both countries equity concerns are real, it appears essential to build institutional capacity to govern and manage health technologies. We observed that in both countries coverage, procurement and reimbursement are actively used to govern technologies to only a minor extent. The decision about their uses is left almost completely to professionals with little direct or indirect guidance provided by national and regional authorities. It is likely that the difficult search for a balance between introducing innovations, containing costs and assuring equity will require stronger regulatory action in the next future. In the same scenario, the use of Health Technology Assessment (HTA) at the central level could become much more important. At present, even if in both countries national agencies (Italian National Healthcare Agency – AGENAS -and Spanish Agency for HTA – AETS) claim to be in charge of HTA across their jurisdictions, their actual role has been very limited. The centralization of some HTA activities together with a stronger coordination of heterogeneous regional initiatives is deemed necessary to govern the diffusion of medical technologies in both countries.

Future research will require more detailed, country-specific data on a series of additional variables thought to influence the diffusion of technologies. These data are essential if we are to construct a more robust hypothesis concerning the economic, cultural and professional determinants of the uptake and diffusion of innovation within and across different countries. Indeed, a more detailed examination of the non-financial drivers of professional and organizational behaviour will be key to understanding the diffusion of health technologies in Italy, Spain and, ultimately, other countries in Europe.

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