Value-based healthcare in Spain
Regional experimentation in a shared governance setting
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Value-based healthcare in Spain: Regional experimentation in a shared governance setting is an Economist Intelligence Unit (EIU) report, commissioned by Gilead Sciences, which looks at health outcomes of treatment relative to cost. In this particular paper, The EIU looks at the structure of Spanish healthcare delivery, the process of making healthcare more accountable in Spain, and the growth and adoption of value-based measures.

In September-October 2015 The EIU conducted three interviews with senior healthcare executives and academics; the insights from these experts on value-based healthcare in Spain appear throughout the report. The EIU would like to thank the following interviewees (listed alphabetically) for sharing their insight and experience:

- José Maria Argimon, director, Catalan Agency for Health Information, Assessment and Quality (Agencia de Qualitat i Avaluació Sanitàries de Catalunya, or AQuAS)
- Rafael Bengoa, director, Health Department, Deusto Business School, Bilbao
- Guillem López-Casasnovas, professor of public finance and founder and director of the Centre for Research in Health and Economics, University Pompeu Fabra, Barcelona; member of the board of directors, Spanish Central Bank

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Introduction

Spain’s 1978 constitution established the framework for the decentralisation of the country’s National Health System from the central government in Madrid to the regional health services of the country’s 17 autonomous communities and two autonomous cities. Rising healthcare costs, concerns about efficiency in healthcare provision and a desire to streamline the process of introducing new health technologies were the main drivers behind the introduction of health technology assessment (HTA) in the 1980s.

Although Spain’s Ministry of Health, Social Services and Equality continues to co-ordinate broader healthcare priorities and set pharmaceutical policy—including assessment, authorisation and pricing—it has transferred significant power over financing, planning and management of healthcare to the country’s regions since 1981. While the Ministry of Health sets pharmaceutical policy, the regions run their own health budgets, with a degree of co-operation and sharing of best practices and HTA between them. However, just a few of them have taken the lead in experimenting with initiatives in transparency, shared decision-making and a greater role for population management.

Meanwhile, as power has devolved from Madrid to the ministries of health in the regional governments, the regions have also taken on more responsibility for the appraisal of treatments and care pathways, and for final price negotiations with drug manufacturers. This gradual process has seen regional health departments take on responsibility for between 30% and 40% of regional governments’ total annual budgets.

Spain’s total (public and private) health expenditure as a proportion of GDP was 8.9% in 2013, the last year for which data are available, compared with 9.6% in 2010, according to the World Bank, with just under €10bn (US$11bn) of cuts in the healthcare budget in the four years from 2009 to 2013. Meanwhile, the country has made €4.3bn in savings on pharmaceutical expenditure since 2012.

A key catalyst of healthcare reforms over the past few decades has been cost containment, with four royal decrees in two years dedicated to reducing expenditure. However, there has been little assessment of the value of what the health system is buying, according to Guillem López-Casasnovas, professor of political economy and founder of the Centre for Research in Health and Economics at the University Pompeu Fabra in Barcelona.

This paper will show that the process of making healthcare more accountable in Spain is evolving in a number of intriguing ways, yet the growth and adoption of value-based measures remain fragmented, in large part owing to the decentralised administration of healthcare in the country. While on the one hand the system enables flexibility for innovation in the regions, on the other hand it also makes it more difficult to roll this out on a national level.

1 International Society for Pharmacoeconomics and Outcomes Research (ISPOR), ISPOR Global Health Care Systems Road Map: Spain – Pharmaceutical, 2009. Available at: https://www.ispor.org/HTARoadMaps/Spain.asp


3 Healthcare information and Management Systems Society (HiMSS), Strategic Interoperability in Germany, Spain & the UK: The Clinical and Business Imperative for Healthcare Organisations, May 26th 2014, p. 7.

4 http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS.


The evolution of HTA in Spain

The history of health technology assessment (HTA) in Spain dates back to the late 1980s, with its introduction driven—as in many other European countries—by the increase in healthcare costs and worries about the efficiency of healthcare provision and the rationalisation of the introduction of new technologies. In Spain HTA takes place at three different levels: at the national level, to define a common benefit package for devices and treatments excluding pharmaceuticals; at the national level, for pharmaceuticals; and at the regional level.

At the national level, the Spanish Agency for Medicines and Healthcare Products (Agencia Española de Medicamentos y Productos Sanitarios, or AEMPS) is responsible for the authorisation and classification of new medicines. Since 2013 AEMPS has prepared so-called national therapeutic positioning reports, in which the clinical benefits, level of innovation and positioning in therapy of a new drug are evaluated.

Drugs assessment falls under the remit of the General Directorate for Pharmacy and Medicinal Products, which is part of the Ministry of Health and is responsible for setting pharmaceutical policy. The General Directorate also evaluates drugs before market entry and assesses them based on a range of criteria, including the severity of indications, the usefulness of medicines, patient requirements, the rationality of costs, the existence of therapeutic options and the degree of innovation.

The inter-ministerial pricing committee (Comisión Interministerial de Precios de los Medicamentos, or CIPM)—which includes officials from the Ministry of Health, the Ministry of Economy and Finance and the Ministry of Industry, Tourism and Trade—deals with reimbursement and pricing, and sets maximum ex-factory prices for every medicine, including generics. Since March 2012 the regions have been members of the pricing committee, with two regional representatives rotating every six months. Like similar bodies in other European countries, they take cost, efficacy, safety and need into account when determining the coverage of “curative care” for both outpatient and inpatient services. Unlike in Germany and England, which are often used as references, however, the Spanish authorities do not consistently evaluate cost-effectiveness or budget impacts.

Pricing in other European countries is used as a reference for innovative medicines. In practice, therefore, although the national government defines the common basket of products, the trend in recent years has been to use the lowest
European price as a reference. The decision on price and reimbursement of a new drug must be taken within 180-270 days in Spain; however, in practice it has taken longer in recent years—the process of setting prices took 431 days on average in 2013, for example.13

For drugs used in hospital settings, funding of medicines is covered by regional/hospital budgets, and the Ministry of Health decides on an official maximum price to be reimbursed by the National Health Service. Regions may apply for specific reimbursement conditions

But while this structure provides an initial pricing framework, regional health services and hospitals may negotiate lower unit prices or risk-sharing agreements, as in the case of Catalonia and Valencia, for example. It is this degree of flexibility that has given the regions an especially powerful role in recent years.14

“European reference pricing is something that is looked at on the national level,” says Professor López-Casasnovas. “There is an inter-ministerial committee on prices, but it doesn’t guarantee what unit price pharma will get; regions are able to negotiate volumes according to discounts because they can decide on prescription levels.”

In practice, therefore, although the national government defines the common basket of products the Spanish National Health Service will cover, the regions have significant leeway to add services and products. Moreover, the process of HTA itself further illustrates some of the fragmentation within the Spanish system.

**Fragmentation**

The number of agencies having some responsibility for HTA in Spain is extensive, in some cases contributing to an overlapping of responsibilities and a sense of fragmentation. The Spanish Agency for HTA (Agencia de Evaluación de Tecnologías Sanitarias, or AETS), which was established in 1994, primarily evaluates equipment, devices, surgical and medical procedures and issues HTA reports commissioned by the government or government-related agencies. Assessment criteria include social, economic and ethical dimensions of the technology or procedure.

Despite the existence of separate healthcare infrastructures in all autonomous regions, only seven—Madrid, Andalusia, the Basque Country, Catalonia, Galicia, the Canary Islands and Aragon—have set up their own regional HTA agencies. Other regions have units for planning and advice on decision-making, which in some cases includes a degree of HTA evaluation. An overview of the regional HTA agencies is given below.

Aragon’s Institute of Health Sciences (Instituto Aragonés de Ciencias de la Salud, or IACS) does not carry out formal evaluation activities, but it does conduct some HTA-related projects, and its new government has announced plans to create a dedicated HTA agency.

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**Region** | **Regional HTA agency** | **Launch**
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Catalonia | Catalan Agency for Health Information, Assessment and Quality (Agencia de Qualitat i Avaluació Sanitàries de Catalunya, or AQuAS), formerly the Catalan Agency for Health Technology Assessment and Research | 1991
Basque Country | Basque Office for Health Technology Assessment (OSTEBA) | 1992
Canary Islands | HTA Unit of the Canary Islands (Servicio Canario de Salud, or SESCS) | 1993
Andalusia | Andalusian Agency for Health Technology Assessment (Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, or AETSAN) | 1996
Galicia | Galician Agency for Health Technology Assessment (Axencia de Avaliación de Tecnoloxías Sanitarias de Galicia, or AVALIA-T) | 1999
Madrid | Unit for Health Technology Assessment (Unidad de Evaluación de Tecnologías Sanitarias, or UETS) | 2003

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14 Pharmaceutical Health Information System, PHIS Pharma Profile Spain 2010.
The regional agencies, like their national equivalents, primarily evaluate equipment, devices and surgical or medical procedures, although some are involved in drugs evaluation, notably AQuAS, which co-ordinates the Committee for the Assessment of Hospital Use of Drugs. Some of the regional agencies—including AETS, OSTEB, and AVALIA-T—also produce clinical practice guidelines. In the case of OSTEB, AETS, AETSA and AVALIA-T, the agencies also undertake some horizon-scanning of emerging technologies.15

A virtual network of the Spanish Agency for HTA and the six regional agencies, known as AuNETS, was formed in 2007 to provide high levels of co-ordination and specialisation and support the trend for the devolution of HTA from government-linked agencies to hospital-based HTA. However, the system still operates largely in an advisory capacity and could play a stronger role as an independent body, according to Rafael Bengoa, director of the health department at Deusto Business School in Bilbao and a former minister of health and consumer affairs in the Basque regional government.

“In the past three to four years those units have begun to get together as a network, dividing the work among themselves and providing advice to ministers,” Dr Bengoa says, adding: “I can’t yet say that the Spanish system has teeth.”

José María Argimon, director of AQuAS, also observes that although the network’s advice runs the gamut from what type of medicines are covered to what types of patients will be treated—and includes devices, processes, diagnoses and clinical practices—its recommendations are not binding at the national level.

Public hospitals, meanwhile, have their own annual budgets set by the health department in each region, which can be used to “rationalise the introduction and diffusion of technologies”.16 Hospitals also have pharmaco-therapeutic commissions, with those in teaching and high-technology hospitals especially likely to be in charge of advising on the purchase of big-ticket drugs. They also assess the added value of innovative drugs approved by the Spanish Agency for Medicines and Healthcare Products after a review of the evidence regarding safety, efficacy and cost.17 On top of these agencies, every region has a regional drug committee.

Recent efforts to refine this process include the establishment by the Spanish Society of Hospital Pharmacies of GENESIS (Grupo de Evaluación de Novedades, Estandarización e Investigación en Selección de Medicamentos), a working group which aims to standardise a methodology for evaluating the added value of hospital drug innovations approved by the Spanish Agency for Medicines and Healthcare Products. GENESIS includes hospitals from 11 autonomous regions, and there is a similar initiative to assess and control the added value of innovative drugs at the primary-care level. This project, known as the mixed committee for the evaluation of new drugs, is co-ordinated among five regions: Aragon, Andalusia, Catalonia, Navarra and the Basque Country.

In the case of pharmaceutical products, Spain looks especially to the UK’s National Institute for Health and Care Excellence (NICE) as a model for its assessment decisions, according to those interviewed for this report. However, unlike NICE, which assesses cost-effective medicines and treatments as those that cost no more than £20,000–30,000 (US$31,000–46,000) per quality-adjusted life-year (QALY), Spain stops short of establishing a formal cut-off point for measuring cost-effectiveness.

Regional differences and experimentation

As mentioned above, six of Spain’s 17 regions have taken the lead in setting up their own health assessment units and taking more decisions on healthcare planning and policy at the regional level. Yet even within this self-selected group there is a significant degree of difference in policy outcomes, whether as a result of the dominant

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15 Garrido et al, Health Technology Assessment and Health Policy-Making in Europe, p. 94.


17 Ibid.
political party in the regional government or because regional health authorities take into account the leverage of industry in the region. These considerations are becoming increasingly important in price negotiations between pharmaceutical companies and the regions.

“At the final step, after prescription levels are assessed by the regional authorities, there is a process that means strong bargaining between the authorities and pharma on a regional basis over rebates,” explains Professor López-Casasnovas.

This process for setting prices can lead to a number of anomalies, including the fact that while there may be transparency over price at the national level, the determination of unit cost of a given drug depends on the regional authorities, including the extent to which the medicine is used in hospitals and what volumes will be required.

“Authorisation and pricing at the national level were formerly more important, but they are not really so important these days,” Professor López-Casasnovas adds. “Whatever you are doing in volume, prescription and appraisal in reimbursement is more important.” In this respect, he says, four regional health authorities—Catalonia, Madrid/Valencia, Andalusia and the Basque Country—are most influential, with the other regions largely following their lead. “Whatever the national government sets, it is not the final price,” he explains.

Ironically, Professor López-Casasnovas notes, Spain’s decentralised system can be beneficial to both sides of the negotiations: taxpayers benefit because manufacturers can no longer determine a final price by lobbying the Ministry of Health, but must instead negotiate individually with at least the largest regions.

But the system also holds advantages for pharmaceutical companies, he observes. “They might go for a regional authority that sees things closer to the way they do,” he points out, noting that the most pioneering regions, such as Catalonia, investigate the degree of therapeutic innovation and efficacy, with the potential for drug makers to increase prices by as much as 15% for the most innovative products. “If they can prove that the drug works the way they say it does, they may show the regions why the treatment should be a standard.”

This leads to a wide degree of flexibility in the way regional governments deal with pharmaceutical suppliers, with some negotiating risk-sharing agreements and others preferring to base their own discussions on unit pricing on agreements reached by neighbouring regional governments. Catalonia currently has nearly 16 risk-sharing agreements in place, according to Dr Argimon of AQuAS.

In addition to enhancing local decision-making on the adoption of innovative treatments, the devolution of healthcare funding and policy has led to a significant degree of experimentation to try to enhance medical outcomes and value.

This is most notable in Catalonia, which has Spain’s oldest regional HTA agency. In 2012 AQuAS introduced a number of programmes aimed at making it easier for Catalan health officials to measure outcomes, the first of which is designed to try to reduce overdiagnosis and overtreatment within the healthcare system.

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“Today, there is enough evidence to show that, within clinical practice, there are procedures that do not add value,” explains Dr Argimon. Taking the example of patients who receive X-rays or magnetic resonance imaging (MRI) scans for pain despite having no neurological symptoms, he notes that there are some 40,000 such procedures carried out in Catalonia every year, costing a total of €700,000. Eliminating those that are unnecessary “can free up resources to fund a primary-care team or 280 knee replacements,” he adds. AQuAS operates the project in collaboration with scientific societies and healthcare providers, so all recommendations are evidence-based and quantifiable.
One example of an area in which new guidelines have helped to reduce unnecessary expenditure is AQuAS’s decision to recommend that doctors should no longer prescribe bisphosphonates to post-menopausal women with a low risk of bone fractures. In the year after the guideline was changed the number of women over 50 treated with bisphosphonates for more than five years fell by 28%, equivalent to savings of €8m, according to Dr Argimon.

Also since 2012, AQuAS has been publishing the results of 90 indicators relating to outcomes, including mortality, nosocomial (hospital-acquired) infections, surgical complications and patient satisfaction in an effort to make the Catalan region’s healthcare system as transparent as possible. The project, known as the Outcomes Report (Central de Resultats) of the Catalan healthcare system, will introduce patients’ views as an additional indicator later this year, Dr Argimon says. In previous reports patients had suggested that indicators related to services received, such as waiting-room comfort or information on waiting times, were of the greatest interest. The project is now hoping to ask citizens about other indicators they are likely to find most useful.

“For policymakers and health managers, the mortality rate or the number of nosocomial infections are good indicators of the quality of the health system; however, these indicators may not be useful for patients,” he adds.

The information appears on the region’s website in an open-data format, meaning that patients in Santander can access information to compare their hospitals with those in Barcelona. “The idea is that benchmarking is the best way of improving our healthcare,” Dr Argimon explains, adding that although it is too soon to expect changes in patient behaviour, the Outcomes Report is likely to increase transparency and strengthen citizen participation.

The project does not just involve publication of data, but also meetings between different hospitals, in which specialists in areas such as cardiovascular medicine or cancer can evaluate and refine the indicators, as well as having the opportunity to adopt different methods of patient management for replication in their own institution. It also identifies care models that are shared between healthcare-system stakeholders through an open innovation collaboration platform.

“One hospital may say it’s not necessary to do a pre-surgical visit for anaesthesia because there is a lot of information coming from clinical records,” Dr Argimon says. “If a small hospital in Catalonia puts it in the platform, others are copying the idea and allowing a sharing of best practices.”

The More Value to the Health Information in Catalonia Project (VISC+) is another initiative introduced with the goal of making better use of data. VISC+ collects all the information gathered by the Catalan healthcare system in one database, anonymously and securely, in order to improve the quality of research, accelerate innovation and increase the quality of healthcare. “The amount of data digitally collected is vast, and I think the data will change the way healthcare services are provided,” Dr Argimon comments.

A third project, launched earlier this year and building on a similar programme pioneered in the Canary Islands region, is designed to encourage patients to share in decision-making about their own treatment with physicians by providing them with the tools and knowledge to make their own decisions.

“We launched this project with patient associations, with clinical teams giving patients information and trying to make them reflect on different possible treatments, including personal preferences, side effects and so forth,” Dr Argimon explains. The project has focused on diseases where there are several potential courses of action, including prostate cancer and kidney disease, and is expected to extend to breast cancer and hip replacements by the end of the year, he adds.
Chapter 2: Finding more consistent ways to measure value

While Spain’s regions have begun to pioneer ways of extracting greater value from their healthcare investments and are sharing best practices accordingly, some of those interviewed say the system needs to develop better measures of value and learn how this can be best delivered.

In the Basque Country, policy experts are increasingly looking abroad for models that can help them create such a system, according to Dr Bengoa, who is also an adviser to the Socialist Party ahead of the general election in December 2015. As a former health minister, he says he designed a programme for treating chronic diseases that involved much more integrated delivery of care. He adds that he and his colleagues were particularly interested in the evolution of accountable care organisations (ACOs), which emphasise greater integration of healthcare provision as part of a co-ordinated approach to healthcare and are increasingly gaining traction in the US.

In his region, Dr Bengoa points out, policymakers see the value of using HTA to review not only healthcare itself, but also population management, in which preventative care is a crucial element of overall healthcare management. “We are moving towards local integrated care organisations,” he adds. “Once they are organised and you have primary care connected to hospital care, you have an area for responsibility for the health—and not only the healthcare—of the population.”

Dr Bengoa notes that reforming the Spanish system could include lessons from the Triple Aim Initiative for optimising healthcare, developed in the US by the Institute for Healthcare Improvement (IHI) in Cambridge, Massachusetts. The initiative consists of improving the patient experience of care, improving the health of populations, and reducing the per-capita cost of healthcare.18

Stronger focus on value

“The interesting thing about value-based healthcare is that commissioners are beginning to be interested in this,” says Dr Bengoa. “Before, commissioners were buying traditional services and activities, and now they are realising that they don’t know what they are getting. They want value from providers.”

Looking more closely at the HTA agenda, he adds, it becomes clear that if it remains within the existing framework—with fragmented care, delivery and financing—the triple aim will be impossible to achieve. “The change is radical at both the financing and the delivery level, but we have to be able to get the delivery model going,” he points out.

Spain already has some of the tools it needs to implement such a system, Dr Bengoa says, including the ability to stratify populations, electronic medical records, electronic prescriptions and use of telemedicine. A recent report by Accenture, a consultancy, found that Spain was among the top scorers of eight countries on its Connected Health Maturity Index, with one of the highest rates of healthcare IT adoption and health information exchange for both primary and secondary care.19

Moreover, a white paper on interoperability by the Healthcare Information and Management Systems Society (HiMSS), a global non-profit organisation, found that more than 93% of Spanish hospitals had interoperable systems, with 89% interoperable across multiple locations and 62% interoperable with other organisations. This is due to that fact that around 95% of IT budgets are in the hands of regional authorities.20

Opportunities in greater transparency and consistency

Models of how more consistent healthcare delivery might look can be found in the approaches that have been adopted in a comprehensive way at the national level. In the case of Hepatitis C, Spain has a detailed national plan that co-ordinates the collection of epidemiological data about the disease and patient outcomes, provides for the sharing of information between regions, and explicitly spells out how different patient populations should be treated.21

Finding a way of creating greater consistency in the appraisal and pricing of pharmaceutical products at the regional level could also be an advantage, according to Professor López-Casasnovas. He says, however, that even at the regional level “very few agencies go for their own evaluation in terms of cost-effectiveness,” although some agencies do some meta-analyses of drug performance or look at evidence sets from external bodies such as the Cochrane Collaboration.22

Both Dr Bengoa and Dr Argimon say that the lack of transparency about how decisions are made and the unwillingness to acknowledge where difficult choices are being made remain a key problem. “We need to make these decisions like NICE does, available to the public, so tough decisions can be made,” Dr Argimon emphasises.

Spain also has an opportunity to increase its use of generic or biosimilar drugs, with a generic penetration rate of just 38% measured in volume,23 compared with 67% in the UK.24 “We need to identify a new delivery system that is sustainable in economic terms and improves quality,” Dr Bengoa says. “The decentralised system makes it easier, because I don’t think it is going to happen at the national level.”

Developing a more independent HTA system would also help, although it is likely to face opposition from entrenched political interests, according to Professor López-Casasnovas. “Politicians do not want to be subjected to these recommendations; so far, their policies have been fully discretionary, and they don’t want to lose that.” He notes, however, that the uncertainty surrounding the upcoming general election in Spain creates a window of opportunity for those looking to establish a system similar to the UK’s NICE or Germany’s Institute for Quality and Efficiency in Healthcare (IQWIG) at the regional or the national level, “because they need some sort of formal proceeding for cost-effectiveness priority-setting to weaken the otherwise costly political battle over healthcare.”

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19 Accenture, Making the case for Connected Health: Accenture study explore the future of integrated healthcare delivery, February 2012, p. 6.

20 HiMSS, Strategic Interoperability in Germany, Spain & the UK; p. 7.

21 Ministry of Health, Social Services and Equality, Strategic Plan to Tackle Hepatitis C in the National Health System, May 21st 2015.

22 Cochrane, About us, Who we are. Available at: http://community.cochrane.org/about-us


24 British Generic Manufacturers Association (BGMA), “British Generic Manufacturers Association Overview”. Available at: http://www.britishgenerics.co.uk/
Spain’s decentralised health and HTA system has allowed for significant innovation and the sharing of best practices, but the level of regional autonomy has contributed to both a lack of consistency and an absence of transparency. And although the system enables flexibility for innovation in regions, it also makes it more complicated to roll this out on a national level and regional equity access is crucial.

Moreover, while Spanish agencies look at patient experiences and efficacy when assessing medical treatments, devices and care pathways, decisions have largely been framed by cost-containment pressures, with little effort so far to measure cost-effectiveness.

As Dr Bengoa explains: “Although we have the infrastructure to do fairly sophisticated assessments of both drugs and new technologies, and those units produce important results that are even being used internationally, the connection between that advice and the policy decision being taken is not well made. It’s a big point, because it means that policymakers are not deciding based on evidence.”

There are some encouraging signs that change is on the cards. Spanish regional experiments suggest that a willingness to re-evaluate ineffective treatments, involve patients in decision-making and commit to a greater integration of healthcare provision are just some of the ways in which the country could help to enhance value.

The experts interviewed for this paper agree that, looking ahead, mounting health costs and a greater emphasis on value measures in other developed economies will lead to increased pressure for Spanish health authorities to measure value as a proportion of cost more widely. These trends, they say, are likely to drive the development of a home-grown, centralised national body with the authority to make difficult funding choices in a more transparent and consistent way.
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