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DOSSIER

HEALTH AND THE HEALTHCARE SYSTEM

INTRODUCING THE AUTHORS OF THE HEALTH AND HEALTHCARE SYSTEM DOSSIER.

Patricia Barber

http://www.dmc.ulpgc.es/espp/10:patricia-barber.html

An Associate Professor at the Department of Quantitative Methods in Economics and Management at the University of Las Palmas de Gran Canaria.

Researcher in health economics, with emphasis on the use of simulation models applied to the planning and management of systems, mainly human resources. Other research topics of interest include structural models of simultaneous equations and empirical applications in the areas of smoking, economic evaluation of new technologies and equity. Four six-year research periods recognised by the CNEAI. International work experience in Costa Rica, Ecuador, Brazil, Panama and Peru.

Lluís Bohigas Santasusagna

He holds a PhD in Economics and Master in Public Health. He has worked for 40 years in the healthcare sector, in managerial positions in the Catalan and Spanish healthcare administrations, and in the healthcare technology sector. He was a promoter and introducer of the health economy, quality control in healthcare and healthcare planning, both in Catalonia and in Spain. He was secretary of the Catalan Association of Economists, president of the AES (Health Economics Association), president of the SESPAS (Spanish Society of Public Health and Healthcare Administration) and member of the Abril Commission. He is currently an academic at the Royal Academy of Medicine of Catalonia, president of the Health Circle and president of the Health Commission of the Catalan Association of Economists.

Carlos Campillo Artero

He holds a PhD in Medicine and Surgery (University of Barcelona), a Master in Public Health (The Johns Hopkins University) and specialised in preventive medicine. He works in clinical assessment and healthcare services research (Health Service of the Balearic Islands, Mallorca). He is an associate researcher at the Centre for Research in Health and Economics (CRES/UPF), a professor and academic co-director of the Master in Health Economics and Medicine (Master in Health Economics and Pharmacoeconomics, Barcelona School of Management, Pompeu Fabra University). Former civil servant and currently a WHO consultant. He is a member of the Ministry of Health's Technical Committee on Patient Safety. He is also an associate editor and reviewer of more than 20 national and foreign medical and health economics journals, and the author of more than 100 articles.

Ana Clopés Estela

She holds a Degree in Pharmacy (University of Barcelona), specialised in hospital pharmacy (Sant Pau Hospital), and a PhD from the Autonomous University of Barcelona (Department of Pharmacology, Therapeutics and Toxicology). She is a founding member of the Genesis Group of the Spanish Society of Hospital Pharmacy - created in 2005 - and was coordinator of the Group between 2011 and 2014.

Author of more than 200 works published in the form of book chapters, articles in national and international journals, and communications at conferences at national and international level.

A member of the Ministry of Health's Advisory Committee for Pharmaceutical Benefits.

Francesc Cots Reguant

He holds a Degree in Economics from the Autonomous University of Barcelona (1987), a Master's degree in Regional and Urban Economics from the Autonomous University of Barcelona, and a PhD in Economics from the Autonomous University of Barcelona (2001).

He is a health economist and combines management of the Barcelona Parc de Salut MAR health park (Management Control Department) with research at the Hospital del Mar Institute for Medical Research (IMIM) through various cost and healthcare service projects focused on quality, immigration, costs per incident and care process. He is the chief researcher of the Spanish network of hospital costs (RECH) and was the director of the Catalan Open University's Master in Clinical Management (2005-2012). The results of his research are published in 90 articles in indexed journals.

Joan Gil i Trasfí

He holds a Degree and PhD in Economics from the University of Barcelona, and is an Associate Professor at the UB's Faculty of Economics and an Associate Researcher on the Barcelona Economic Analysis Team (BEAT). His research focuses on areas of health economics, social security, the welfare state, ageing and dependency, and the results of his research have been published in various national and international scientific journals, in various books and book chapters, and he has collaborated in several national and international research projects.

Beatriz González López-Valcárcel

http://dmc.ulpgc.es/en/beatriz-lopez-valcarcel-2.html

A Professor of Quantitative Methods in Economics and Management at the University of Las Palmas de Gran Canaria. She is a researcher in health economics (labour markets and human resource planning, new technologies, medicines, public health economics). Leader of research projects, National R&D Plan and European projects. President of the Health Economics Association (2004-2006), of the Public Health Economics department at the European Public Health Association, EUPHA (2011-2012), and of the Spanish Society of Public Health, SESPAS (2015-2017). She is an international consultant in Mexico, Brazil, Argentina, Chile, Uruguay, Costa Rica, Panama and Mozambique. Awarded the Cross of the Order of Civil Merit for Health (Ministry of Health, Social Services and Equality). Adoptive daughter of the City of Las Palmas and the island of Gran Canaria. Member of the Health Advisory Board (2019). She is an academic at the Royal Academy of Sciences of Galicia.

Pere Ibern Regàs

He is an economist and researcher at the Centre for Research in Health and Economics (CRES-UPF) and director of Strategic Development at DKV Insurance. He holds an MBA from ESADE and a PhD from the University Ramon Llull. He studied healthcare organisation management at Yale University and business governance at INSEAD. He has held senior managerial positions in healthcare organisations. He was a researcher at the Centre for Demographic Studies at Duke University, a

consultant to the World Bank and various multilateral agencies. Former president of the Health Economics Association and a member of the board of the Spanish Society of Public Health and Healthcare Administration (SESPAS). He has authored many scientific and journalistic articles. In his blog https://econsalut.blogspot.com he closely monitors the current situation in health economics and healthcare policy.

Félix Lobo

http://www.felixlobo.com/

Emeritus Professor at University Carlos III de Madrid. He co-directs the Master in Healthcare Assessment and Market Access (Pharmaco-economics) and has been in charge of the FUNCAS Economics and Health Policies since 2017. He has been the President of Ministry of Health's Advisory Committee for Pharmaceutical Benefits, also since 2017.

He was a visiting scholar ar the University of California, Berkeley (1975-1976 and 2003) and visiting professor at the University of Minnesota.

He has authored numerous scientific articles, books and educational publications.

He was Director General of Pharmacy and Healthcare Products (1982-1988) and President of the Spanish Agency for Food Safety and Nutrition (2005-2008). He was a member of the drafting committees for the preliminary drafts of the General Health Act of 1986 and the Medicines Act of 1990 and launched the first drafts of the Food Safety and Nutrition Act of 2011.

He was awarded the Grand Cross of the Civil Order of Health in December 2009.

Guillem López Casasnovas

He holds a Degree in Economics (awarded outstanding) and a Degree in Law from the University of Barcelona, as well as a PhD in Economics from York University (1984). He was a professor of Economics at Pompeu Fabra University where he was vice-rector and dean. He was a visiting scholar at Stanford University (1991), and in 1996 he founded and directed the Centre for Research in Health and Economics.

Former Governing Director of the Bank of Spain (2005-2017). He is a distinguished member of the Catalan Association of Economists; full member of the Royal Academy of Medicine of Catalonia and the Institute for Catalan Studies. Former president of the World Health Economics Association. He is president of the Free Theatre Foundation and is patron of the Temple of the Sagrada Familia. He was awarded the Saint George's Cross and the Trueta Medal for Healthcare Merit, and the Balearic Islands' Ramon Llull Award. He holds an honorary doctorate from the ISALUD University of Buenos Aires.

Ricard Meneu

He holds a Degree in Medicine from the University of Valencia (UV), specialising in Preventive Medicine and Public Health; a Master's in Health Economics and Healthcare Services Management (University of Alicante), and a PhD in Economics (UV).

Author of more than a hundred articles and book chapters, and a lecturer in numerous master's and postgraduate health programmes, he is an associate researcher at Pompeu Fabra University's Centre for Research in Health and Economics (CRES).

He is editor-in-chief of the publication *Gestión Clínica y Sanitaria* (http://iiss.es/gcs/index.htm), vice-president of the Health Service Research Institute Foundation (f-IISS), former vice-president of the Health Economics Association and former secretary of the Spanish Association for Healthcare Technology Assessment (AEETS).

Toni Mora

http://www.uic.es/ca/personal-page?id_user=tmora

A professor of Applied Economics at the International University of Catalonia (UIC) and director of the IRAPP (Research Institute for Evaluation and Public Policies). He was former Dean of the Faculty of Economics and Social Sciences at the UIC, as well as Vice-Rector for Research, Innovation and Transfer. He is currently president of the Health Economics Association (AES) and director of the Chair of Public Economics and the Real World Evidence Chair at the UIC:

http://www.uic.es/ca/irapp

Author of numerous publications, he has participated in multiple research projects in both the public and private spheres, as well as in various collaboration agreements.

Juan Oliva

Professor of the Department of Economic Analysis and member of the Health and Economics Research Seminar (SIES) at the University of Castilla-La Mancha. His scientific work is focused on health economics and management with specific emphasis on the social cost of disease and the use of economic evaluation of healthcare interventions applied to decision-making. He has had more than a hundred articles published in peer-reviewed scientific journals and nearly forty collective pieces of work. He has collaborated with the Ministry of Health in the design of various comprehensive strategies for the fight against diseases and in the drafting of the Report on the National Healthcare System, as well as with various ministries of Health and Welfare and healthcare sector companies. Member of the Board of Directors of the Health Economics Association between 2007-2013 (president between 2010-2013).

Vicente Ortún Rubio

https://www.upf.edu/web/vicente-ortun

Emeritus Professor and former Dean of the Faculty of Economics and Business at Pompeu Fabra University (UPF). Chief researcher and former director of the Centre for Research in Economics and Health (CRES-UPF). Co-director of the Master in Healthcare Services Administration and Management at the UPF-Gaspar Casal Foundation in Madrid, editor of *Gestión Clínica y Sanitaria*, member of the Governing Council of the Parc de Salut Mar health park, and UPF delegate for the Schools of Engineering, Business and Health at the TecnoCampus, Mataró. Distinguished member of CAMFiC.

He has an MBA from ESADE, an MSc from Purdue University as a research assistant, doctoral studies in Public Health at The Johns Hopkins under the Fulbright grant scheme, a PhD in Economics from the UB, and he was a visiting scholar at the Massachusetts Department of Economics Institute of Technology (MIT).

His career portfolio includes work with Arthur Andersen & Co, Geseco-Banco Urquijo, Hospital de Sant Pau, Generalitat de Catalunya and the Ministry of Health and Consumer Affairs.

Olga Pané Mena

A doctor specialised in occupational medicine, she has a Master in Healthcare Services Management, and postgraduate degrees in management from ESADE and IESE business schools.

She is currently director of the Parc de Salut Mar health park in Barcelona, CEO of the Reference Laboratory of Catalonia, CEO of Imatge Mèdica Intercentres, and president of the Bonanova Foundation and the Academic Committee of IS Global.

She has an extensive career as an international consultant with the World Bank and the IDB in several Latin American countries.

She previously managed the Anoia Health Consortium and the General Directorate of Healthcare and Social Projects (PROSS), where she participated in the planning and implementation of community health centres and primary healthcare.

Salvador Peiró

He has a degree and PhD in Medicine specialised in Preventive Medicine and Public Health. He is currently a researcher at the Valencia Regional Health and Biomedical Research Foundation (FISABIO), and collaborating researcher at the Centre for Research in Health and Economics at Pompeu Fabra University in Barcelona.

He was deputy director general of Research and Innovation in Health for the Ministry of Health of the Generalitat Valenciana Regional Government (2015-2017), manager for the Valencian regional node for the Research Network in Health Services for Chronic Diseases (REDISSEC), co-coordinator of the Atlas Project for Variations in Medical Practice and vice-president of the Health Economics Association.

He has authored approximately 250 articles in indexed scientific journals, as well as other articles, book chapters and various other publications.

Jaime Pinilla Domínguez

http://www.dmc.ulpgc.es/jaime-pinilla.html

Industrial Engineer in the speciality of Industrial Organisation, he graduated from the University of Las Palmas de Gran Canaria (ULPGC). He has a Doctorate in Applied Economics, and has been an associate professor at the ULPGC since March 2003. His work as a teacher is mainly related to quantitative methods: statistics and econometrics. He also teaches in different master's and courses for experts. He develops his research work in the area of health economics, and his main lines of work are the tobacco economy, the dental care services market, and applications tailored to innovation in health, where he has has several articles published in top international and national journals. He has twice been awarded the prize for the best article in the field of health economics (2008 and 2014), an award granted by the Spanish Association of Health Economics.

Joan Rovira Forns

Technical Engineer, PhD in Economics. Professor Emeritus of the Department of Economic Theory at the University of Barcelona. He was coordinator of the first postgraduate course in Spain on Health Economics, and an Associate Professor at EASP Medical School. Director of Research SOIKOS, SL (Centre for Studies in Health Economics and Social Policy), 1988-2006. A Senior Health Economist for Medicines, World Bank (2001-2004).

Consultant and advisor for public and private organisations: Catalan Department of Health, Directorate General of Pharmacy and Healthcare Products for the Ministry of Health, Ministry of Public Health of Ecuador, IDB, European Commission, WHO, PAHO, OECD, UNIDO, pharmaceutical industry and pharmaceutical companies.

He has experience as a consultant in: Spain, Brazil, Moldova, Romania, Indonesia, Burkina Faso, Ghana, Panama, Ecuador, Guatemala, Kenya, Mexico, and Vietnam.

He is former president of the Health Economics Association. Chief editor of *Cost Effectiveness and Resource Allocation*.

José Antonio Sacristán del Castillo

He has a Degree in Medicine from the University of Salamanca, and a PhD in Medicine from the Autonomous University of Madrid. He specialised in Clinical Pharmacology. He has a Master in Business Administration and Management from IESE business school. He is currently the Senior Medical Director at Lilly Spain and Portugal, and director of the Lilly Foundation.

He is a professor at the Department of Epidemiology and Public Health of the Autonomous University of Madrid, professor of medicine at CEU University, and Honorary Professor of Pharmacology at the University of Alcalá. He is a patron of the Complutense University of Madrid's General Foundation.

He authored more than two hundred scientific articles and book chapters on clinical research methodology, health economics, healthcare outcomes research, and bioethics. He is a regular reviewer of journals such as *Annals of Internal Medicine*, *Journal of Clinical Epidemiology* and, *Clinical Pharmacology and Therapeutics*.

Rosa Urbanos Garrido

Associate professor of applied economics at the Complutense University of Madrid (UCM). Associate researcher at the Centre for Research in Health and Economics (CRES-UPF). Author of more than 100 scientific publications.

She has a Degree in Economics from the UCM and in Political Science from the UNED, a Master in Public Finance and Economic Analysis from the Institute of Fiscal Studies and a PhD in Economics from the UCM.

She was the first director of the Observatory of the National Health System, she worked as an advisor in the Ministry of Health and Consumer Affairs Cabinet and was general director of Cooperació Autonòmica.

She is a former treasurer of the Spanish Society of Public Health and Healthcare Administration (SESPAS), former secretary of the Association of Health Economics, and is currently a member of the Health Advisory Council.

INTRODUCTION

Vicente Ortún
Pompeu Fabra University

The majority of the authors of this Dossier have participated in other reports in the past that have reflected concern for the future in the Goethe sense: "Knowing is not enough, we must apply. Willing is not enough, we must do."

Two of the most significant of these are: the *Abril Report* (Enrique Costas, JJ Artells, Lluís Bohigas...), presented by Fernando Abril Martorell at the Congress of Deputies on 25 September 1991, while Felipe González was president; and the *National Health System: Diagnosis and Proposals for Progress*, by the Health Economics Association, published in 2014 by a board chaired by Juan Oliva[1].

In this 81st issue of the *Economic Journal of Catalonia*, the authors involved in the aforementioned reports (among others) return with renewed wisdom, to address both the current agenda of ongoing issues and the new scenarios emerging before us. We decided it was best not to distract the youngest -and most powerful- members from the sphere of academics, healthcare service managers and researchers, who make up our international forces -most of whom are women- such as Pilar García in Rotterdam and Sílvia Ondategui in Zurich. Just like Isabel Barreto in the 16TH century, they are currently embarking on unprecedented voyages of their own, trying to reach the 21ST century equivalents of the Solomon Islands or the French Polynesia.

1 Available at http://www.aes.es/Publicaciones/SNS_version_completa.pdf.

The content has been summarised below, however, this in no way intends to undermine the masterful contributions to this issue,
all of which have been perfectly structured and present their own conclusions. They are classified from the most general to the most specific, although readers can enjoy them in any order, independently of each other:

- There are two articles on health policies focusing on the determinants and effectiveness of policies, with an emphasis on lifestyles, written by leading academics from the universities of Las Palmas de Gran Canaria, Barcelona and the International University of Catalonia, all of whom have extensive experience in scientific consultancy: Jaume Pinilla, Patri Barber, Beatriz González, Joan Gil and Toni Mora.

- One article -a fantastic overview- on the economic and managerial crossroads, and the fiscal solvency of the means with which it is financed, by Guillem López-Casasnovas, who was awarded the Josep Trueta medal for merit in the sphere of healthcare.

- Three articles on healthcare management: the first is related to management in organisations by Francesc Cots and Olga Pané, Head of Management Control, and Manager of the Parc de Salut Mar health park respectively. The second is an analysis of the experience gained in shared risk agreements, which is one of the measures aimed at striking the delicate balance between setting prices for new treatments, consistent with their effectiveness and safety, while ensuring the industry obtains reasonable benefits to maintain the investment in R&D

and guarantee, at the same time, access to, and the sustainability of, the health system. This is by Ana Clopés, Hospital Pharmacist, Director of the Catalan Institute of Oncology, and Carlos Campillo, Epidemiologist Researcher. The third, relating to designing contracts between public administrations and private healthcare organisations, by Rosa Urbanos (Complutense University of Madrid), Ricard Meneu (doctor of economics and director of *Clinical and Health Management*), and myself Vicente Ortún, sets out the tools required to make it possible to improve the public-private interface in an environment with an unparalleled wealth of data and the need for a modern, logical legal framework, which must be centred on quality to ensure transparency.

- There are a couple of articles there on two key sectors, the pharmaceutical industry and insurance, by leading experts in these fields: Félix Lobo (Carlos III University and chairman of the advisory committee for the financing of medicines), Joan Rovira (University of Barcelona) and Pere Ibern (Centre for Research in Health and Economics at Pompeu Fabra University).

- There is an article on sustainability and solvency - the golden keys applicable to policies and management: the evaluation of healthcare interventions, by two of its most excellent practitioners (one of whom is doctor and manager, José Antonio Sacristán, and the other, the economist, Joan Oliva).

- An article on recent scientific developments with the greatest predictable impact from both a clinical, and political and management standpoint, that is, personalised and precision medicine: promises and ways of approaching it, by one of the most outstanding healthcare service researchers in Europe: Salvador Peiró.

- Finally, a closing article, partly resulting from reading the Dossier itself, reflects on the concern for possible “sinking ships” that could lead the healthcare component of our welfare state to irreversible damage, even to the public sale of its assets. This goes on to explain how to avoid this new-found “confiscation” - or privatisation. With the authorship of Lluís Bohigas, awarded the Josep Trueta prize for healthcare merit as chairman of the Health Economics Commission of the Association of Economists of Catalonia, and myself as coordinator, Vicente Ortún.

On behalf of all the authors, I would like to extend my gratitude both for the suggestions for improvement, and the support provided by the Editorial Board of the *Economic Journal of Catalonia*, Anton Gasol, Dean of the Association, and especially the directors (Martí Parellada, and his successor, Guillem López-Casasnovas) and the secretaries of the Editorial Board (Antoni Garrido, and his successor, Judit Vall).

In the words of Beatriz González López-Valcárcel at the beginning of her period as president of the Spanish Society of Public Health and Healthcare Administration, "We are all on a journey, and along the way we will find ourselves attempting to unite science, action and awareness."

And with that, I will conclude this introduction, because, as Borges says, you become great from what you read, not from what you write. ■

THE DETERMINANTS OF HEALTH AND THE EFFECTIVENESS OF HEALTH POLICIES

Jaime Pinilla Domínguez
Patricia Barber Pérez
Beatriz G. López-Valcárcel
University of Las Palmas de Gran Canaria

In the mid-1970s, the Lalonde Report (Lalonde, 1974) identified four groups he called "Determinants of Health" (lifestyles, human biology, environment, and healthcare system). Two years later, Dever (1976) quantified the potential contribution to the reduction of mortality in each of these four groups, at 43%, 27%, 19%, and 11% respectively, and pointed out the disproportion between the low marginal productivity of healthcare aimed at improving health and the expenditure actually allocated to that care. Health standards are determined by the conditions in which people are born, grow and age; and in turn, these conditions are directly related to behavioural, socio-economic, environmental, and other factors, including the organisation of healthcare services and policy decisions. Much of health policy is still focused on healthcare, while non-clinical prevention, health promotion and interventions on the social environment - the "causes of the causes" are overlooked. Although health is individual, we speak of population health to refer to the prevalence or incidence of a particular disease in a community. In addition to individual interventions to maintain or restore health —surgical treatments, for example— community interventions and policies targeting certain groups of the population should also be considered. The likelihood of a person becoming chronically ill can be reduced with changes in policies and dynamic initiatives not only in the field of health, but also in other sectors.

Non-communicable diseases (NCDs) are the leading cause of death worldwide (WHO, 2013)[1]. The four major types of NCD —cardiovascular disease, cancer, chronic respiratory disease, and diabetes— cause three out of five deaths worldwide. Many of these diseases could be prevented by changing the way we live, as they are associated with modifiable and preventable risk factors such as smoking, alcohol consumption, consumption of other drugs, an inadequate diet (e.g., overeating, red meat and processed meat, sugary drinks, etc.) and sedentary lifestyle or low physical activity.

It is interesting to establish and quantify the cause-effect relationships between risk factors and health/disease to help subsequently define health policies that would act efficiently on these causes. The cost of the disease, or *disease burden*, is a starting point from which to determine the scope of the problem, or the size of the effect. However, as we shall see, this alone is insufficient.

The following sections define the conceptual framework of attributable risk factors and the need to estimate the avoidable cost of the disease (section 2), proposing a typology of polici-

1 WHO Global NCD Action Plan 2013-2020. Geneva, 2013. http://www.who.int/nmh/events/ncd_action_plan/en/.

es according to their intersectorality and objectives (section 3), while presenting the methods for evaluating policies (section 4) and the empirical evidence resulting from their application (section 5). Finally, section 6 concludes the article.

Conceptual framework: the causes of the causes and the attributable risk factors

The classical conceptual model of determinants of health by Dahlgren and Whitehead (1991) describes the strata of influence on health using a social and ecological model (Figure 1). People are at the core of the figure, and have unchangeable characteristics (age, sex or genetic makeup). Surrounding this core are the potentially modifiable factors that influence health, starting with the (so-called) "lifestyles". This is an unfortunate name because it seems to assign individual responsibility to the person about their health, when this is actually a consequence of social determinants and conditions. Social and community networks (more external) can support community members. Other structural factors such as housing, working conditions or access to essential services (housing, education, health, etc.) envelop the above. Finally, there is a broader group of characteristics related to the cultural, socio-economic and environmental conditions of the surroundings.

The conceptual framework proposed by the Marmot Report (2013), commissioned by the WHO, goes deeper into these "causes of causes" or social determinants of health. The interrelationships of these determinants with each other and with health are extremely intricate, so it is very difficult to isolate the effects of each of the factors. The model of social determinants implies that, since many of the factors influencing health are beyond people's control, it is not right to blame them. It also implies that improving health (and reducing inequalities) requires the design of global strategies, which are not specifically focused on the healthcare system. The key is to implement Health in All Policies (HiAP).

Figure 1. Determinants of health model by Dahlgren and Whitehead

Source: Dahlgren and Whitehead, 1991.

> *Spain has good health indicators. We outperform the EU-28 in life expectancy at birth and at age 65, and we have better standardised and preventable mortality rates.*

The Institute for Health Metrics and Evaluation (IHME) maintains the Global Burden of Disease[2] project, which uses a homogeneous methodology to estimate the burden of the disease and its temporal evolution, in terms of mortality and disability-adjusted life years (DALY), for every country in the world. This macro project regularly publishes its data and results in the *Lancet* Journal.

Spain has good health indicators compared to other European countries (European Commission, 2019). We outperform the EU-28 in life expectancy at birth and at age 65, and we have better standardised and preventable mortality rates. The health system as a whole is very efficient, because these favourable health outcomes are achieved with reasonable healthcare spending. Most of the chronic diseases that Spaniards suffer from have attributable causes, many of which correspond to behavioural (smoking, alcohol and diet) and metabolic risks. Behavioural risk factors cause more than a third of deaths in Spain (in 2017, according to the IHME, 16% of deaths were attributed to smoking; 12% to diet; 8% to alcohol; and 2% to sedentary lifestyle). The key to public policies is, therefore, how to reduce attributable risks using health policies, which will not only or always be healthcare policies.

Figure 2 represents mortality per cause in Spain in 2017. The size

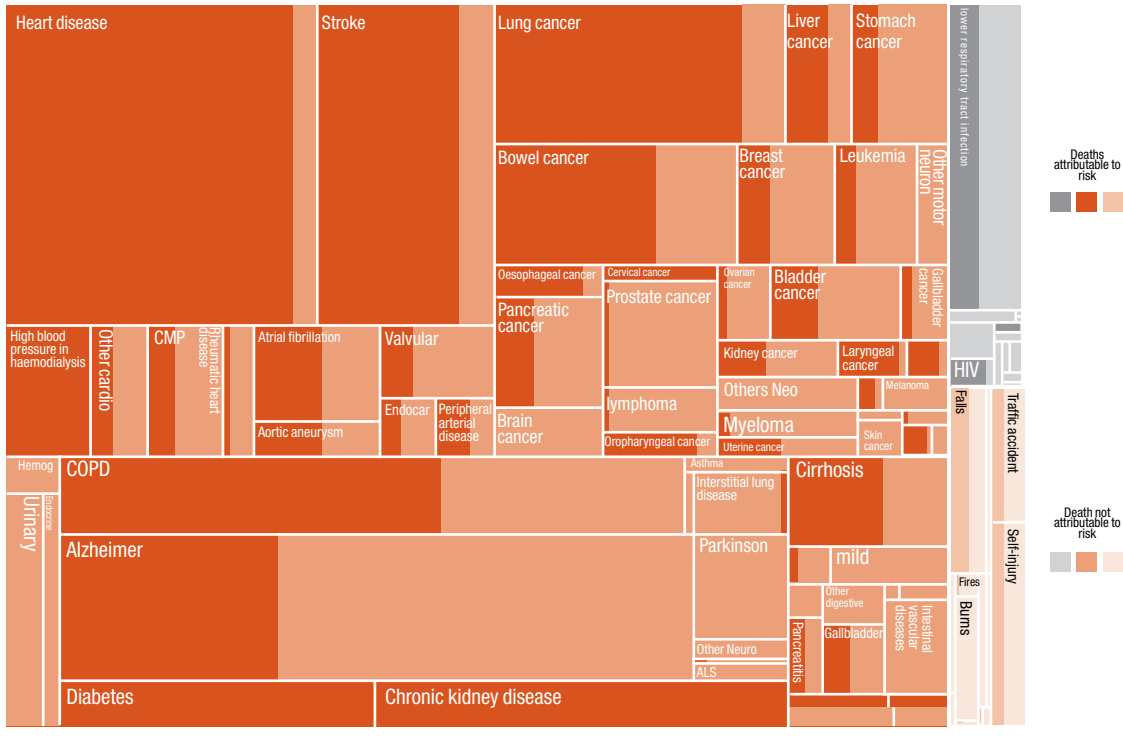
2 http://www.healthdata.org/gbd.

of the rectangles is proportional to the mortality rate. NCDs are illustrated in dark orange; infectious diseases in grey, while those attributable to external causes are light orange. The darkest part represents mortality that can be attributed to known causes or risks. Some of these can be treated (they are modifiable), others cannot (for example, genetics). It is useful to establish the total cost of the disease in order to calculate the importance of the problem and advocate for health. But the most relevant factor is establishing the avoidable cost of the disease, and especially how it can be avoided through effective public policies.

Let us imagine for a moment the perfect world in which there is no poverty, no environmental or employment problems, the whole population does the recommended amount of physical exercise and keeps to a Mediterranean diet, no one smokes, no one drinks excessive alcohol... Even so, there would still be diseases, because, after all, they are a sign of success in the fight against infections, and because the body still wears out and something has to die. The question is, in this ideal and orthorexic world, what would the cost of disease be? Because the interesting part is knowing, not so much the cost of the disease, but the cost attributable to risk factors that are, in principle, within the control of individuals and governments, and are modifiable.

Individual risk factors —smoking, low physical activity, and diet— are largely responsible for most of the non-communicable burden of disease. One study (González López-Valcárcel et al., 2017), estimates the social cost of potentially preventable (chronic) diseases in Spain, specifically type 2 diabetes, ischemic heart disease and bone fractures due to osteoporosis. Prevention in this case would be to eliminate smoking, alcohol and a sedentary lifestyle from the equation, and optimise diet. The conclusion is that these three diseases cost us about €26 billion a year (3.15% of GDP), 62% of which are preventable with changes in behavioural risk factors, including sedentary lifestyle (€5,153 million) and, above all, diet (€10,483 million).

Figure 2. Death per causes, Spain 2017 Attribution to risk factors



Source: IHME. Global Burden of Disease

Typology of public health policies and the HiAP

The HiAP movement inspired European public health during the Finnish presidency in the mid-2000s, and became a new paradigm in Europe. This movement, the Health in All Policies strategy, promotes incorporating health objectives into the design and evaluation of all policies. It placed health on the political agenda and represents a major step forward in health advocacy. But it requires a consistent and robust *health impact assessment methodology,* beyond traditional economic assessments, which are not designed to assess multi-sector and community strategies.

Health would therefore become a meeting point in urban, healthcare, environmental, labour, housing, policies etc. implemented by health departments or other government offices, and may or may not have budgets allocated to them. However, these policies are aimed at multiple objectives and can have unintended side effects on health. In Table 1 we have illustrated the typology of policies according to the department that leads or executes them, and according to their objectives (only health, or health and other social welfare objectives). In order to make decisions in this complex framework of policy possibilities, they need to be evaluated (see section 4 below), without losing sight of the fact that policies aimed at problems affecting large populations require multifactorial solutions and will be better achieved with community interventions than individual approaches.

The table shows examples of health improvements as effective means to improve education. According to one of the most renowned experiments in development economics, conducted in 75 primary schools in Kenya with more than 30,000 students[3], deworming school children increased their participation by at least 7%, and reduced school absenteeism by 25%, at very low cost: the additional cost per year of active schooling is just $3.27. Implementing health education or hiring more teachers would not have been able to achieve a similar impact.

Other very representative examples of the effectiveness of intersectoral or other sectoral policies on health are those carried out by the General Traffic Directorate (the driving licence points based system, among others), which significantly reduced mortality in traffic accidents. Many health promotion policies

> *"Healthy and natural foods that improve the diet are one of the success factors of sustainable agriculture and fishing, which preserve the environment and enable the regeneration of resources."*

are developed from outside the healthcare system, or even if they are led by the health system, require the participation of other departments. A paradigmatic case is taxes on tobacco, alcohol, or unhealthy foods. From the point of view of the Treasury, they are sources of income. From a Department of Health perspective, they are instruments of health policies, and the lower the amount, the more effective. That is why the Departments of Health should take the lead, seeking alliances with other government departments and even with private organisations. The economic interests of those sectors with great economic power and media resources can frustrate regulatory initiatives, and in Spain, there are examples of success (smoking) and failures (alcohol) from which we can learn (Hernández-Aguado and Chilet-Rosell, 2018; Villalbí et al., 2008). We can also learn from experiences of initiatives implemented by other departments that achieve health impacts, even if it is not their main goal. An example of this is the *From Farm to Fork* movements, led by the Department of Agriculture[4]. Healthy eating is promoted as being green, because the concept of organic is integrated into collective culture and reaches people better. Healthy and natural foods that improve the diet are one of the success factors of sustainable agriculture and fishing, which preserve the environment and enable the regeneration of natural resources[5].

A guide for public policy: beyond the principle of cost-effectiveness and budgetary impact

It is much easier, and more common, to evaluate, from an economic standpoint, pharmacological treatments than prevention programmes. It is much easier to evaluate individual than community interventions.

3 http://www.povertyactionlab.org/evaluation/primary-school-deworming-kenya.

4 https://cafarmtofork.cdfa.ca.gov.

5 https://ec.europa.eu/eurostat/documents/3217494/5723961/KS-BU-10-001-EN.PDF/c028cee1-62bd-43db-8e87-a33f032e5cb4.

Table 1. Policies with an impact on health per department responsible and main aim. Some examples

Aims → / Department responsible ↓	Health	Other social aims
Health	• Healthcare • Clinical prevention	• Family planning • Deworming school children (Kenia)
Other departments	• Health promotion • Points based driving licence • Hygiene and safety at work • Water chlorination	• *Sin taxes* (taxes on tobacco, alcohol, and sugary drinks) • Urban planning • Employment policies • Environmental policies and action against global warming • School lunches • Sustainable agriculture and fishing *From farm to fork* • Consumer protection • Historical milestones: the right to vote, equality, democracy that ended famines... • Basic sanitisation, with drains • Active employment policies • Promotion of equal opportunities, particularly in education

Cost-effectiveness has become the socially agreed principle for prioritising, and making decisions regarding, resource allocation in society, and the same is true of Spain. This is not only a principle of efficiency, it is also a principle of equity, and a moral criterion because there is an opportunity cost for resources earmarked for a purpose, which, however legitimate, is lost for other purposes.

Cost-effectiveness, always based on groups (never individual patients), is behind the new paradigm of value-based healthcare systems. The EU has appointed a panel of experts on the subject[6]. Furthermore, the cost-effectiveness of health promotion and disease prevention interventions to reduce chronicity is important, but the opportunity -the budgetary impact- is equally important.

6 https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/024_valuebasedhealthcare_en.pdf.

Assessing the cost-effectiveness of prevention is difficult in terms of specific methodological aspects as well as incentives. Regarding the former, the possibilities for experimentation are limited: clinical trials cannot usually be performed; the consequences or effects will only be perceived in the long term; they generally respond to multiple causes and have multiple effects, and many studies fail in their external validity, because the effectiveness of the interventions being evaluated depends on cultural elements, the socioeconomic context and the local conditions. In terms of incentive issues, these tend to arise because there is usually no funding available due to the lack of interest in the results (which cannot be sold under patent). Additionally, these studies have high associated costs, especially if they involve social experiments.

However, while it is important to determine the cost of the chronicity that could be avoided with behavioural and policy changes, it is equally important to determine who finances it or who bears these costs, because for some diseases more than others, a large part of the costs are invisible, as they are off the market radar. These are costs covered by families. The costs of informal care. Thus, while only 17% of the €6,997 million that cardiovascular diseases cost to society in Spain correspond to informal care off the market radar[7], these treatments represent 68% of the €14,557 million that dementia costs[8].

Cost-effectiveness analyses of public interventions to reduce attributable risks (primary or secondary prevention) and to combat health problems are a necessary, but not sufficient, condition for the evaluation of public interventions. Other methods, in the process of consolidation and standardisation, are health impact assessment and studies in the social return on investment.

Health Impact Assessment (HIA) is defined by the WHO (1999) as: “A combination of procedures, methods and tools used to evaluate the potential health effects of a policy, programme or project and their distribution in the population." In Spain, this has been applied to design and evaluate some urban transformation projects, such as the Urretamendi-Betolaza Integral

7 Leal, J.; Luengo-Fernández, R.; Gray, A.; Petersen, S.; Rayner, M. (2006). “Economic burden of cardiovascular diseases in the enlarged European Union”. European Heart Journal, 27 (13), 1610-1619.
8 Luengo-Fernández, R.; Leal, J.; Gray, A. M. (2011). “Cost of dementia in the pre-enlargement countries of the European Union”. Journal of Alzheimer’s Disease, 27 (1), 187-196.

Reform Project (PRI) and the Circumvallation (UBC)[9], and the urban development plan for Vitoria. With a more qualitative than quantitative content, one of the strengths of this type of exercise is the exercise itself, since it makes the various players involved, the departments and organisations, sit down at the same table to talk, including those from the Department of Health. Another notable example of multisectoral health strategies that use the Health Impact Assessment is the PINSAP (Interdepartmental and Intersectoral Public Health Plan), currently reporting the period 2017-2020[10]. This is a version of traditional health plans, adapted to the HiAP strategy. The two fundamental cornerstones of the PINSAP are to increase the number of years in good health of the population of Catalonia (to promote a healthier Catalonia), and to incorporate health in the design and the evaluation of public policies (health impact evaluation).

The analysis of the Social Return on Investment (SROI) is becoming a standardised method for evaluating interventions in which various groups of stakeholders define different types of objectives, among which health is included. Its widespread use over the last decade stems from the UK government's efforts to improve accountability for social, economic and environmental benefits in a broad sense, within third sector organisations. The Public Services (Social Value) Act 2012, which came into force in 2013, requires public authorities to consider these types of impacts on welfare in Government contracts. The World Health Organisation's (WHO) European Office accepts the SROI as a criterion for decision-making in public health with the best available evidence, which it collects through the Health Evidence Network for investment in health and welfare. Although most empirical studies on SROI that consider health impacts are external (i.e. they are conducted outside the healthcare sector, which is considered just another aspect, but does not lead it), there are some specific studies for the Department of Health (González López-Valcárcel, 2019).

Evidence on the effectiveness and cost-effectiveness of public health policies

Several international studies on the cost-effectiveness of preventive activities[11] agree that:

— Cost-saving interventions (i.e. with a positive benefit-risk ratio) are usually outside the healthcare sector. These include "sin taxes" (on smoking, alcohol and unhealthy foods) and bans (advertising at certain hours, smoking in public places, etc.) and other coercive regulations, such as limiting the amount of salt in certain foods (bread, cereals, margarine, etc.).

— Pharmacological treatments are among the clinical prevention measures with a good cost-effectiveness ratio to reduce the absolute risk of certain conditions in different subgroups of the population (statins, for example).

— Most vaccines included in the vaccination schedule are cost-effective in the long term.

— Municipal actions to cut off traffic on Sundays through the city's main thoroughfares for leisure, walking and exercise are very cost-effective, with benefit-cost ratios of up to 4: 1. More generally, the design of healthy cities is cost-effective in terms of health.

— Environmental interventions are usually much more cost-effective than individual clinical interventions (Chokshi and Farley, 2012).

An extensively studied case is that of smoking. There is clear evidence that policies and programmes aimed at reducing the demand for smoking products are highly cost-effective. Increasing taxes on the price of tobacco, banning the tobacco industry's marketing and advertising activities, the use of graphic labels with health warnings, and implementing smoke-free policies are very inexpensive interventions, while they obtain very good results. In the medium and long term, these interventions are successful in reducing cardiovascular and respiratory and lung cancer morbidity and mortality.

9 http://www.osakidetza.euskadi.net/r85-publ01/es/contenidos/informacion/publicaciones_informes_estudio/es_pub/adjuntos/EIS_PRI.pdf.

10 http://salutpublica.gencat.cat/web/.content/minisite/aspcat/sobre_lagencia/pinsap/continguts_antics/pinsap-cast.pdf i http://salutpublica.gencat.cat/ca/sobre_lagencia/Plans-estrategics/pinsap/.

11 This section is a synthesis by Oliva et al. (2018). Health Economics. Editorial Piràmide, section 14.4.2 Health Economics. Editorial Piràmide, section 14.4.2.

Conclusion

The scientific community goes to great lengths to calculate the burden of disease or the cost of disease. Aside from science, it seeks, in terms of health advocacy, to justify spending ("investment") in measures that can reduce the burden of disease. In this sense, it is important that advocacy and science are scrupulously differentiated. There is no standard methodology for studying the cost of the disease, however there are still crucial aspects to standardise (the top-down or bottom-up approach? Should we include the extra cost due to inefficiencies? Should we use an approach based on incidence or prevalence?). Health economics need to take on the challenge of contributing to the standardisation of these studies.

Public health systems are structured around health, and the role of non-clinical prevention and health promotion is still limited. The individual approach continues to prevail over the community approach. The Health in All Policies strategy requires the commitment of all relevant sectors and players in the generation of health. This HiAP strategy is based on the idea that health is in everyone's interests, and implies the need for a new governance model in which health sector policies are coordinated with those of other sectors, with commitments at different levels of government and agreements with the private sector. It also requires new specific methodological developments to assess the impact on health and other social goals. One of these developments is the methodology of the social return on investment (SROI), in which health ceases to be the central axis to be considered one of the other great social goals.

Some experiences, such as the road safety policy of the General Directorate of Traffic, the urban regeneration project in Bilbao or the programmes developed under the umbrella of PINSAP in Catalonia mark the way forward and are a good example of how intersectoral actions can have very beneficial effects on health. ■

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THE MANY CROSSROADS FACED BY THE HEALTHCARE SYSTEM IN THE REFORM OF THE WELFARE STATE AND THE FISCAL SOLVENCY OF THE MEANS USED TO FINANCE IT

Guillem López-Casasnovas[1]
Pompeu Fabra University

Upon invitation from the coordinator of this issue, I would like to write a piece directly addressed at identifying the dilemmas -or crossroads- that the healthcare system is facing in the context of our welfare state and its funding issues. I would like to do this with the reader's trust in the sense that "I know what I'm talking about." This will save me the countless footnotes and bibliographic references on which my statements are based. The limited scope in the length of the article justifies this in order to give it a firmer focus on healthcare policy.

In the first part, I will specify what I mean by crossroads and which ones I am referring to, and in the second, I will look a little into the content of the fiscal "first aid kit" that applies to them and provides options for viable financing.

1 I would like to thank Vicente Ortún for his comments. Naturally, any mistake in understanding is my own and can be explained in the more specific analysis on the majority of the subjects covered here in the collection "Health Policy Papers" from the Centre for Research in Health and Economics (CRES) at the UPF, and can be viewed at https://www.upf.edu/web/lopez-casasnovas.

Ten crossroads for the future of the healthcare system

These are, in my opinion, the most significant crossroads our health system faces, the future of which will depend largely on which direction is taken.

Crossroad 1. How to make our healthcare system sustainable

If we take into account the majority social perception, the financial sustainability of the healthcare system is largely in jeopardy. On one hand, in terms of our system, citizens have shown to place virtually all the responsibility for healthcare in the hands of the public authorities (BBVA Foundation, Values Survey 2019: 87% of Spaniards consider that the state must have a high degree of responsibility in providing healthcare coverage to all citizens (70% is the average of the other four countries studied: Germany, France, Italy and the United Kingdom), and, on the other hand, there is very little willingness to pay more for its financing. Currently, co-payments are identified with private prices and not with public taxes. So the general idea remains that financing it with general taxes (wha-

tever these are) will always be a fairer way of doing things than users themselves paying, which is obviously not true. At the same time, internal pressures (social medical care) and external pressures (evolution of the technological frontier) continue to increase spending, and are resolved today in an uncoordinated way, often with decisions made without sufficient budgetary support, which puts a strain on various parts of the healthcare system.

The situation described is general and extends to most regional systems, including the Catalan system, which, in any case, is rather accustomed to paying tolls on things, albeit hidden or not explicit (such as double insurance coverage), with co-payments whose effects are silent despite the overpowering idea of them providing "universal access." The greater proportion of supplementary insurance raises the question of whether it should be subsidised with tax deductions. Currently this is only permitted in collective policies, in the form of corporate tax expense, so the fact that it cannot be deducted from individual policies affects many Catalan people and sectors of self-employed professionals in particular, who have a greater presence in our country. The debate here lies in whether or not private insurance decongests the public system or increases the use of both equally. Although there are articles that analyse this, the evidence is inconclusive but the point remains that a priori, it does more or less decongest it. Elderly pensioners and the self-employed who lose their income are the most likely groups to move away from private insurance, and retain the right to the full use, as citizens, of the public healthcare system. So the crossroads here therefore, is whether private insurance will withstand the new contexts of demographic transition and lower spending power, and whether the public sector will be able to cope with it. This adds an additional element to the aforementioned issue of sustainability.

Crossroad 2. If our healthcare system is so good, why change it?

Spain (and Catalonia!) have a good healthcare system. It has even been said to be the best in the world. If this is to be believed, there is little room for criticism and improvements. It is acknowledged that this is thanks to its professionals, who later say that they are "burned out" and want better salaries, although this is part of the basis of efficiency and financial sustainability mentioned above. In Catalonia, as in other prosperous regions, *burnout* is possibly lower, as the explicit or implicit compatibility of many professionals in the private sector succeeds in patching up the gaps. This, of course, causes collateral friction between professionals from different regions and specialities.

Catalonia leads the way in understanding healthcare from a standpoint that is more open to consultation and innovation in management, but is currently showing symptoms of exhaustion. This is the case both because of the political fear of continuing to innovate without sufficient self-funding -given that it depends on state transfers- and on the political agenda of restoring the network of public use from the alleged traceability of public funding. We may be guided in one direction or another at the crossroad by restoring the division between regulation/supply and production, believing in the autonomy of suppliers on a meso and micro scale, and overcoming the temptations of both our own authorities and controllers from the European system of accounts. Here, one's own model requires one's own resources and, therefore, more funding linked to the tax capacity of the Catalan people.

Crossroad 3. Decentralisation is questioning social coherence

Healthcare decentralisation certainly reveals the differences (of access, use, benefits of services, etc.) rather than creating them; but at the same time it gives them a political means of correction. When they are a result of decisions taken with fiscal responsibility, the differences cannot be considered inequitable. Decentralisation is more part of the solution -due to the processes of emulation and improvement it enables- than of the problem. It is a different matter if, without realising it, what it may end up doing is to propel public spending on a continuous upward spiral. Spain is neither the most decentralised country in the world nor the most unequal. In fact, from a territorial standpoint, the most centralist states are the ones with greater inequality, among other reasons, because they do not need to justify their differences to any regional parliament. In addition, in accordance with the gauges used by the OECD, observing the level of fiscal autonomy, discretion in spending, ability to establish its own budgetary frameworks and long-term spending commitments, Spain is more a constitutionally unitary state than fiscally federal state.

How all this will evolve with politics in the future is the big question. If a certain asymmetry in regional funding is not finally accepted, the forces will predictably swing in favour of standardisation, providing the Ministry with new spending powers

and more effective regulations in the supposed name of "cohesion and quality of the system." The crossroads we are at here is, whether the pressure for uniformity will still allow us to speak of a "Catalan healthcare system".

Crossroad 4. How the healthcare system embraces innovation

Faced with innovation and the extension over time of knowledge to operate a true evidence-based health system, the dilemma is "wait and see". This can generate type 1 errors -some benefits may be lost through the lack of decision- or accepting innovations, with the losses associated with type 2 error — whereby what ends up being ineffective becomes pure waste.

In the real world, an asset shows its true value when users consume it. But in healthcare, the information of users or prescribers is far from perfect and "use" does not have the same meaning as it does with private goods. If this makes for a macro dilemma, in the field of micro and meso management payment systems, vendors need to adapt to the changes they sell. Predictably this will reinforce uncertain decisions with greater supplier autonomy. These will have a more or less technical *assessment*, but I don't think the *appraisal*, the application to the specific case, can be taken away from the meso-micro decision makers. To protect themselves from risk, they are likely to look to share the risk. Especially if their funding is results-based (rather than for doing or being) and they compete by incorporating innovations. The remuneration system will have to vary, particularly when digitalisation changes the concept of appointments, and with innovation, the focus is on processes rather than products. So DRG-type hospital payments and other case studies lose their essence.

The crossroads faced here is the fact that, on one hand, we want to prevent but encourage activity, and on the other, we want to favour integration and coordination but the system pays for the miscellaneous expense of segmented agents. Payment and the autonomy given to suppliers needs a rethink.

Crossroad 5. The often suspect, non-redeemable drug sector

The drug industry often boasts the highest levels of innovation, sometimes with resounding successes, and many other times with deficits that they attempt to cover with the former. The

"The drug industry often boasts the highest levels of innovation, sometimes with resounding successes, and many other times with deficits that they attempt to cover with the former"

challenge here lies in how to compensate for innovation without further forcing the patent regime and how to offset prices related to value when this is not known for sure, at least in the short term. The scenario in which pharmaceutical innovation does not replace but complements. Or when the hospital dispensation of certain drugs grows in double digits. When this occurs, the anxious funder, under a rather crude regulation (can choose to go ahead or not, and if it does, will have identical public reimbursement), has a tendency to replace the pharmaceutical policy with strict spending control ("capping", for example, its growth according to the increase in nominal GDP, or with similar calculations). This policy does not distinguish between products with different contributions in innovation, price and quantity effects (number of prescriptions), but implements very complicated financial returns from producers who have the capacity to act as a monopoly against a supposed monopolist. In any case, and erroneously, it isolates the drug as an input from the other factors in the value chain, so that the substitution effects against other inputs with respect to relative productivity are hindered. In any case, it is not clear how to integrate the chain (from the healthy population to final consumption inputs —typically medications—) from the drug to treating different types of patients (integrating home care or hospital admissions). But they do know that isolating such a heterogeneous asset as medicine from the rest of the system's funding has little scientific basis.

Crossroad 6. Will our politicians be bold enough to prioritise and bear the consequences?

Public systems work on the basis of prioritisation. This must come from evaluation, not only from innovations, but also from questioning obsolete practices. It's not just about *doing* but *undoing*.

To tackle this, health economists work with the quality-adjusted life year (QALY) tool; which is our way of calculating the

opportunity cost of treatment and outcome for beneficiaries. However, there is wide-raging debate about the ethical questions on whether "a QALY is a QALY", regardless of who it refers to. As an alternative to this idea -which is fairly widespread when applied to rare diseases without alternative treatments, and which are life threatening, etc.- proposals arise based on Multiple Criteria Decision Analysis (MCDA). The application of this algorithm to prioritisation runs the risk, if generalised, of classifying with inconsistency and using a rather ad hoc criteria. In any case, it would seem reasonable to ask, that if the MCDA is applied, it is done so in a transparent manner and limited to decisions to provide differentiated silos (sources of financing) for treatments or potential beneficiaries. But there is no reason why the QALY should not be used within each silo (the idea of treating between, say, rare diseases or between those without therapeutic alternatives).

Once prioritisation is done, the challenge lies in political pressures not wasting it *ex post*, as this delegitimises the *ex ante* procedure. Will our healthcare policy makers know how to do this? Will the results be respected by our politicians and withstand the pressures of the affected patients, the industry concerned and the professionals caught off guard?

Crossroad 7. Health insurance schemes for the public administration: a fetish, or a thorn in the side of the general system?

In Spain, the health insurance schemes for the public administration (MUFACE for civil servants, MUGEJU for judges and ISFAS for the armed forces), and their free choice between agreed private insurers, constantly give cause to question the legitimacy of the system drawn up by the General Health Act. Either its scheduled extension or its abolition should be the way of dislodging *the thorn*. The credibility of the equity pursued by the system is generally questioned because the figures are derived from the officials themselves, who, whenever they are able to do so, and for whatever reason, decide to choose private insurance, at no cost to them.

Embedded in the unresolved theoretical debate on the privileges granted to government officials, we find the question of the benefits of free choice; a right reserved today for our "mufaces", "mugejus" and "isfas" (military). It represents a real "voucher" (one of the few existing *vouchers* in Spanish public management). Their virtues are debated in terms of the degree of adverse selection they contain, and risk transfers, from private to public, "creaming off" the market. The analyses should focus more, in my opinion, on the selection of services offered and of the greatest quality possible, by private insurers, rather than the selection of personal risks, which is more difficult or impossible when operating with *open enrolment* (at the decision of each beneficiary on 31 January). The results are not clear in terms of the profitability of these agreements with the existing rates. But an insurer can always cross-subsidise the public rate if the member ends up subscribing to an additional premium for other supplementary services (*top ups*) that are more profitable for the insurer. Here one can detect a private sector that bases its survival on "the worse the public sector is going, the better for the private", while the other would like a public sector with sufficient financial robustness to establish an agreement with the private sector.

At the crossroads of the role of the private sector in a public healthcare system, the so-called *public and private partnerships* also require greater evaluation. From known experience comes light and dark. Here political prejudices often obscure the way and so does the ideological bias of health economists.

Crossroad 8. How to treat an ever ageing population

There is no one exogenous factor that marks the predictable evolution of healthcare spending in the future. As with so many other things in the health system, how to deal with the ageing population is an endogenous issue, one of clinical practice, and of protocols if you like. It is not so much about ageing, as is already well known in health economics literature, but the proximity to death -fortunately increasingly delayed- that triggers healthcare spending in the final stretch of a person's life. But how the end of life is confronted by the individual and the system is decisive: there is a wide gap between palliative care and therapeutic *obstinacy*, while aspects such as social acceptance, the consequences on system costs, and patient well-being all come into the equation.

Predictions for the future —for example, to assess the sustainability of a system— are also very sensitive to technological developments and social sensitivity. A similar benchmark can also be established in the treatment of premature infants, although of unequal importance.

The challenge here lies in the evolution of social culture and clinical practice in end-of-life treatments.

Crossroad 9. Obesity, lifestyles, risk behaviours

In the past, a certain level of obesity indicated well-being, opulence, if you like. Today this is more an indication of poverty. In the same way as filling a child's mouth with food is. In the past, labour markets were relatively stable and both dwellings and living conditions were more predictable for better or worse. In today's employment market, everything is uncertain. The obsolescence of human capital is marked by technological progress that leads both to transhumanist scenarios and posts becoming obsolete, with the replacement of man robots. Some of life's satisfactions are increasingly associated with risk: the pleasure of running, enjoying new adventures, taking risks as a form of pleasure, and displaying success as supreme forms of supremacism. The effects of all these elements are externalised and internalised in the medium to long term (childhood obesity today, diabetes tomorrow; sex without condoms and HIV infections, etc.). Tax discounts applied to these policies are decisive in favouring their prevention, in the same way as some vaccinations, certain educational policies, or new medications.

In a political world based on short-term glory, it cannot be assumed that the alternative to prevention is the right route to take. Social medicalisation and a certain *disease mongering* ("fabricating" new diseases) play against it. In any case, once prevention is evaluated, in the short term it does not stop any reactive policy (due to the unforeseen past) - a sum of resources that further complicates the budgetary frameworks.

Crossroad 10. What does the future system want to look like? An NHS or an SIS? (Social Insurance System)

European public systems are made up of diverse genetics. Some are based on national health services "in the British way": NHS, services managed with a homogeneous national aspiration and centred on population health; at least in theory. Others (SIS) are configured as social insurance systems -of multiple agents- in which coverage and affiliation is explicit (public funding of regional premium, not actuarial adjusted to individual risk). Both systems are of a public nature (regulation, financing and often provision). The second is easily supplemented by premiums (for additional services) and co-payments (to limit demand). The first (NHS), states that it does not cut back based on prices, although it does so in terms of quantities: waiting lists, exclusions of benefits in basic packages, often not due to lack of efficiency but due to a cost-effectiveness that is considered too high, which equates to a one hundred percent co-payment. SISs tend to commit more public resources to spending than NHSs, although some come from contributions other than taxes. They spend more but tend to produce higher levels of satisfaction among the population (more choice, more access). NHSs are often more intervened, work with waiting lists, prioritise more harshly without allowing add-ons... and frustrate consumer expectations of certain users more; so in this sense, NHSs serve more as an input to the interests of taxpayers than to patients.

Both systems tend to agree on the answers, since the vectors that impact them are the same: ageing population, innovation and healthcare tourism. But one system cannot play in the league of the other, or vice versa. If you want an SIS, the portfolio may be wider, and the greater the choice or less relative efficiency, the more co-payment is required. Given that a NHS does not accept explicit co-payments, prioritising the basic package (included/not included) needs to be harsher and more transparent. Both things at once are impossible. At a crossroads of sustainability and solvency (how to solve the various challenges), the algorithm must be coherent.

The way out from these crossroads will be absolutely marked by the willingness to finance the different alternatives, which may or may not be feasible depending on the fiscal or financial commitment the society agrees to. From the metaphorical "first aid kit" of treatment possibilities, I would like to include a few possibilities in this final part.

The fiscal first-aid-kit to face the way out of the crossroads with solvency

In order to be able to make progress in the public financing of welfare services, the Spanish tax system today presents several issues, ranging from the distortions imposed by dual taxation in terms of labour and capital incomes, to the imbalances between personal income tax and corporation tax, those between the treatment of consumption and savings, assets kept, donated or inherited. All of which has an impact on the proper functioning of the economy and is affected by the scope of tax evasion and fraud, which delegitimise the tax system.

When the capacity to collect taxes is diminished, the sustainability of the welfare state is questioned at every stage, whether or not they can turn to public deficit and low reserve funds. Furthermore, their budgetary solvency pools, used as pro or

counter cyclical measures, which work well as automatic stabilisers and discretionary fiscal policies, are very scarce.

In order to make the necessary tax collection changes, there is a basic need to access information (which is always of a private nature), in order to be able to make distinctions when it comes to taxing economic operators, between individual effort, capacity —human capital— and luck, on a gradient that goes from less to greater tax burden.

Taxation has a renewed interest in economic theory, not so much for its redistributive capacity, which is limited due to its effects on wealth creation, but for its potential capacity to counter the economic cycle, affecting residual income (spending capacity). This may be through net compensation of labour or generation of flows of certain assets, correcting the *output gap*, affecting the productivity of the economy, the timing of responses to corrections and through the new formulations of the digital economy: better identification of taxpayers, of taxable events, against *profit tax shifting* or BEPS, and in the link between the tax databases and the beneficiaries of public policies. Among the challenges of the global economy posed by digital change, however, are the "zappers" in new forms of tax evasion, online commerce and new software that erases the traceability of certain transactions. The vulnerability of cybersecurity is always the weakest link in public control and regulation.

The complexity of taxation to pursue equity comes, on the one hand, from the observed economic reality with regards to the concentration and high earnings of a few, achieved thanks to technological innovation, rather than through pure and consistent entrepreneurship, in the sense of recurrent work and sectoral investment. The concept of *one winner takes all* forces the issue for a new model of taxation that avoids polarisation, and that under the premise of the diminishing marginal utility of income, applies very high rates for those few earners of great fortunes. The question of how capital and robotics are replacing part of labour also needs to be addressed, and how value-added taxation should gain ground over the alternative payroll taxation. An even greater challenge is posed in following the transactions of currency platforms, *blockchains* in particular and the so-called cognitive computing *(machine learning)*. Furthermore, when it comes to transaction control, the fact that the location of multinational profits can be changed means that new expertise on the subject is necessary.

> *Inheritance tax plays an undisputed role, even from a liberal position, in any society that wants to be fairer and more meritocratic*

A fundamental aspect which should not be underestimated regarding the new taxation to support the maintenance of the welfare state is that it must have an environmental basis and embrace aspects that affect lifestyles. This is not so much for its collection capacity, as for its double dividend characteristic: collection by the user if demand remains inflexible, or without income but saving on expenses and improving welfare if the demand becomes more flexible. This, for example, is the case of taxes on excessively sugary drinks, foods containing saturated fats, environmental taxes against pollution, and ecotaxes for certain fruits and maintenance of the ecosystem.

It is also necessary to rethink the taxation on all business assets that are not affected by corporate activity. These assets are treated differently when they are taxed via corporation tax (because companies taxing their gains makes them eligible to a deduction on certain expenses), compared to the income tax on individual persons, because it is much harder to tax their in kind benefits from their tax base, as these are derived from using part of their business assets. A tax of this type on the assets of legal entities should not be ruled out order to boost the economy - not only to discourage the overflow of profits that is observed, but to tax "at source" those assets that do not affect business activity.

Inheritance tax plays an undisputed role, even from a liberal position, in any society that wants to be fairer and more meritocratic. It must tax increases in economic capacity due to unearned income. Simply exempting the first kinship may be insufficient. However, there is no scope for very high rates or a whole jumble of supposedly remedial deductions and random exemptions that end up offering too many opportunities for tax evasion, as this ends up meaning that the tax is paid by just a few, and not those who should be, opening up a great endorsement argument for abolitionists.

Finally, in terms of productivity, the goal of the new solvency tax is to reduce distortions in the allocation of resources due

to systematic tax deductions, which are not levelling the playing field enough in favour of undesirable tax arbitration, reducing the costs of tax compliance and eliminating arbitrariness in the type of treatment of debt *versus* own financing, distinguishing between types of assets and the formal and informal areas of the productive economy.

Final reflections. Solvency of the tax system, sustainability of the welfare state and a road map marking the way out of our healthcare system's crossroads

Sustainability is an eminently political concept. It depends on the funding that society is willing to allocate to it. The fiscal pressure that an economy can withstand is debatable. It depends on many things. And also on the return of public services —their effects on income and wealth creation, and thus new tax bases— the international context in which the economy operates, the weight of taxation on the cost breakdown, and the productive orientation of the economy (services support it better than marketable goods).

More interesting is the *solvency* of a tax system, in the sense of the resources that public intervention has, to deal with changing economic and social challenges. Solving problems requires a broad view: a deep knowledge of the tax effect and the degree of capitalisation of each financial action or real action, it requires maintaining a perspective of general balance of the economy, knowledge of a balanced budget in public finances, a good capacity of analysis, of the differential effect of taxes, throughout the life cycle, intergenerationally and intragenerationally with overlapping generations, etc. Resolving fiscal challenges, such as the sustainability of the welfare state, requires examining which part of the benefits is accrued from taxed funding and which from non-taxed funding, from the funding that logically should be born either by the taxpayer or the user. It requires knowledge of the tax technique through taxation, duties or prices; of tax deductions or equivalent expenses; ordinary or extraordinary financing (deficit and debt under the golden rule, the timely disposal of assets in exchange for investment expenditure or debt replacement). And finally, if the answer to solvency is tax, not ignoring the excess burdens of tax (economic efficiency) linked to each tax category, and how equity suffers or improves its balance depending on which instrument is used. Hence the importance of assessing the welfare aspects of taxation when talking about the welfare resulting from new social spending.

As part of a social policy, spending on health makes an important contribution to economic growth and social cohesion. But at the same time, it can be the weakest part of the link in the welfare state, highly valued but with little social willingness to finance it, with little tradition in society in favour of the collective responsibilities of social healing. Our healthcare system has often seen the possibility of new funding restricted, both from lack of fiscal effort through government policy -which despite the limited room for manoeuvre has been repeatedly challenged by the state- and lack of improvements in funding and reducing the fiscal deficit. In this context, in the case of Catalonia there is a general feeling of disenchantment among the different parties for the potential of the healthcare system, which has been recognised to have been given a positive diagnosis for the present but a rather poor prognosis for the future; especially, depending on the direction it takes at the different crossroads analysed here. ■

LIFESTYLES: WHAT CAN POLICIES DO AND WHAT CAN PEOPLE DO?

Joan Gil
Department of Economics and BEAT (Barcelona Economic Analysis Team), University of Barcelona

Toni Mora
Research Institute for Evaluation and Public Policies (IRAPP), International University of Catalonia

Unhealthy lifestyles (LSs) (such as smoking, drinking too much alcohol, taking drugs, eating a poor diet, living a sedentary life, having high-risk sex, or sleeping poorly) are all the type of health-related behaviours that we will address in this article. Key determinants of health status —such as medical care, medicine, income, or educational level— are at least partially characterised by being the result of personal choice, and therefore, they are modifiable.

Table 1 shows the evolution of some of these unhealthy habits in Catalonia in the last twenty years based on data from the ESCA (Catalan Health Survey), although this is self-reported data. This shows that the prevalence of tobacco use in both sexes has decreased significantly over the last few years (from 32.1% in 2002 to 25.6% in 2018), although it is higher in younger age groups that have lower education levels. Regarding the prevalence of alcohol risk consumption in the population over the age of 15, there is no clear trend, rather it is irregular and remains stable at around 4%, although this figure is much higher in men.[1] In terms of physical exercise, the data shows something of a drop between 2010-2014 coinciding with the economic recession, but a significant recovery from and until 2018, reaching 8 out of 10 people aged 15 to 69 who do healthy physical activity. Exceptionally, the highest rates are recorded in men with university level education. Finally, in terms of obesity (BMI≥30 kg / m^2) relative to the population aged 18 to 74, there is a gradual upward trend, which in recent years has been higher among men. According to data from the 2018 ESCA, there is a fairly noticeable social gradient in obesity in Catalonia, in that this condition is higher among those with primary education level (or less) or those who belong to the less favourable social classes.[2] Similar trends can be observed in the case of the Spanish population based on data from the National Health Survey.[3]

The aim of this article is to briefly discuss the main health effects of unhealthy LSs, to outline a few explanations as to why these bad habits are observed in the population and finally, to highlight certain policies aimed at guiding them in the right direction.

1 High risk consumption in men is considered as an alcohol consumption of ≥ 28 units / week, while in the case of women it is 17 units / week; or 5 consecutive alcoholic drinks at least once a month for the past year. One unit (unit of a standard drink) equals 10 grams of pure alcohol.

2 This gradient is the same for related chronic diseases such as diabetes or high blood pressure.

3 Available at: https://www.mscbs.gob.es/estadEstudios/estadisticas/encuestaNacional/encuesta2017.htm.

Table 1. Temporary evolution of unhealthy lifestyles in Catalonia

	2002	2006	2010	2011	2012	2013	2014	2015	2016	2017	2018
Tobacco consumption	32.1%	29.4%	29.4%	29.5%	28.5%	26.5%	25.9%	25.7%	24.7%	24.0%	25.6%
High risk consumption of alcohol	4.5%	4.5%	6.2%	4.7%	3.9%	3.9%	4.5%	3.8%	4.5%	3.4%	4.0%
Healthy physical activity (*)	N/A	N/A	72.2%	71.6%	70.5%	68.6%	67.8%	74.2%	80.9%	80.7%	82.8%
Obesity	N/A	12.7%	11.8%	13.7%	13.8%	14.2%	15.0%	14.7%	14.6%	14.9%	14.9%

Notes: The data refers to the whole population (both sexes). The reported population for tobacco consumption (daily + occasional), alcohol and hours of sleep is over the age of 15; for physical activity, aged 15 to 69, and for obesity, between 18 and 74 years of age. (*) Up until 2015: instrument International Physical Activity Questionnaire short-adapted; from 2016: instrument IPAQ. N/A: data not available.

Source: different surveys from the ESCA (Catalan Health Survey). Department of Health. Generalitat de Catalunya.

Lifestyles and adverse effects

The literature has shown numerous different types of adverse effects of unhealthy LSs on the population. Firstly, bad habits have been proven to be a high risk factor for many chronic diseases —cardiovascular disease (CVD), certain types of cancer, respiratory disease, cirrhosis, type 2 diabetes, high blood pressure, cholesterol, and obesity— which negatively affect people's quality of life and make it essential for those affected and the health authorities to change these habits. The close relationship between very unhealthy yet modifiable LSs and premature death is more than evident (McGinnis and Foege, 1993; McGinnis et al., 2002). Indeed, from a meta-analysis on seventeen countries, Loef and Walach (2012) demonstrate how the combination of several healthy LSs (no smoking, moderate alcohol consumption, regular exercise, eating a healthy diet and within a normal weight range) is associated with a 66% decrease in mortality, compared to individuals who do not follow any of these healthy LSs. Similarly, Li et al. (2018), using three decades of survey data from the United States, prove how adhering to these five healthy habits could prolong life expectancy at age 50 by about 14 years in women, and 12.2 years in men, with respect to those who do not. Secondly, but equally important, are the negative effects of some of these unhealthy LSs on mental health, such as depression, anxiety, schizophrenia, cognitive impairment, irritability, etc. Finally, it is also important to consider the impacts bad health habits, mainly alcoholism and addictive substances, have on issues such as aggressive behaviour, certain criminal activities, sexual abuse, fires, vehicle accidents, in addition to poorer school performance, working conditions or wages (Corman and Mocan, 2015).

Lifestyles: determinants

There are several theories that explain the high presence of unhealthy LSs in the population, although their detrimental effects are widely acknowledged (Cawley and Ruhm, 2011). Firstly, some say that these habits are simply the result of rational and consistent choices, so the consumption of addictive goods (such as alcohol, tobacco, or cocaine), or addiction in general (to food, work, etc.) is the result of fully rational behaviour and maximising stable preferences, while still taking into account that the consumption of these goods will have adverse effects on health and income in the future (Becker and Murphy, 1988). This approach to *rational addiction* has been empirically proven. An example is the work of Becker et al. (1994) on addictive smoking behaviour with aggregated data from the US.[4] In Spain, based on a non-linear "double-hurdle" tobacco consumption model and individual Spanish panel data, Labeaga (1999), takes into account unobserved diversity and the presence of endogenous regressors.

Secondly, other authors believe that the adoption of unhealthy habits is a consequence of an inappropriate "discount" that tends to reward short-term pleasures (Cawley and Ruhm, 2011). In fact, Fuchs (1982) shows the existence of an educational gradient in temporary preference rates, so that the more education, the lower the discount rate or the greater the patience, resulting in more healthy habits and better health. Similarly, Becker and Mulligan (1997) consider schooling to

4 Specifically, Becker et al. (1994) show that the cross-prices effects are negative and that long-term price elasticity of demand exceeds short-term demand, so lower tobacco prices in the past and future will also tend to cause an increase in current consumption. Therefore past (addictive) consumption tends to reinforce current consumption.

be a resource (such as culture or wealth) to reduce the same rate of temporary preference - an "investment" in greater patience that would make future pleasures less remote. Specifically, in relation to obesity, a positive association has been documented between the temporary preference rate and obesity through a calorie-rich diet and little physical activity (Komlos et al., 2004).[5] However, this approach has been questioned for its insufficient statistical significance or weak correlation, which according to these theories, should be expected, between the differences in discount rates and variations in unhealthy behaviours (smoking, alcohol consumption, and obesity), in prevention (using medication, vaccinations or cancer screenings) or in lifestyle changes over time in each individual (Cutler and Glaeser, 2005; Cutler and Lleras-Muney, 2010).[6]

Thirdly, the adoption of unhealthy LSs can be explained by inherent cognitive limitations in individuals that lead them to be unable to predict all the adverse consequences of associated diseases, and therefore persist in their unhealthy behaviour (Cawley and Ruhm, 2011). Once again, it would appear that cognitive skills are unevenly distributed in the population and an educational gradient is observed. Here, Cutler and Lleras-Muney (2010) estimate that around 30% of the gradients referring to education and unhealthy habits in the United States and the United Kingdom would be explained by variations in cognitive skills influenced by education. Similarly, the *bounded rationality* to which we humans are subjected —challenging the notion of rationality with perfect foresight— could explain certain unhealthy types of behaviour. According to Akerlof (1991), in environments of repeated decision-making over time, limited rationality may mean that the various choices made by individuals end up significantly erroneous. This author cites the phenomenon of procrastination that leads us to postponing tasks until the next day (quitting smoking, exercising, etc.), without anticipating that when it is tomorrow, this decision will be postponed again.

Fourthly, some believe that the acquisition of unhealthy behaviour —which usually begins in adolescence— is due to having been born and raised in an unfavourable social environment. According to Marmot (2015), behind this, we necessarily find poverty, social exclusion and disempowerment. The fact that these situations are not evenly distributed in society means that unhealthy LSs are not either. There is a *social gradient* as with health or mortality. In fact, there is much empirical evidence that consistently shows, in different countries and population groups, a higher probability or prevalence in smoking, alcohol, drugs, fast food, sedentary lifestyle, and risky sexual practices in low-income brackets or educational levels (Cutler and Lleras-Muney, 2010). Although in some cases, such as smoking, the socio-economic gradient has tended to grow over time (Costa-Font et al., 2014), and in others, such as obesity, it has tended to diminish (Zhang and Wang, 2004; Ljungvall and Gerdtham, 2010; Costa- Font et al., 2014).

Finally, mention should be made of the explanations focused on social influences, either through social interactions or friendship networks, or through social norms, which are more closely linked to real or perceived cultural traits, and make unhealthy behaviour become more rigid. In fact, the literature on health economics contains several empirical studies that prove the extent of peer effects on starting smoking, alcohol or drug abuse and illiteracy in adolescents (e.g., Gaviria and Raphael, 2001; Lundborg, 2006; Clark and Lohéac, 2007; Harris and González López-Valcárcel, 2008), on harmful eating habits (Fortin and Yazbeck, 2015) or obesity itself in young people (e.g., Trogdon et al., 2008; Mora and Gil, 2013; Gwozdz et al., 2015).[7] Closely connected with these theories are explanations linking unhealthy lifestyles among young people with parental influences or intergenerational transmissions of values and norms.[8] In the case of smoking, Loureiro et al. (2010) find evidence in favour of a same-sex effect, so that fathers who smoke, influence the smoking decisions of their sons, and mothers, of their daughters. Regarding obesity or body mass index (BMI), the literature has also found evidence in favour of this transmission from parents to children (e.g., Classen et al. 2010; Dolton and Xiao, 2017), although the

5 The authors, however, admit that this alleged association could be skewed by the effect of unobserved confounding variables.

6 Others question this by arguing that if irresponsible growth due to enjoying the present can explain the rise in obesity, how does this explain the decline in smoking? (Marmot, 2015).

7 For evidence of how obesity in the adult population spreads through social relationships (with data from the Framingham Heart Study between 1971-2003), see the seminal work of Christakis and Fowler (2007).

8 Ultimately, many decisions that affect children and young people about how much and what to eat, how much exercise to do, how to spend their free time, etc., are made within the family with the decisive participation of parents.

educational level of the parents and the quality of the upbringing of the children would act as mediating factors. Interestingly, Dolton and Xiao (2017) show that the intergenerational elasticity of BMI is similar between countries with very varied societies and degrees of development, and that it tends to be higher for obese children, while it would be low for the thinnest. These results are important in terms of fostering healthy environments, as bad habits acquired in adolescence tend to go through to adulthood, with the resulting repercussions in terms of health and healthcare costs.

What needs to be done to change unhealthy LSs?

The literature has identified several options for redressing unhealthy LSs. Policies have mostly referred to: (i) taxes on "harmful" products (tobacco, sugar, alcohol, etc.), (ii) incentives (monetary and non-monetary), and (iii) preventive policies (encouraging or dissuasive). All of these have very different consequences and there are always pros and cons when they are applied.

When it comes to taxes, their effectiveness has been more than proven in terms of smoking and alcohol consumption. However, in the case of smoking, once certain figures in smoking rates have been reached, the reductions have not dropped further and appear not to decrease the prevalence in the young population group, nor even rise again, as is currently the case in Catalonia. Here, the impact of preventive policies that prohibit smoking indoors (premises, offices, etc.) had an effect and achieved reductions in consumption. In the case of alcohol, the so-called MUP (minimum unit price) applied in Scotland succeeded in reducing the number of drinks per individual for those who consumed them in excess, but also in the low-income sector. However, the regressive nature of the tax (affecting large consumers in lower income brackets) is a point against the measure. We also find there is an impact on the amount of sugar consumed when sugary drinks are taxed, although reductions in consumption are small in all the different economic sectors where the tax measure has been applied.

Preventive policies also have positive consequences. But the question is whether these are sufficient. Imagine a GP who gives me information about my health and tells me that it would be advisable for me to do some kind of sport. Will this recommendation, even if it is accompanied by blood tests that show signs of future illness, be enough to influence me and make me start running when I get home? Probably not. The health economics literature has shown that monetary incentives to go to the gym provided by private companies to their staff have been quite effective (Charness and Gneezy, 2009). Some critics claim that some of these impacts diminish in the short term (Frey and Rogers, 2014). So the right question should be: what kind of incentive should be provided, and if monetary, what would the right amount be?

The incentives suggested by the economics literature, according to Gneezy (2019) refer to four types: (1) creating habits, (2) destroying habits, (3) providing first incentives, and (4) removing barriers. For example, in the specific case of eating habits, interventions are more effective when they aim to reduce the consumption of unhealthy products than if they seek to increase healthy ones or simply reduce total intake (Cadario and Chandon, 2019). In any case, the impact of incentives varies depending on the environment in which they are applied (Hummel and Maedche, 2019).

However, besides this classification, it is important to note that incentives can be monetary and non-monetary. People tend to always think of monetary incentives, but there are circumstances in which training / education *per se* is already a measure worth considering. There are whole sections of the population who have never had access to certain training, so providing them with this training could encourage new habits to be formed. A clear example is the labelling of food products on the shelves. There is a diversity of colours and categories. So a large campaign will be needed to provide knowledge before implementing this, as the most favoured classes will probably be the only ones to fully understand the measure.

To conclude, we need to ask ourselves where the solution lies when it comes to modifying unhealthy lifestyles. While much of the responsibility lies with the individuals themselves, we must not forget that many people are deeply attached to their own circumstances, and that bad habits are an inevitable result. Therefore, public policies must act as drivers for the necessary changes. So, the temporary discount (second determinant of unhealthy LSs) and cognitive limitations (third determinant) call for actions to be focused on better educational policies. In our opinion, primary school (secondary school is already too late) is the right place to make future generations aware of the consequences of their actions. An unfavourable socio-economic environment (fourth determinant) calls for measures to fight against poverty and social exclusion while guaranteeing equal educational opportunities for children aged 0-3 from disadvantaged so-

cio-economic backgrounds. Finally, nearby social environments (fifth determinant) call for strengthening the country's fabric or social capital, given its multiplying effects on the proposed interventions. ■

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MANAGEMENT IN HEALTHCARE ORGANISATIONS THE ROLE OF MANAGEMENT CONTROL

Francesc Cots
Director of Management Control at Barcelona Hospital del Mar - Parc de Salut MAR health park and researcher at the Mar Institute for Medical Research

Olga Pané
Manager, Hospital del Mar - Parc de Salut Mar health park in Barcelona

Traditionally, organisations designed their internal structures based on two major criteria: nodes of responsibility and information flows. Information was expensive and scarce, and that is precisely why having and managing information was one of the factors that empowered an organisation.

Disclosing and disseminating information within any company was one of the strategic keys to its operation, however, it required staff devoting a huge amount of their time to attending long meetings, where lengthy data presentation often limited the time available for analysis. As a result, information was seldom properly processed, and more importantly, information rarely determined actions, changes, and improvements in procedures.

Fortunately, things have changed a lot in recent years thanks to the rise of data processing and analysis technologies. The availability of information sharing networks and the internal and external connectivity of organisations has led to a very profound change in their management techniques, in their organisational structure and in decision-making. Information has become cheaper and it can be almost immediately shared at all levels of an organisation, internally as well as externally. However, this opens up a new scenario of problems, such as those arising from excess data and the contamination of information with incorrect or outright false data.

Hospitals and healthcare centres in general are the paradigm of companies whose results depends on the management of certain, solid, well-crafted and combined data to provide accurate analyses and lead to appropriate decisions.

Hospitals work in highly *de facto* decentralised environments, "green, pluralistic organisations", as described by Frederic Laloux (Laloux 2015). Slowly but steadily, the organisational structures reflect the decentralisation of decisions in an environment where the most qualified professionals with the highest impact on results are at the base of the pyramid. Outdated structures designed as circuits with responsibility nodes that are completely uncoordinated with the technologies they work with, are becoming phased out.

In this context, one of the most substantial changes in the organisation was the role of the departments called "management control" and their work tools (business intelligence). In organisations where decision-making is highly decentralised, management controls need to distribute information so that the likelihood of making the right decisions is increased.

Finally, equally important is that the data makes sense (which requires the integration of a lot of healthcare, functional, and economic records) and must be comprehensible for the clinic staff.

In this article, we aim to set out some key points to the adaptation of the Management Control Departments (MC) to the new needs of our healthcare organisations. We will talk about our own experience at the Parc de Salut Mar health park in Barcelona, but also a wealth of knowledge on other successful experiences in the sector, including outlining the problems encountered, and what we expect in the near future.

The value chain of information and its importance in defining a contemporary MC.

Behind the ability of MCs to evolve from simple accountants to information systems managers for decentralised management and decision-making, is the information value chain. From the perspective of the exhaustive information management aimed at improving management, the first definition of MC could be: **current MC is the application of data science to management**. A hospital does not generate tangible physical products, nor does it have a small number of very well defined circuits where value is generated, but quite the contrary.

In order to be able to analyse the relationship between resources and results, it is necessary to have a lot of information about the process and the intermediate products that are incorporated in a patient's care.

Today, almost everything that is done in a hospital is recorded digitally and there are fewer and fewer dark areas remaining, so managing these digital records, and turning them into valuable information, while generating added value from their analysis that is useful for continuous improvement, is the challenge of today's MC with the indispensable support of the Information Systems Department and the Quality Department. But MC is doing this in an area where evidence based decision-making has not been common or possible until recently. Hospital management and clinical management require a very large amount of information to understand what is being done by the multiple decision-makers in the diverse and unstructured healthcare processes that take place in a complex healthcare centre. Lack of proper records, the difficulty in dealing with these flexibly, and the lack of analysis methodology have made this task difficult to date. With the help of new tools in the sphere of information integration, transformation and analysis, MCs can now provide quality information that helps in decision-making. Figure 1 summarises the degree of responsibility of MC in the assessment and interrelation with other departments.

The process an MC follows for generating useful information can be described in five essential steps:

1. Digitising the process and the use of resources. The simple process of recording of any care or support becomes a very complex operation when it means recording all activities related to care. Thoroughness counts for everything in this first element.

Figure 1. Degree of implication and responsibility of an MC in the evaluation process of information with regards to other players involved

	Management Control (+ Documentation)	Information Systems	Economics and Finance, and Human Resources	Epidemiology / Evaluation / Quality
Digitalisation of reality: how data is collected (ERP and HIS)	Coordination	Key player	Collaborators	Collaborators
Extraction of information with criteria that enable alignment with the care process	Coordination	Key player	Collaborators	Collaborators
Transformation	Key player	Technical support	Specialists	Specialists
Reporting	Key player: priorities, criteria, tools	Technical support	Dept. knowledge	Collaborators
Analysis	Key player: priorities, criteria, methodology, tools		Dept. knowledge	Specialists
Relation with third parties: invoicing, records required by health administration	Guidelines for transformation and homogeneity	Technical support	Technical support	Specialist

Coordination: has to mark criteria and keep leadership.
Main player: assigned the final responsibility for the task.
Specialist: limited to certain areas of knowledge: quality and epidemiology.

2. The structure of the information. The huge volume of records available must be organised it an way that does not lose sight of the whole.

3. Standardisation with coding that enables cross-dimensional work. When we talk about a literal diagnosis written by a doctor, we have relevant data; if this is coded with structured logic as part of code of the International Classification of Diseases (ICD10), it is a relevant, comparable and classifiable fact; and if we use coding to define products, using CCS (Clinical Classification Software), Diagnostic-Related Groups (GRD) or similar, we have valuable information that defines the cause of admission, what has been done to diagnose and treat it, and finally the possibility of assessing the outcome (Busse, 2013).

4. Data extraction and the added value supplemented by data repositories, where evaluations and labels with predefined and systematic criteria are added. In this point, MC has two tools of great specific weight: patient costing[1] and productivity analysis, where all the cross-checked departmental information can be synthesised.

5. We currently have **new tools** for building key indicators (KPIs) that can be structured into scorecards, which in turn align with strategic objectives. Some of the most significant of these tools include those that manage business intelligence (BI) and those involved with business analytics (BA) (Figure 2). As a result of these new capacities, the management by objectives (MBO) or management contracts they need, have been reinvented and are based on this management information system architecture (Figure 3).

MC is currently the benchmark for healthcare institutions as the place where the management intelligence is supported.

1 We have always referred to analytical accounting, as this was done as an addition to general accounting (financial or budgetary). In reality, what is being done today is to close the circle of information on the patient's medical history by providing the monetary value of each activity, (hence the relevance of the activity-based cost, CBA), in order to be able to establish the final value of the entire care. Patient costing therefore has two main parts, a comprehensive overview of the clinical information as a whole from a health centre and the unit costs built on the basis of the real cost of the allocation of resources to each centre. Correctly aligning activities with their unit costs is what generates high-quality information that establishes a high priority outcome variable: the cost per patient.

What does an MC do today?

Currently in many hospitals, MC is no longer a department of economic and financial management, but is directly linked to the entities' highest management body. If it reports to the financial department, then an MC controls the departmental economy and finance management, rather than the whole. If it reports directly to general management, it maintains a level of autonomy that gives it a global vision of the business and provides, if necessary, that small dose of control that comes with the name (Amat, 2017).

It should be understood more as a "management and decision-making support" than a "management controller", which generates the ability to compare its operation in its key variables with other comparable companies (Rivera, 2018).

Its basic portfolio of services would be:

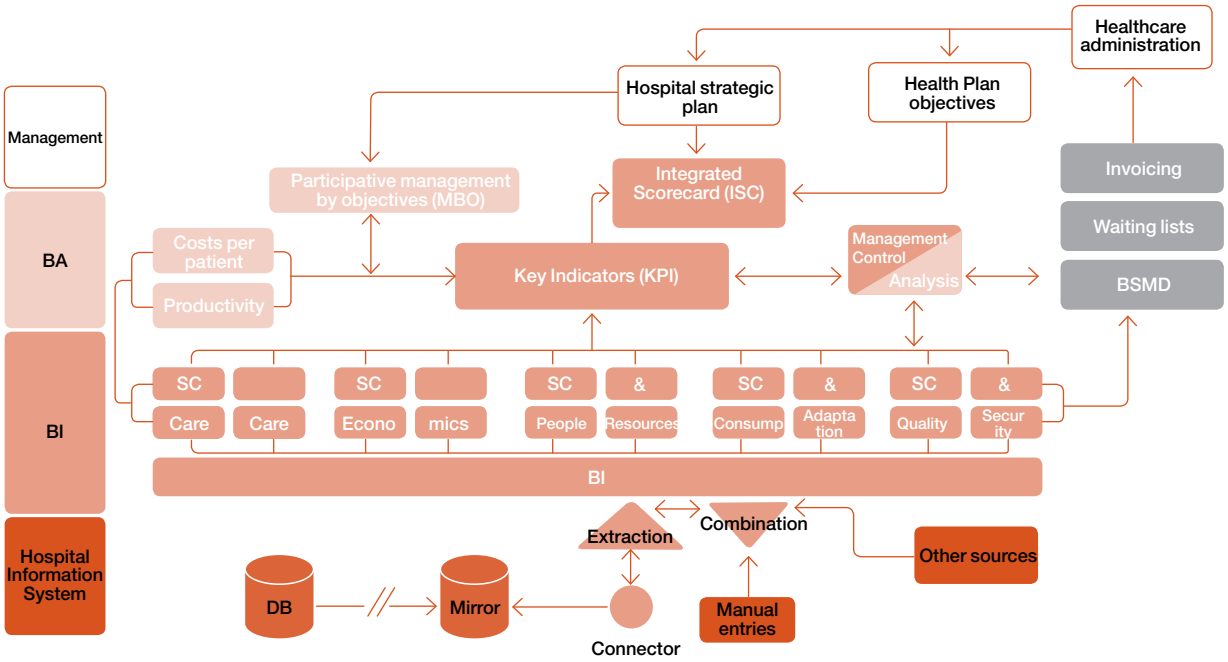
- Patient and disease costing system (in a more or less extensive sense of the process) that is as powerful and accurate as possible (Cots, 2012).
- Information system aimed at the most comprehensive management possible with different target audiences: management, clinics and third parties (includes healthcare administration).
- A comprehensive set of indicators to monitor lengthways and crossways the operation of the hospital in a homogeneous way.

Ensuring this supply of information is maintained, is the necessary condition for the existence of modern MC. But there are a series of conditions that would be enough for it to be useful:

- To act as a facilitator between management and between management and *staff*.
- To build the elements of continuous management support (scorecards, management contracts, participatory management by objectives or objective follow-up).
- To allow integration of own information, which is required more and more exhaustively by the sector.

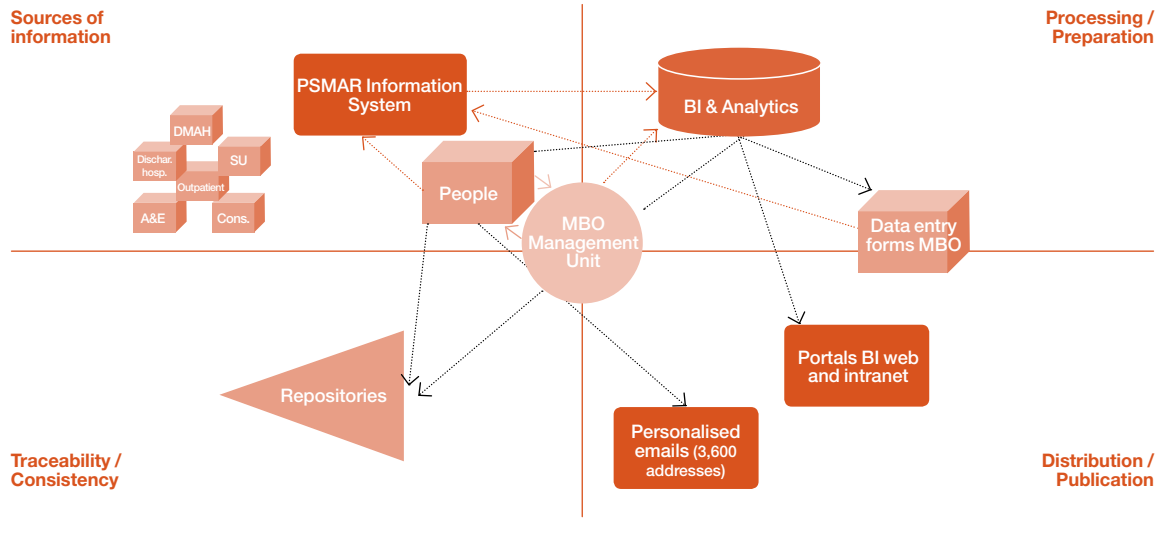
Once we have introduced the organisational factor into the functions of the MC, a second definition can be added: **the**

Figure 2. Information Systems for Management



Mirror General DB at the hospital (HIS, ERP, HR, etc) is an online copy of the operative DB, but separate for security and performance.
Extraction and combination in any mode (ETL, direct connector with DB) where the necessary information is transferred to the BI/BA platforms.
Departmental scorecards for all aspects.
KPI: summary of the key indicators that enable us to evaluate and monitor all aspects of the care process and its support.
BA: process, costs per patient and MBO follow up, are elements based on the combination of information on resources and activity.
ISC: integration of strategic objectives with result indicators that make it possible to assess the achievement of the strategic objectives.
Information for the healthcare administration: once the information has been processed and analysed, the output standards required by the administration can be generated.

Figure 3. Model DPO PSMAR: Business Intelligence Integration



purpose of an MC is to inform, coordinate, evaluate and motivate. That is, it does not only report back in order to make decisions, it also coordinates sources of information so that they are ready to constantly evaluate the actions being carried out, with the information that is being built, which is linked to the needs that are to be evaluated. Finally, an MC directly returns the information in the form of personalised objectives for the different professionals involved, so that despite their diversity, they achieve the common objectives of the company.

In order for the information to be useful for clinics and compatible with that requested by the management and at the same time, in line with that requested by the buyer/funder/healthcare administration, it is necessary to define a stable system to report in the short term, evaluate in the medium term, and propose long-term actions (Carnicero, 2018).

Practical examples of what an MC does today

MCs currently work to maximise the volume and quality of the information used to determine the real operation of the hospital as a whole:

- **Example 1:** An MC is not only designed to determine how staff evolve and whether or not a fault is due to absenteeism, or know that the ratio of professionals per bed or operating room is one or another. An MC should analyse the level of productivity, have a good notion of how it evolves over time, and a benchmark idea of how it can be compared to third parties.

- **Example 2:** An MC does not only know if the activity is growing or if the cost of consumption has varied in a certain way. It must be able to adjust the cost of consumption according to the mix of the activity carried out, and be able to construct adjusted time ratios and compare them with those of third parties comparable to risk-adjusted criteria.

- **Example 3:** An MC does not only know that state-of-the-art cytostatics are essential for assuring excellence in the treatment of various cancers, and that the cost of innovative drugs grows above 10% annually and that of cytostatics in particular, above 20%. An MC should also provide your organisation with useful information about how many patients are taking each drug in real time and monitor the impact of new drugs prescribed. A monitoring system of this nature takes into account peer management agreements over the year, so that if a certain maximum specific expenditure is available for the year, the organisation will be able to adjust to it, despite a degree of friction generated by this way of working.

- **Example 4:** An MC does not only know how long the waiting list is, but also knows how the flow of admitted and discharged patients occurs for each type of care, so that it can link the forecast of activity with the expected evolution of the waiting list. Moreover, it can inform heads of clinics about changes in their surgery capacity and about how their waiting lists are progressing, and provide tools to enable them to prepare forecasts for the coming months (basic predictive analytics).

Ultimately, once the indicators are available to track both sides of the equation -care and resources- it is possible to create a space that aligns the activity and the professionals with the strategic objectives and keep it continuously monitored.

The growth and change in functions of the MC has coincided with healthcare organisations becoming more data orientated and incorporated as a basic element in management

The MC begins its journey where the information systems department's ends and so it is essential that the existing raw material enables it to build the intelligence and business analytics (IN + AN), which are the MC's raison d'être. If extraction and transformation are done by the information systems, and all the MC does is to analyse it, we have a more traditional overview of a department analysing existing information, maintaining a volume of known indicators. On the other hand, if information systems only extract it and leaves the transformation and analysis in the hands of the MC, this presents us with a different scenario in which the goal is to obtain the maximum added value from the information, in an aim to provide measures for the maximum number of key aspects in the entire internal and external operation of the hospital.

At this point we come to a third definition of modern MCs, from the standpoint of organisation and competence: **an MC is the hospital administrator that governs, develops and operates information systems for management.**

In the organisational structure of a hospital, the role of MC may have a tendency to invade the space of information

systems. Regardless of which is the best way to divide areas of responsibility, it is true to say that an MC that doesn't have the ability to manage the IN+AN as an autonomous driver and access all the information of the organisation's systems (ERP, HIS, HR), will find it very difficult to operate as a tool that adds any value to the organisation. The main tools required for the action and development of the MC are precisely to collect and organise information in order to use it for analysis, standardisation, comparison, and decentralised transmission to users and reporting.

Professional job profiles. Can we still find any trace of the *controller*?

If we consider that an MC is a method rather than one typology of professionals, it is not uncommon to find nurses, doctors, mathematicians, statisticians, biologists or engineers in an updated MC. The reason is that if you are analysing information processes, you need figures like the process engineer who knows how to interpret and intervene with knowledge. Similarly, if the volume and structuring of information is growing and becoming complex, experts in massive data and applications are needed to analyse it, and this is where economists, mathematicians and statisticians come in, because they have the most suitable base profile.

Once there is a good amount of information and knowledge of the business, the next step in the growth of added value information for management begins; we are verging on management-orientated data scientists. This is an evolution of the *data management* "species" from 10-20 years ago, but now incorporates more analytical skills and increasingly sophisticated design skills to convey the information in the best conditions to the recipient. This whole set of professionals has gone from mastering only statistical and data management tools (Access, Spss, SAS, R, Stata, Python) to having a range of BI/BA and mass data management tools at their disposal: (from the classic *BO* or *Cognos*, to *ClikView* and now *PowerBI, Web Focus, Tableau*, etc.).

The role of *controller* has got left behind, from when centralised information was not available at all times, but was rather an expert, internal decision-making advisor.

The environment does not help

Two major problems weigh on the strategic capacity in terms of use and usefulness of the information generated by MCs. In fact, they do not weigh on the MCs themselves, but directly hamper the management capacity of public healthcare entities and a large part of private ones that work for the public sector:

1. A governance model that is too bounded by rules of administrative procedure, preventing changes in management from being applied or transferred in a smooth manner. Room for manoeuvre has been limited in recent years on the basis of the need to control corruption and a perception of hospitals as part of the administrative fabric of the public sector. Ultimately, you don't need a lot of information from alternatives to manage expenses.

2. A financing system that does not allow resources to be generated for self-sufficiency. This is a problem in a way derived from the first point. The current financing systems that govern payment to Catalan hospitals is, in theory, the most advanced out of the set of health systems in Spain. In reality, however, it is a system that determines the allocation of resources based on the economic results of the previous year and the tactical needs of the service buyer.

The absence of strategic signals from the purchasing system and the frequent changes resulting from the cash-flow problems of the utility buyer make it very difficult to sustain strategic approaches in any hospital, as one would expect from a large and complex company. Faced with this environment, the knowledge of the strategic strengths as a supplier resulting from the good analysis of the production process is no use in terms of positioning the institutions to maximise health performance adjusted to any economic constraints.

Medium-term contracts (between 3 and 5 years) that are able to stabilise health outcomes (accessibility, quality, safety, efficiency, and finance), are the framework in which the IN can really help the qualitative growth of organisations. In addition, in those cases in which the entity has a strategic business plan that can be materialised, the MC is a great help.

The interior environment. Responsibility nodes

Even in the event that a hospital has little room for strategic management, it has an essential duty, which is to provide the best healthcare, and in this sense, clinical management and adherence to decision-making is crucial, both for the safety it offers patients and for the efficiency it provides for the centre.

Hospital management always incorporates internal forces and objectives that are not exactly in line with those proposed by an MC. The management environment is made up of centripetal forces that remain in an unstable equilibrium, but which in extreme situations are counteracted and lead to the paralysis of management. In an unstable environment, the main virtue of the MC is to encourage it to do just that (manage) to the greatest possible extent. This is the virtuous circle of the MC: to generate the conditions that help provide the support to decision-making that facilitates agreement between the objectives of each different areas as much as possible, all thanks to the evidence provide by the data.

Medical/care management with a corporate mission but with a trade union at its core comes into conflict with its tertiary, university and research component, which leads to a "real" need for constant growth. This need is essential in order to exercise leadership using the knowledge of each speciality. From a short or specific standpoint of each area of knowledge, their needs are unquestionable, and it becomes difficult to argue against the evidence of "either we do it or the others will do it for us". This is the most powerful weapon of unsustainable expansionism.

The support departments (human resources and economy and finance) hold the lifeline of the budgets and everything that happens must fit into a certain *ex ante* forecast. This sometimes leads us to absolute truths expressed in a language that is incomprehensible to the rest of the institution, and where the first ones who must feel uncomfortable are the MCs themselves.

Overcoming these internal tensions caused by these nodes of responsibility that are detached from real decision-making involves decentralising decisions to the base of the pyramid, where we find the professionals with the capacity to make decisions in the key processes of the hospital. With this approach, the nodes of responsibility multiply and are directly related to clinical and care knowledge.

In order to progress towards this, we need a significant volume of high value-added information that allows them to know what they are doing, how they are doing it, what resources they are using to carry out each of the activities, and how decisive they are when faced with the current and foreseeable demand, all of which bubbles up from the unattainable magma of unexpressed need.

Discussion

Very little remains of the old management control that only determined the adjustment to the budget of the overall expenditure by type and little else. Today, what was then called MC (and can now be expressed in many other ways) centralises all the information generated and its main priority is optimising the information generated in order to foster improvements that can be applied to care and support processes.

Up until now, a management control was mainly concerned with information that could affect the invoicing and characterisation of its expenditure (rather than cost); but now what defines the need and priority of information is the quest for efficiency, safety and quality of the activity. Recently, there is an increasingly clear possibility of working with information on results from the patient's point of view (PREM: Patient Reported Experience Measures and PROM: Patient Reported Outcome Measures).

Taking responsibility that the information generated is useful for effective management has become a huge challenge due to the complexity of the business which is based on: the information provided by the patient, which is generated by the diagnostic and treatment systems, with the added difficulty of defining the value of what has been done in the care process, together with a multitude of ultra qualified professionals involved. And this challenge is being taken on more and more efficiently.

The problem lies in the potential usefulness of this management-oriented information. What is the use of knowing the causes of certain problems if there is no room for manoeuvre to make changes? The loss of income (resulting from reductions in rates and activity, and the increase in expenses such as Social Security, VAT and CPI) of Catalan hospitals in the period 2010-2019 was 21%[2]. In the face of growing demand and a clear reduction in resources, the economic problem of decision-making in a scenario of budgetary constraints is obviously complex. This situation does not unduly worry us economists and managers: it is what defines economic science, but what has already changed is the ability to make the right decisions. Legal restrictions on management autonomy raise doubt concerning the need for the existence of IN. In

2 Information prepared by the Parc de Salut Mar health park in Barcelona.

fact, IN has a real cost, which makes sense if applied to management improvements.

The conclusion of this approach may lead us to believe that MC transforms a lot of data and information generated by the hospital into business intelligence, or value, which is clearly valid and necessary for decision-making, but that in the current framework it limits autonomy to minimal levels, and may not prove worth what it costs. In any case, in terms of stability and in terms of the business plan that it facilitates, is where an MC can help, thanks to the evidence provided by the data, but also to the coordination capacity of the information systems and the reassurance provided by making IN available to all parties involved in an objective and unhurried way. ■

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PAY PER RESULTS SCHEMES IN ONCOLOGY

Carlos Campillo-Artero
Balearic Islands Health Service, CRES/BSM/Pompeu Fabra University, Barcelona

Ana Clopés Estela
Deputy General Manager, Catalan Institute of Oncology, Barcelona

As well as exploring the extent and focus of innovation in oncology, the following is an analysis of the accumulated experience in shared risk agreements, one of the measures aimed at achieving the difficult balance between pricing new treatments in consistency with their efficiency and safety, to provide the industry with reasonable benefit in order to sustain investment in R&D and to guarantee*, at the same time, the access and the sustainability of the health system.*

What is the extent and focus of innovation in oncology?

The incorporation of therapeutic innovations must ensure the balanced achievement of a triple objective: the guarantee of granting patients with access to solutions that are truly effective, the efficiency and sustainability of the system and the compensation of the innovative effort. But first we must define what *innovation* is exactly; no definition of the term has become the definition of international reference. They are incomplete and vague, although some of them are extremely clear (the first motorcar, plane, submarine or physiological serum; the first light bulb; penicillin; *reading* DNA), and others are of a much smaller magnitude, incremental, gradual (the umpteenth ACEi, model of a car brand or pacemaker). Classified in this way, they offer a blunt approach to the degree of innovation, but are nevertheless intuitive (Puig-Junoy and Campillo-Artero, 2019).

The International Society of Drug Bulletins has proposed three types of innovation in terms of medicines (Kopp, 2002): commercial, technological and advances in therapy, that is, those that benefit patients when compared with the standard treatment. Obviously, this last type of innovation is of great interest to us. And, to decide what to include in the portfolio of services from the perspective of efficiency and social welfare, it is imperative that we differentiate innovation that is disruptive from that which may be considered marginal.

How do you innovate with medicines and, specifically, oncology?

There is the technological innovation of new treatments. We have gone from having medicines which are very small molecules, simple in structure and with just one usage, to having biological medicines, obtained from living beings, with enor-

mous relative molecular masses and remarkable structural and functional complexities (erythropoietin, monoclonal antibody fragments, complete monoclonal antibodies, molecules bound to antibodies, etc.). Today, we administer viruses (innocuous and carrying genetic information that integrates into the human genome), oncoviruses (which attack tumour cells), and whole cells, such as genetically modified T lymphocytes.

There is innovation in pharmacodynamics (what medicines do to the body): there are medicines that inhibit the action of enzymes (tyrosine kinase, for example) which affect the regulation of the life cycle of cells, including tumours, and monoclonal antibodies that block the receptors in these cells preventing them from being attacked by lymphocytes (*check point* inhibitors); molecules that prevent the growth of tumour vascularisation or specifically damage the DNA of cancerous cells rendering their natural cycle deficient when they come to be repaired (poly-(adenosine-pyrophosphate-ribose) polymerase), and medicines that perform several of these actions simultaneously.

There is also innovation in other areas, such as the development of new biomarkers in oncology and other specialities (although their diagnostic validity, clinical utility and discriminatory capacity vary considerably and they have not all been adequately validated) and with artificial intelligence models that improve the diagnostic, prognostic and predictive capacity of response and toxicity, combining information from different sources.

What is the extent of the innovation?

Besides the innovation described, if we focus on the definition of innovation as a breakthrough in therapy, evaluations carried out in recent years clearly show that the benefits of marketed treatments vary depending on the drug analysed — paradoxically, lower than expected in the design of the clinical trial — and the price of which, as a common denominator, bears no relation with the benefit provided.

A recent analysis (Wieseler, 2019) by the German Institute for Quality and Efficiency in Health Care (IQWiG) on the contribution of 216 oncological and non-oncological pharmaceuticals authorised between 2011 and 2017 indicates that 25% provide a benefit that is considered greater or considerable; 16%, less or unable to quantify, and 58% offer no benefit in terms of mortality, morbidity or quality of life.

Another specific analysis of the 51 oncological pharmaceuticals approved by the FDA between 2000 and 2015 shows that, according to the clinical benefit scale of the European Society of Medical Oncology (ESMO-MCBS), only 35% have a significant clinical benefit (level 4 or 5) and, according to the American Society of Clinical Oncology (ASCO-VF), the range is from 3.4 to 67, with an average of 37. Equally, it highlights that no relation has been found between the contribution of clinical benefit and the commercial price (Vivot, 2017).

In conclusion, there are some very promising advances in pharmacodynamics and technology with incremental therapeutic value which, at the moment, is mainly low, and a price that has little relation with the benefit provided (Workman, 2017).

The challenges of innovation in medicine from the viewpoint of R&D and the regulator

Motives aside, the productivity of R&D (new medicines authorised by resources invested in R&D) has reduced gradually over the last few decades (productivity paradoxes). Incremental *improvements* in health are lower than expected whereas the costs are rising. The failure rate of the development of new medicines (from phase I to when they are authorised in oncology varies globally between 70% and 90%) highlights their complexity (difficulty in proving proof of concept in phases I and II; insufficient pharmacodynamic and pharmacokinetic results; progression to phase III with insufficient results from phase II; difficulty in extrapolating mechanisms of action and targets from one disease to others; errors in the evidence, in pivotal superiority trials, of efficacy and safety versus placebo in a new treatment or active control, or only marginal benefit or therapeutic equivalence). Also, the extension of the R&D period reduces that of cost recovery during the monopoly granted by patents (Dowden and Munro, 2019; Heemwong and Siah, 2019).

The industry's main challenge is to recover its investment in R&D (including capital costs and those of failures) and make a profit. That of the regulators is to ensure that the new therapies comply with the regulatory standards of effectiveness, safety and quality, and that their prices make them accessible to patients without undermining the efficiency and sustainability of the system and for the manufacturers to recover the high costs of R&D (fixed and sunk), authorisation and production plus a *reasonable profit margin* (Campillo-Artero, 2016).

Achieving all of this means overcoming many barriers. In the clinical trials, even those that are well designed and carried out right through to phase III, with a substantial sample size and a long duration, as in all studies, all estimates of the causal effects of treatments (efficacy and safety) have an associated element of uncertainty; it is consubstantial to them. Over the last few years, early authorisations (even in phase II) of promising treatments seek to promote early access for patients who may benefit from them. This increases the aforementioned uncertainty (*evidence*) and the result is summarised by the *evidence versus access* aporia.

If we add to this the asymmetry of information between producers, regulators, prescribers and patients; a regulatory system that is no longer binary (either it's authorised or it's not authorised), and regulatory errors: authorising a treatment very early on which turns out to be neither effective nor safe in the end or, although it is efficient to a certain extent, its risk/benefit balance is inadequate (type I), delaying its authorisation when it is subsequently proven to be efficient and safe, thus depriving patients of its benefit or delaying it (type II), and the opportunity costs associated with both errors (type III) (Eichler et al., 2008).

As well as relatively low *efficiency and* safety, the prices and spending on new oncological medicines continue to increase greatly and are a threat to the efficiency and sustainability of the system. Numerous investigations have proven this: their price is not the *socially* optimal price (the lowest so that the producers recover the R&D and production costs; a little higher than the marginal cost so that the innovator makes a *reasonable* profit) and lower than the maximum that society is willing to pay. However, current prices are so high compared to the marginal cost that the producers not only recover the R&D and production costs (including those of capital, failures and the authorisation process), but they also aim for very substantial investment returns. The consequences of reductions in productivity are offset by a sharp increase in prices, which does not justify the low relative efficiencies observed. This unbalances the distribution of the social surplus: the producer's profit (greater) plus that of the consumers (smaller).

How are these challenges being faced?

To reduce limitations, inefficiencies and negative externalities and proceed with facing the challenges highlighted in the industry, over the last decade and a half, the regulators and citizenry have been introducing reforms in *assessment*, coverage, funding and reimbursement *appraisal*. Due to a lack of space, these are summarised in table 1, although some of them still need to be postulated.

Table 1. Improvement measures for regulating medicines

In authorisation
• Promotion of the use of new experimental designs: *basket*, *umbrella*, platforms and those that remove the barriers between phases I, II and III (*seamless drug development*).
• Improvement of information on *safety* in clinical trials (PK/PD studies, risk-benefit assessment, risk tolerance thresholds, validation and qualification of biomarkers, prediction of toxicological profiles using *in silico* models, reinforcement of pharmacoepidemiology and results reported by patients.
• Incorporation of technical validity, clinical validity and utility as standards for regulating diagnostic tests, including biomarkers of diagnosis, prognosis, response and toxicity associated with drugs (*co-development*), to improve their validity and diagnostic performance.
• Review of uncertainty thresholds to reduce regulatory errors associated with authorisations and their consequences.
In coverage, pricing and post-authorisation
• New schemes for authorisation and access to new medicines: *priority review*, *fast track designation*, *early access*, *accelerated approval* and *parallel review*.
• Authorisations based on relative effectiveness and safety as opposed to absolute, and reinforcement of the monitoring of their fulfilment and of the regulatory and conditional standards (*law enforcement*), such as that limited to a subgroup of patients and subsequently expanded with new evidence, *adaptive pathways*.
• Greater and better use of economic evaluation as a fourth barrier.
• New pricing models, such as *value-based pricing*.
• New coverage, funding and reimbursement schemes (*coverage with evidence development, patient access schemes*), and shared risk agreements.
• Reduction in disparities and between criteria for authorisation, coverage, pricing and reimbursement between regulators, funders and health technology assessment agencies.
• Reinforcement of post-marketing surveillance and *comparative effectiveness*, *big data*, *real world data* and *machine learning* to increase and improve the information and prediction of effectiveness and safety post-authorisation.

Insufficient compliance with authorisation standards, coupled with the increase in early authorisations (conditional or not) requires, on the one hand, an increase in post-authorisation monitoring to gather information on effectiveness and safety, reduce uncertainty, and control the effects of increased usages, of *reversals* and inadequate substitution (including compassionate and unauthorised use). On the other hand, the use of dynamic coverage, pricing and financing models, adapted to the progressive results of the aforementioned monitoring.

Despite the already fairly widespread tendency to recommend value-based pricing systems, there are controversies that reveal that we should not lose sight of the economic theory on which they must be based (depending on their true characteristics, their effects may differ from those expected), that not all practical applications correspond to these models themselves and, in the absence of *pure* models in practice, shared risk agreements could be considered the closest approach to these models (Campillo-Artero, et al., 2019). The additional resources that all of this implies (the transaction costs are high) must be anticipated along with an assessment of the extent to which the marginal social benefits of the reforms are greater than their marginal social costs.

The evaluations of these reform measures (table 1) indicate that their implementation varies considerably between countries and that, all in all, they are solutions that are partial, slow, provisional, insufficient and must be adapted to changing conditions in the short, medium and long term, without forgetting that some are structural. The loss of social welfare (that of everybody) due to negligence or regulatory inefficiency can be extensive.

The Gordian social knot consists of an intricate balance: compliance with minimum regulatory standards of efficiency and safety, adequate thresholds for aversion to uncertainty and error tolerance, notable health benefits, and prices and measures (like the monopoly of patients), so that the industry recovers its expenses and keeps investing in R&D without diminishing efficiency, sustainability and the solvency of the system. Below, we will examine whether shared risk agreements (just one of these measures) may contribute to the *untying* of said knot.

Pay per results schemes (PRS) as an alternative to the traditional scheme

Faced with this scenario of uncertainty in the evaluation of innovation, which goes hand in hand with a highly standardised medicine pricing system, which is failing to respond to the uncertainties raised (Espín, 2010), new models need to be developed and validated. In Spain, decisions regarding the incorporation of therapeutic innovations into the Basic Services Portfolio of the National Health System (NHS) and setting their prices, access conditions and funding are one of the State's direct responsibilities (Law 29/2006, of the 25th of July). However, the decentralised territorial areas of the NHS are responsible for their own management and funding, along

> *"In Spain, the incorporation of therapeutic innovations into the Basic Services Portfolio of the NHS and setting their prices and access conditions are one of the State's direct responsibilities"*

with the development of measures to guarantee equitable and efficient access (Segú, 2014). In turn, public hospitals have to adjust the procurement of medicines to systems that, due to their rigidity, do not allow for major changes and in these systems there must be, and there are, opportunities. Below, we will analyse how PRSs may not only be an option based on value payment models, but also on information feedback models with *real-world data*.

Medicine payment schemes have traditionally focussed on the inclusion or exclusion of a certain medicine in the portfolio and on negotiating a price, in theory, according to its contribution in terms of benefit and the volume of the population that is likely to be treated. In these schemes, the price is fixed, regardless of the results and adequacy. In the event of new usage of a medicine which has already been marketed, the price usually changes, but it is still fixed, regardless of the differential contribution between the usages. The fundamental characteristic of these schemes is that the buyer assumes all of the risk, both budgetary and regarding the impact in terms of health deriving from usage and the results of the medicine in real practice (Segú, 2014).

These traditional systems find it hard to face up to the challenges implied by innovations, especially the uncertainty surrounding comparative effectiveness and safety, budgetary impact and cost-effectiveness. Some countries have added to these traditional systems, including prioritisation methods based on incremental cost-effectiveness thresholds that show the social ability to pay, such as that of NICE England-Wales, which leads to a "yes/no" decision regarding inclusion in the portfolio. Additionally, they have the advantage of being transparent decision-making systems; they have an influence on the portfolio and, laterally and not always, on the price, and they act upon local decisions, although they do run the risk of creating endogenous prices.

> *PRSs are an approximation to value-based payment and have the advantage of providing real-world data that provide feedback for the decision-making system*

In terms of this traditional pricing system, there is currently some discussion among academics and also on social media proposing the use of information on development costs when calculating the price. In this regard, the World Health Assembly recently approved (28th of May, 2019) the ruling *Improvement of the transparency within markets for medicines, vaccines and other health-related technologies*[1], which has a series of guidelines for the States to improve access to information on the different R&D processes and pricing, and improve collaboration between them and the health systems. It is designed to give governments the information that they need to negotiate fair and affordable prices.

In terms of the challenge of new medicines, the uncertainties when evaluating innovation and traditional payment schemes with fixed prices, in some countries flexible access models have been put forward and implemented. The common denominator in all of these models is that the benefits and risks associated with these uncertainties is distributed between the supplier and the healthcare system. For this reason, they are called *shared risk agreements* (SRA), although the naming varies and they are also known as *patient access scheme* (PAS) (Carlson, 2010; Garrison et al., 2013) or *managed entry agreements* (MEA) (Pauwels, 2017). These flexible access models for medicines cover a wide range: from financial models, such as price-volume or spending ceilings, to results-based agreements.

When these results-based models are applied on an individual scale, we are talking about PRS. Here, the health system only finances the cost of patients who respond to treatment within a certain period of time. PRSs are an approximation to value-based payment and, what's more, have the advantage of providing real-world data that provide feedback for the decision-making system. They also aim to include the co-responsibility of the industry in sustaining the health system and evaluating health results, that is, progress in reducing uncertainty with more awareness of the effectiveness, safety and cost-effectiveness of medicines in healthcare practice and, finally, providing therapeutic solutions for patients based on the clinical results obtained. We will spend more time discussing the experience gained with PRSs, since PRSs are the SRAs that provide the most value, because in their application the price of innovation is dynamically linked to their conditions of use and to the results obtained in real practice.

As an article of special interest, it is worth highlighting the one published in 2013 by the *International Society for Pharmacoeconomics and Outcomes Research* (ISPOR) (Garrison et al., 2013) with a stance on good practices for the design, implementation and evaluation of SRAs, including PRSs.

Implementation experience with PRSs

A recent report by the consultancy Ernst & Young (2019) on the application of access models on an international scale highlights the fact that they focus on the five main European countries: Germany, Spain, Italy, France and the United Kingdom. It identifies that oncology is the therapeutic area where they are used the most (38% of the agreements signed).

Financial schemes are the predominant ones (57%) while those based on results make up 23%. In terms of Spain and flexible results-based models, Catalonia and Andalusia are the most active communities reviewing the experience of SRAs with oncology medicines in Europe and finding that it is a common policy used by payers to ensure access to high-cost oncology drugs (Pauwels, 2017).

Ultimately, there are four basic elements that must be assessed in decisions for defining which payment scheme is the appropriate one for a given medicine/prescription (Segú, 2014): aspects related to the medicine and the prescription, the existence of a degree of significant uncertainty, willingness to pay and instrumental and organisational elements of the environment of application. This last element has a particular impact on the appropriate organisational and instrumental conditions in the environment that allow for its operational application.

1 https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_ACONF2Rev1-sp.pdf.

When defining the outcome variable, it is especially important for the objective to be clear, measurable, objective and relevant to the clinic. If surrogate variables are used, they must be good predictors of the end variable (tumour response *versus* overall survival) and the model must always be based on routine clinical practice and not on creating new structures or requirements.

The maximum objective and value provided by incorporating PRSs into the work dynamic of an institution is the focus on aligned results between the professionals, managers of the institution and the pharmaceutical industry. If we break down these objectives and incorporate other benefits provided, we could indicate that PRSs:

- Allow the reduction of uncertainty inherent to incorporating new medicines into the health system, by sharing the associated risks between the health funder and the supplier.
- Favour the medicine being accessible to the target population and avoid the prescription of medicines in unauthorised usages.
- Satisfy clinicians, reducing their uncertainly.
- Limit the budgetary impact if the defined health benefit does not occur.
- Make it possible to export and share the results obtained in a robust manner to the practice of care outside of the clinical trial.
- Offer guidance to the pharmaceutical industry in the search for the best medicines to achieve a balance between quality and economic profit.
- Build bonds of trust between the academic world, that of healthcare and the pharmaceutical industry.

To develop experiences, it is important to be aware of the barriers for the implementation of PRSs, among which the following stand out:

- Their implementation requires powerful information systems that allow the effectiveness of the treatment to be monitored reliably, something that can be complex and costly depending on the illness in question. A report by the *Cancer Network Pharmacist Forum* (2009) alerted to the fact that the SRA schemes that up until then had been implemented in the United Kingdom were too complex and had variables that were not covered in care practices. For this reason, PRSs may have high implementation, follow-up and monitoring costs.
- They imply a significant bureaucratic burden and high administrative and financial costs. Also, the necessary negotiations are lengthy in terms of time.
- They are highly complex, depending on the characteristics of the technology in the agreement, especially when the agreed results are uncertain and the indicators for measuring them are poorly defined.
- Without sufficient trust between the payer and the pharmaceutical company, it will be difficult to make the agreement work successfully and conflict of interest may arise between them.
- It is not advisable to use them in treatments where the effects can only be seen in the long term, where there are no specific, objective or relevant response measures or where a control group cannot be formed.

In terms of practical experiences, it is worth mentioning that of the Catalan Institute of Oncology (ICO) which, since 2011, has implemented the PRS strategy from their management model and medicine policy (Calle et al., 2014) in line with that developed by CatSalut. The results are that, since 2011, the ICO has already signed 19 agreements for 9 oncological illnesses and included follow-up results for more than 1,600 patients.

The ICO published the first evaluation of a PRS agreement signed in Spain (Clopés et al., 2017). The main conclusions are that the clinical results under the PRS have managed to equal the results of the pivotal clinical trial and achieve certain economic profit on the cost of treatment. But the most important conclusion draws from the intangibles, because the strategy has made it possible to align professionals, funders and suppliers towards results and guide them towards the protocolised use of medicines, according to the criteria outlined in the agreement, which are those based on evidence.

Ultimately, the potential impact of the PRS, from the perspective of outlining the usage conditions of therapeutics, can have a much greater economic relevance than that of failures themselves. It is reasonable to believe that aligning all agents (manufacturer, payer and professionals) in the same direction in terms of use and the link with results incorporates incentives for optimising therapy and its efficient application. ■

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PUBLIC HEALTHCARE MANAGEMENT.

THE DESIGN OF CONTRACTS BETWEEN PUBLIC ADMINISTRATIONS AND PRIVATE HEALTHCARE ORGANISATIONS IN SPAIN[1]

Ricard Meneu
Health Services Research Institute Foundation

Rosa Urbanos-Garrido
Complutense University of Madrid

Vicente Ortún
Pompeu Fabra University

The recent reform of public procurement

The current framework for procurement within the private health sector by public administrations underwent some substantial changes with the recent Public Procurement Law of 2017 (PPL). Although the legal complexities call for referral to specialised literature (Domínguez Martín, 2019), it seems inexcusable not to begin by highlighting some of the main features of this new situation. The PPL removed the service management contract, substituting it for the concession of services and the people's service contract, where the criterion of delimitation between both formulas is the transfer, or not, of the operational risk to the contractor (table1).

The concessionaire is understood to assume an operational risk when there is no guarantee that, under normal operating conditions, they will recover the investments they make or cover the costs incurred as a consequence of performing the work that is the subject of the concession. The risks transferred to the concessionaire must involve real exposure to market uncertainties, implying that any estimated potential loss incurred by the concessionaire is not merely nominal or small.

"Personal health service contracts" should be added to these modalities as they can evade the concurrence rules of a service contract when carried out through non-contractual formulas: reserve and concerted action. In this sense, regional regulations have already been passed (Law 7/2017, of the 30th of March, by the Valencian Government) which provide for mo-

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Table 1. Types of contracts in the public sector

	The operational risk is transferred	The risk is not transferred
Is a public service	Public service concession contract (articles 15, 284 and 285)	Service contract that involves direct provisions in favour of the citizen (articles 17 and 312)
Is not a public service	Service concession contract (articles 15, 285 and onwards)	Service contract (articles 17 and 308 and 313) Service contract that involves direct provisions that are not public services (article 312)

Source: modified from García Rosa (2018).

dalities for the management of health benefits, as well as the direct management or management by own means, and the indirect management in accordance with some of the formulas established in the regulations on public sector contracts, that which corresponds to concerted action agreements with public entities or with private non-profit entities which are unattached or created *ad hoc* by another non-profit company or group of companies, seeing these agreements as "organisational instruments of a non-contractual nature".

Thus, the new relational framework between the health administrations and private operators, despite modifying some of the formulas available, does not alter the basic balances that existed previously. Given the extent of a priori oppositions to these relationships that, regardless of their legitimacy, are based on inexact data and facts, it should be highlighted that the PPL explains that "the public powers are still free to provide certain categories of services themselves, specifically, services that are known as 'services for people'". The transferred directives also state that "no provision obliges Member States to subcontract or outsource the provision of services which they wish to provide themselves or to organise them in a way that does not involve public procurement" (Directive 2014/24/EU).

However, the PPL cannot be expected to address issues that are specific to different areas, such as labour relations, which are, for contractual purposes, of significant importance in the medium and long term in a sector such as health, which is labour-intensive and requires a high level of qualification and specificity. Thus, for the 10 years of maximum duration intended for health service concessions (table 2), the first contractor must recruit the set of professionals who will provide the service, and will also continue to do so for the rest of their professional life by successive subrogation — private or public —, if they do not voluntarily decide to change jobs.

Ultimately, this regulatory harmonisation should result in significant margins in order to manage more adequately based on the characteristics of the services and the agreements to be established. But this expanded panoply means that the options adopted come to depend on the limited knowledge of

Table 2. Duration of concession contracts.

Types of concession	Maximum duration (including extensions)	Specifications
Works concession and service concession (article 29.6-a)	Maximum 40 years	Those of service concession only if they include the execution of works and implementation of a service
Concession of services that are not related to the healthcare service provisions (article 29.6-b)	Maximum 25 years	Implementation of a service that is not related to the healthcare service provisions
Concession of services for the provision of health services (article 29.6-c)	Maximum 10 years	Including the implementation of a service with the objective of providing health services as long as they are not included in 29.6-a

Source: own elaboration using Law 9/2017, on public sector contracts.

advantages and risks surrounding the different types of relationship, the perceptions and feelings regarding them, as well as the willingness or resistance towards different procurement mechanisms. In this sense, the competences, skills and dispositions of the technical bodies involved in the design, quantification, qualification and supervision of these agreements is critical, given the important discretion involved in their decisions, far greater than the objective responsibilities they face. In view of the executions shown above — practically modelled concession contracts, identical over a decade, the absence of credible penalisation provisions true to the risks of partial breaches of an implausible rescission, suspicious absent-mindedness or systematic omissions, etc. —, the minimum caution required would be overwhelming transparency throughout the procurement process, allowing inappropriate guidelines, custom designs, vagueness or punishable non-specifications to be detected, highlighted and corrected in time, among other unacceptable shortcomings and weaknesses.

This said, it seems fitting to highlight that, in some of the stipulations in these new regulations, we are seeing hopeful investments starting to be made in the burden of justifiable proof of a certain choice or, at least, the review of a previous one. Specifically, in the PPL articles covering the new rescue regulation through direct management by Administration, which is admitted for reasons of public interest even in spite of the sound management of its holder. However, the reversal of the concession also requires proof that direct management is more effective and efficient than that of the concessionaire (article 279). Although it may be a source of scandal for some, we consider that the demand — albeit generalised — for reasonable, evidence-based justification, not merely a priori, of the superiority in effectiveness and efficiency of the proposed alternative, will always be preferable to any prejudiced assumption.

The experience of public-private collaboration in Spanish healthcare: what do we know?

The absence of a true evaluation culture in the Spanish Administration makes it difficult to obtain abundant and rigorous evidence as to how the different health management formulas have functioned up to this point, be they entirely public or stemming from a public-private collaboration (this last group includes the traditional agreements to the complex contracts of administrative concessions, which provide comprehensive medical assistance in certain areas of healthcare). With regard to collaboration in the field of primary care, the few studies available that evaluate associative-based entities (EBAs), something experienced exclusively in the Catalan sphere made up of cooperatives of professionals with which the Catalan Health Service arranges assistance in exchange for capital, show positive results both from the perspective of cost savings and quality and satisfaction indicators (Ledesma, 2012). However, with regard to specialised care, there is no conclusive evidence that tilts the balance towards private entities.

The usual practices for measuring the efficiency of health organisations indicate that rather than the model (public or private), what matters is the specific way in which each centre is managed (Alonso et al., 2015; Peiró, 2017). A recent study (Pérez-Romero *et al*., 2019) suggests that a flexible hospital regulation and management framework tends to be associated with greater efficiency. However, one must highlight the excessively productivist orientation of the majority of these studies. The few studies that incorporate end result and quality indicators illustrate that there are no significant differences in terms of clinical adequacy, safety, efficiency and effectiveness (Serra et al., 2017; Comendeiro-Maaløe et al., 2019a). A handful of reports, on the other hand, warn of the problems associated with highly complex collaboration contracts, such as those characterised by the newest procurement formulas (work and service administrative concessions). These include the limitations on the effective competition that these contracts, when put into practice, have brought about (CNC, 2013), the absence of explicit quality objectives or the poor monitoring of the different aspects (financial and clinical) of the contractual relationship (Syndicate of Accounts, 2017 and 2018). Subsequently, the risks of failure in the integrality of the health service or the loss of clinical knowledge that may be derived from some outsourcing processes should be noted (Meneu and Urbanos, 2018).

Also, European evidence does not support the thesis that privately run centres are systematically superior to public ones. The review work of Tynkkynen et al. (2018) indicates that, in general terms, public hospitals tend to perform better than private non-profit providers and that the latter, in turn, performs marginally better than for-profit private providers. On their part, Kruse et al. (2017) agree that public hospitals in a good number of European countries are at least as efficient (if

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not more so) than private centres, and conclude that the growth of private provision in hospitals is not related to improvements in performance.

Certainly, the growth of collaboration formulas with the private sector has been fundamentally based on the promise of potential improvements in management efficiency than on a contrasted reality. This prejudice, combined with the possibility that the concession contracts granted governments the opportunity to invest significantly while dodging (at least at first) the public debt limitations, helps to explain the recourse to these formulas over the last two decades. In this regard, the European Court of Auditors (ECA) recommends that, looking forward, procurement decisions with the private sector be based on "sound comparative analysis" that allows the best option to be selected (European Court of Auditors, 2018).

Nevertheless, and no matter how much it is claimed that public decisions are "evidence-based", the whole process of collective choice is influenced by the interaction between voters and politicians. Popular pressure has significantly conditioned what has happened in Spain with some concession contracts in recent years. Thus, the attempt of the Autonomous Community of Madrid to approve new tenders to transfer the management of 6 hospitals and 27 health centres to the private sector (Plan of sustainability guarantees for the public health system 2012) was halted as a consequence of the "White Tide" mobilisations, a movement against cutbacks in healthcare and "privatisation" which involved a significant part of health professionals. Finally, and after the Superior Court of Justice in Madrid placed a precautionary halt on the process of outsourcing management, the government of the community abandoned its intentions, which led to the resignation of the Community's then Minister of Health in 2014. In the Valencian Community, the reversal of the concessions was one of the star measures in the left-wing parties' electoral campaign in 2015, which has so far resulted in the non-renewal of the Alzira contract when it expired in 2018[2].

It can be concluded that the decisions, of one type or another, on relations between the public and private sector, have been more the fruit of ideology than of a calm debate allowing the virtues and risks of different management models to be analysed objectively. Advocates for granting the private sector a more prominent role ignored the fact that, on some occasions, those obligated to act in general interest prioritised, instead, the defence of particular interests, and also perverted their own market game rules: risk-taking as a requirement for obtaining economic gain (Gimeno-Feliu et al., 2018). On their part, supporters of keeping management in a purely public environment unsettled the ghost of privatisation, thus contributing to the social delegitimisation of the public-private partnership (CPP).

We must not forget that, in terms of some services, the responsibility that citizens attribute to the public sector is extraordinarily high. In Europe, Spain is one of the nations that attaches the most importance to the work of the state in guaranteeing a decent standard of living, particularly when it comes to providing universal health coverage. According to the 2019 Values Survey by the BBVA Foundation, 87% of those interviewed believe that the State has a great deal of responsibility in ensuring health coverage, compared to an average of 70% in neighbouring countries (Italy, France, Germany and the United Kingdom).

According to the same survey, the perception of corruption (on a scale of 0 to 10) is also higher in Spain (8.4) than in other surrounding countries (6.7). This perception is also justified by the decline in our transparency and good governance indicators following the Great Recession. It is important to remember that the institutional context plays a crucial role in the functioning of the different public-private collaboration formulas, so that in environments where there is a significant regulatory capture, the risks associated with these formulas can easily exceed their advantages. As Gimeno-Feliu et al. (2018) remind

2 An analysis of the reversal process of the Alzira concession can be found at Comendeiro-Maaløe et al., 2019b.

us, the success of any public-private collaboration initiative is based on three transversal elements: legal certainty, transparency and accountability. The deficits registered in these elements go a long way to explain the problems that have occurred in the CPPs, and they are behind the most recent scandals in the relationship between the public and private sector in the healthcare field (like that of the company Fresenius in Spain and other countries, or the fall of the giant Carillion in the United Kingdom[3]).

This implies that any regulatory proposal related to the procurement formulas between public administrations and private health organisations must address the current institutional context and/or recommend institutional reforms that favour synergies between both sectors.

How can the collaboration between the public and private sectors be improved?

In a world that is increasingly globalised in services (75% of the European GDP) like those of health and social care, what can be done to prevent Spain from facing a "confiscation" not just in terms of these areas, but also public universities?

We are basing ourselves on what is written above and on previous work in a scenario of the progressive sclerosis of public management: "We need very good public management (more than just better) to guarantee the operation of both the most intense forms of public-private collaboration and the more conservative or regressive options to republicise and renationalise, in a return to the past that is unjustifiable for a 21ST century society", (Meneu and Urbanos, 2018). We know how to improve the quality of the policy and the design of our institutions (Hernández, 2018) thanks, in part, to the beneficial influence of the European Union, for example, promoting evaluation or providing help with bodies such as the Independent Authority of Fiscal Responsibility (AIReF), which has been in operation since 2013, or the Supervisory Office for Public Procurement, created by Law 9/2017 and awaiting provision, which will be key for the design that lends its title to this article.

The economic benefits obtained from the private provision of public services may be socially convenient if they reward efficiency, innovation and offset risk, but will be socially detrimental if obtained on the basis of restricting competition, taking advantage of contacts and regulatory capture (wealth creates power, power creates wealth) (García-Altés and Ortún, 2018).

As mentioned in the first section of this article, concerted action in the social, health and education sectors constitutes a new relational instrument with the non-contractual public administration, with public funding, access and control. Article 11.6 of Law 9/2017 on public sector contracts states: The provision of social services by private entities is excluded from this Law, provided that this is done without needing to sign public contracts, through, among other means, the simple financing of these services or the concession of licences or authorisations to all entities that meet the conditions previously implemented by the contracting authority, without limits or fees, and that said system guarantees sufficient publicity and complies with the principles of transparency and non-discrimination". The 49a additional provision gives the Autonomous Communities the power to legislate using non-contractual instruments. Many have already done so and not necessarily reserving this "concerted social action" for non-profit organisations. It is, therefore, an ad hoc solution adapted to the status quo, suitable for services without economies of scale and which do not compete with each other.

We know, however, that the level of competition is an exogenous factor that affects the quality of management. And even though the healthcare sector is more "Amazon-proof" than other sectors, we must go about introducing the idea that the resources received by a health organisation will depend, initially and to a minimum, on the quality that it offers compared to its equivalents. We must go beyond the status quo, especially in the health services furthest removed from "local craftsmanship" susceptible to concerted action. Those aware of the economies of scale, range and learning required to innovate in a world where genetic editing techniques, neural interfaces or artificial intelligence have long been realities that are hard to ignore, have to keep pace with organisational change in a re-

3 Fresenius is a leading global dialysis service company, sanctioned for bribing doctors from the health service to refer patients to their centres, as well as for carrying out other corrupt practices in order to obtain privileged information or have an influence on the drafting of the technical specifications of public tenders (Securities and Exchange Commission, 2019). Equally, Carillion was one of the main contractors in construction concessions in the United Kingdom, with significant presence in the healthcare sector. Its bankruptcy, along with estimates of the cost that current public-private collaboration contracts will incur the British government over the next few years (nearly 200 billion pounds by the end of 2040, according to the National Audit Office), forced the then Minister of UK Finances to announce that no new concession contracts were to be initiated.

gulatory context that facilitates competitive public procurement between the Administration and the private sector.

The dichotomy between a service contract with transfer of risks, and a service contract without, must be overcome with a medium and long-term vision that learns from experiences such as those of the Netherlands. Transferring risks like they did there not only required the removal of incentives for selection by insurance companies through risk-adjusted capital payments. It also required a gradual transfer over time, from almost nothing at the beginning to a major transfer of risk twenty years later. It is important to highlight that both learning — about how to adjust according to risk — and perseverance and predictability in policies are essential in relationships between the public administrations and the private sector.

The aforementioned dichotomy, with and without the transfer of risk, also affects other types of public-private collaborations, particularly those involving investment in infrastructures. Whether there is full or partial public risk, the investment counts as public expenditure. It would be more logical, as suggested by Andreu Mas-Colell (2018), to give economic meaning to the European accounting standards and adjust the part of the investment that is considered public according to the level of risk assumed, something that has always been done in the financial sector.

The legal framework for procurement with the private sector offers sufficient, and fortunately homogeneous, menus within the EU, with a record in health that does not rule out a good use of this framework (Meneu and Urbans, 2018). However, the incompetent way of contracting infrastructures, which has a substantial impact on public opinion, weighs heavily: the radial roads of Madrid, the Perthus tunnel and the Castor gas deposit are clear examples. In all three cases, the profits made from construction largely offset the loss of the little private capital contributed by the concessionaires. Public loss was, however, tremendous (Bel et al., 2019).

Therefore, and in line with what the Independent Office for the Regulation and Supervision of Procurement pointed out in their first report (Oirescon, 2019), we insist on highlighting that there is significant room for improvement in the design of these specifications, the conditions stipulated in the contracts and the monitoring and supervision of these, which should be used to encourage competition, the quality of the service contracted and, ultimately, efficiency in the use of public resources.

But more than the competition between the private bodies that form contracts with the Administration, it is urgent to stimulate competition by comparison so that funding is managed collectively, between the aforementioned actors and the public entities and also, between the latter themselves, something of particular interest. Competition by comparison between public sector entities creates both civic culture (which stimulates accountability) and data and algorithms that can greatly help to reduce asymmetry in information (which would favour other agents, for-profit or not-for-profit, entering into the public services market).

Public sector entities where there is room for competition by comparison can be encouraged by the National Markets and Competition Commission (CNMC) and the AIReF on the basis of three recently developed pillars:

- The growing social demand for transparency, a necessary condition for achieving democracy and efficiency. The commitment to meeting this demand should also be strong enough so as not to renounce it by giving credit to the imaginative pretexts of those who defend their own interests, resisting with *cartelised* stubbornness.

- The substantially increased technical possibility of providing very rich data, broken down by centres, on usage, satisfaction, results, etc. This is a possibility that didn't exist 10 or 20 years ago. In an age where data as a fundamental input, one simply cannot turn one's back on all of the emerging artificial intelligence applications that can be used, not only to diagnose macular degeneration better than an ophthalmologist themselves, but also to compare health centres (or educators) better than any classical frontier analysis.

- A new procurement regulatory framework, adaptable and monitored by the EU, authorities like the CNMC and responsible citizens, aimed both at positive regulation and a better operation of the public sector.

In short, nothing new: competition for transparency (with an unprecedented wealth of data, and a modern and sound legal framework). Of course, starting by giving a small example that

can be built upon, without relying on permanent protectionism, in a society where there will increasingly be only one way to do things: do them like the one who does them best. ■

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PHARMACEUTICAL INNOVATION AND SOLVENCY OF THE WELFARE STATE

Félix Lobo
Emeritus Professor, University Carlos III de Madrid

Joan Rovira
Emeritus Professor, University of Barcelona

The pharmaceutical industry (PI) and the national health system (NHS) have a common interest to promote therapeutic innovation, but conflicting interests in terms of the price and spending on medicines. However, both need each other and finding a balance is in their best interest. This article will go over some of the burning issues concerning the pharmaceutical policy, such as social value, complexity, lifecycle, pace, costs and profitability of R&D+I (research, development and innovation) and the innovation-sustainability dichotomy of the NHS. It will also study the case in Spain and draw up some conclusions.

1. Social value and complexity of pharmaceutical R&D+I

The pharmaceutical industry (PI) is based on science, research and the innovation of products. OECD countries spend 14% of their added value on R&D, just behind the aeronautical and space industries (18%), and electronics and optics (17%), and much more than the average for the entire industry (6%) (OECD, 2017). The subsequent social value is an influx of new medicines that improve our health, allowing us to treat, heal or alleviate illnesses or symptoms. The large industrial economist, Scherer, estimates that "they have provided substantial benefits in terms of prolonging the human life and reducing the burden of diseases" (Scherer 2010) and, in terms of the economy of the development and the economic history, Nobel Deaton states that "they have saved millions of lives [...] and allowed millions of people [...] to continue working, having an income and loving each other..." (Deaton 2015, p. 159). One only has to point out the spectacular recent events in the treatment of hepatitis C, oncology, rare diseases and other spheres.

However, new treatments frequently carry high costs, with five or six-digit figures in euros per patient. Tisagenlecleucel (Kymriah®), the first of the CAR-T therapies, was included in the portfolio of the Spanish NHS in 2018 with a price of €320,000 (although this is a "catalogue" price subject to special risk-sharing agreements). This was a cause for concern, for the sustainability of the NHS and the displacement effect of other possibly more cost-effective treatments. Orphan drugs are another example. They have proven that motivation in R&D works but there are doubts as to whether the implicit order of priorities over other options, according to effectiveness, cost and the populations affected, is the right one.

These concerns lead us to question the allocative efficiency of R&D+I processes and medicines[1]. Is all the research necessary for social welfare being carried out, including in developing countries? Is the industrial R&D model efficient? Does the health value of medicines compensate for their price? To respond to these questions, the innovation must be defined and measured.

1 A more extensive examination of these questions can be seen in Lobo (2019a) and Lobo (2019b), articles that we will touch on here.

2. Innovation in the life cycle of a medicine

Innovation is defined and measured in different ways that are often contradictory. In terms of administrative decisions, an explicit and operational definition would be appropriate. Given that we are dealing with healthcare medicines and technologies, it seems reasonable to focus on the added therapeutic value; that is, on whether it has incremental effects on health and well-being, with regard to the best existing technology. This implies that not all newly marketed medicine is necessarily innovative.

The public decisions that mark the life of a medicine and have an influence on its contribution to health are: the patent, the marketing authorisation, the pricing and the financing or acquisition.

2.1. Patent

The aim of patents is to promote private investment in innovation, allowing the innovative product an exclusive marketing timeframe (monopoly). To obtain this, the requirements are: a) novelty, b) inventive activity and c) industrial application. However, in the case of medicines, the patent is requested and granted a long time before the clinical trials which determine its efficiency and safety. Thus, the patent does not guarantee contribution to health, but simply a molecular structure or a production process that is different to those that already exist. Despite the homogenising international legislation (WIPO or TRIPS of the WTO), the specific definition of innovation is decided by each country and, in practice, there are notable differences.

2.2. Marketing authorisation

In all countries, the marketing of a medicine requires prior administrative authorisation, conditioned to demonstrate efficiency and safety through clinical trials. If the clinical trials compared the new medicine with the best existing alternative, in theory, this would guarantee its innovative character. However, the legislations don't have that much scope and allow for comparison with a placebo, or a demonstration of its non-inferiority to an already available medicine. Thus, the authorised medicine may not imply a therapeutical advantage over the existing ones, although it may add other values, such as a reduction in costs.

2.3. Pricing and financing

If we want to maximise overall health and well-being to determine whether a product is innovative, as well as its therapeutic effectiveness, we must consider the costs and other effects on resources. If the cost makes a treatment unaffordable, the therapeutic innovation is not effective and the product cannot be considered a true innovation but, at the very least, a potential innovation.

In Health Technology Assessment (HTA) it is common practice to measure the therapeutic contribution in terms of the incremental cost-effectiveness ratio, with respect to an appropriate comparator. Effectiveness is measured through a gain in QALYs (quality adjusted life years), a general health index that combines increased survival with a life quality indicator. The value of this index, in relation to an expressive set threshold of willingness to pay, gives us, in theory, a decision criterion, as we know how many additional euros we have to pay for each QALY gained and we can compare with other alternative interventions.

3. The pace of innovation

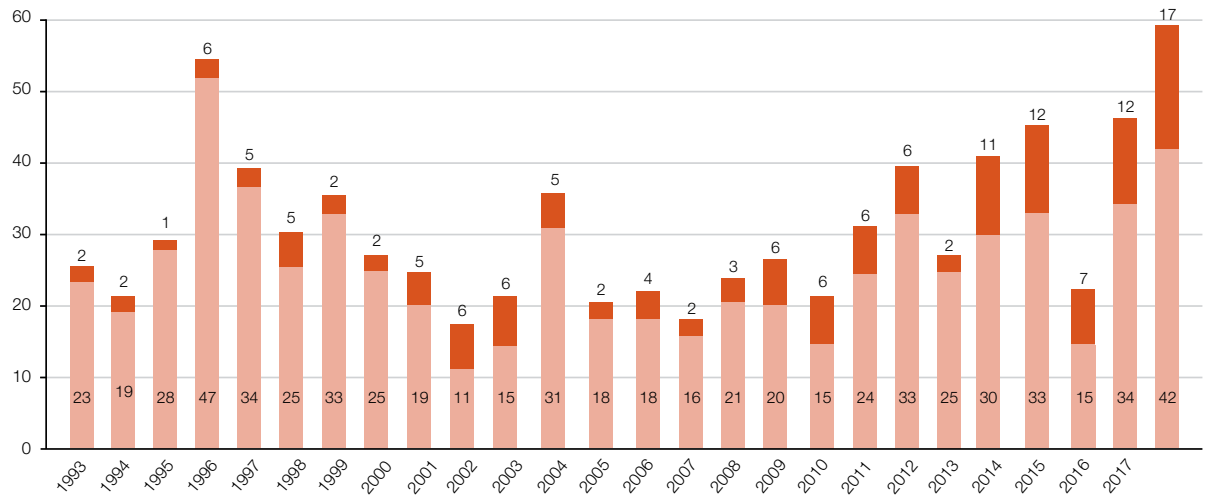
Does innovation oscillate over time or is it stable? One measure in response to this is the one in point 2.2: the newly marketed products approved by the health authority, for example, the American one (FDA) or the European one (EMA). Since 1950, the annual average of "new molecular entities (NMEs)" approved by the FDA rose to 15 in the 1970s and between 25-30 in the 1980s. There was a peak in 1996 followed by a steady decline until approximately 2005 (Kinch et al. 2014). This decline, together with the high increase in the alleged R&D costs brought about the thesis of the decrease in pharmaceutical R&D productivity (figure 1), which led to a demand for more protection and justified high prices.

Today, this thesis seems to be refuted by data that quantify a wave of innovation in biotechnological products and in spheres such as immunology and oncology. Between 2011 and 2018, the FDA approved 309 medicines, with a record of 59 in 2018 and an average of 38 per year, "the greatest sustained productivity in the modern era" (LaMattina 2019). However, it is still too early to state that there has been a Copernican turn.

However, the measure used (NME) is debatable. Not all NMEs constitute an innovation, given that one need only demonstrate a positive risk-benefit balance, but not one that is better than that of products that already exist[2]. Therefore, it doesn't take into account the varying quality. In 2018, the FDA qualified fourteen products as *breakthrough therapy*, 24% of the annual cohort (Mullard, 2019).

2 There are some differences between the US and European law on this topic, which we will not go into here.

Figure 1. New molecular entities and biological products approved by the FDA (1993-2018)



Source: Mullard, 2019.
Note: includes all NMEs and PBAs approved by the Center for Drug Evaluation and Research (CDER) of the FDA. Excludes strictly biological products approved by the Biologics Evaluation and Research (CBER) of the FDA, such as clotting factors and vaccines.

Precisely, in the US and in Europe, there are currently discussions underway regarding the preferential authorisation procedures used in the last decade that try to speed up the availability of new medicines for patients with evaluations and assessments that transfer some of the trials and final decisions on their clinical application to real practice. For some, the controls are less rigorous and favour the marketing of products that are not very innovative. Wieseler et al. (2019) estimate that 75% of medicines introduced into Germany between 2011 and 2017 do not contribute significant therapeutic benefit and that the international R&D+I processes and legislations should be reformed. Is this 25% that has contributed large or considerable benefits a lot or a little? The glass can be considered half empty or half full. On the other hand, innovation that does not focus on products should be taken into account, such as that based on new uses of existing ones (new clinical uses), which would increase their productivity.

4. Profitability of R&D+I

One big question is whether the R&D of medicines provides "adequate" profitability or if it is excessive and society is paying exaggerated business profits. In the sphere of business, the profitability of the PI really stands out. Measured by the after-tax rate of return as a percentage of the capital, it is consistently higher than in other industries. In the period from 1968-2006 it featured 27 times in first or second place in the list of 22-50 sectors ordered by *Fortune* (Scherer 2010, pg. 562). However, the persistence of higher profits may indicate a monopoly problem and has generated many criticisms.

The fact that there have been higher gains has been justified with two arguments. First, that investments in pharmaceutical R&D are considered high risk. This is a crucial question as a higher risk demands more return on capital with the consequent rise in R&D costs and prices. How is the risk measured? It has been noted that the success rate of clinical trials (probability of a product that is beginning to be studied in humans being authorised for marketing) is from 7% to 12% according to the most recent studies, and this has dropped over time. In addition to this, the risk of failure persists in later stages. However, some argue that the investor associates risk with profit stability, more than the technical characteristics of the innovative process. Because the profits of the PI remain stable over time at a high level, the risk would be less acute.

Secondly, it is alleged that the accounting rate of profit has limitations as it doesn't represent the internal business return rate. However, using other more refined variables, Scherer (2010)

concluded that the gross margin of the PI in 1987 was the sixth highest and double that of the industry as a whole, and the Office of Technology Assessment (OTA) of the United States Congress, now defunct, using a risk-adjusted "cash flow recovery rate" (close to the company's internal rate of return), found that the profitability in the PI between 1976 and 1987 was two or three percentage points higher than that of similar industries, which would be enough to encourage a substantial flow of new investment into pharmaceutical innovation. The OECD, in its recent and significant study on innovation and access to medicines (2018), provided calculations with recent data (2002-2016) on the difference between rate of return and cost of capital, which would already take into account the various risk profiles, which reveal that it has been more profitable than other innovative industries (aerospace and defence, information technologies, other health technologies...).

We can also analyse profitability from the point of view of R&D products or projects. To do this, we need to define and be aware of the costs, something which is incredibly important, as they affect the pace of innovation, condition the type of innovative companies and have a decisive influence on the prices of the medicines, which are usually justified by the level of costs mentioned.

But large question marks hover over these justifications. The first is the lack of reliable and transparent data. The studies that are best known and most used by the industry, those of DiMasi, Grabowski and Hansen (the latest from 2016) and that of Mestre-Ferrándiz et al. (2012), cannot be duplicated, as they are based on confidential surveys of pharmaceutical companies[3]. As stated by the Office of Technology Assessment (OTA, 1993) of the United States Congress, which no longer exists, companies "could overestimate costs, without the slightest chance of being discovered", although their information corroborated data from the first studies in this series.

New questions arise from other methodological characteristics of these studies and their serious limitations, which are summarised in table 1. It is extremely important to highlight that they attribute an opportunity cost to the capital invested to reflect the expected return on what investors relinquish when they invest in R&D, instead of an equally risky portfolio of financial assets. The results depend critically on hypotheses surrounding the magnitude of this cost — which is about 50% of the total estimated cost — and other key parameters.

It is not surprising, therefore, that there is much discussion about the real extent of medicines' R&D costs and the acceptability of the studies cited. On this topic see, among others, the reviews of Light and Warburton (2011), as well as the response of DiMasi et al. (2016).

Subsequently, we must handle these average cost estimations for developing a new product with care. The last calculation by DiMasi et al. (2016), with secret data, refers to 2013 and reaches 1,476 million of monetary expenditure, capitalising 2,706 million dollars. However, Prasad and Mailankody (2017), with public and reproducible data, albeit limited, on ten companies and ten cancer medicines, authorised by the FDA between 2006 and 2015, reach a much lower average per product of 793.6 million dollars.

With all of these cost insecurities as baggage, we may ask ourselves about the average profitability per successful product that ends up being marketed, to find out whether the return on investments in R&D is larger or smaller than the rate required to encourage investors. If returns greater than the amount needed to justify costs and risk persist, we would be facing unnecessary power over prices.

Table 1. Limitations of the cost studies

Small samples
Lack of data transparency
Little data from the pre-clinical phases
They critically depend on hypotheses surrounding fundamental parameters: • ratio between pre-clinical costs and total costs • success rate • time-lapse between the initiation and authorisation of the medicine • discount rate
Higher discount rate for public projects
Average variability of costs according to product types
The calculations are before tax

3 There is an interesting review of the studies on costs in R&D, but it ended in 2009 (Morgan et al. 2011). Mestre-Ferrándiz et al. (2012) also review eleven studies in detail.

There are not many analyses that provide an answer to this complex question. The OTA, in its 1993 study, concluded that profitability was positive, as the after-tax returns obtained from each product represented approximately 4.3% of the annual profit of each medicine along the duration of its life cycle. In contrast, a few years later, DiMasi and Grabowski concluded that the profitability of the PI was aligned with other industries and would only be slightly greater than its capital costs. On their part, Prasad and Mailankody (2017) deduced a much higher profitability. A simple comparison: the total costs including capital was 9.1 billion (7%) opposed to a total income of 67 billion in four years, for the ten medicines.

All of these estimates are affected by the limitations of the studies on the aforementioned costs. If the industry provided data or administrations gathered transparent and comprehensive statistics, we could carry out new analyses and come to more solid, valid and credible reproducible conclusions.

In any case, we are faced with three pending questions. The first, in the field of industrial economy, as highlighted by Scherer (2010): how does one explain the combination of high research spending on sales, high gross margins and rates of return on investment that are only slightly higher than the average of all industries? If the expected benefits are regular, why invest in costly and risky projects? The response would be an income achievement model (excess profits) that would explain the dynamic of R&D activities: when faced with profit opportunities, companies compete by increasing their investment in R&D, until the growth of costs dissipates the majority or all of the profit (Scherer 2010). In the process, substantial innovations would be achieved.

The second and third questions involve political economy. If the research costs are high and increasing, and the investments have to be remunerated by fully offsetting the opportunity cost of the capital, the prices that consumers, health insurance companies or public health systems will have to pay must be high enough to cover them. However, it must always be guaranteed that they have some type of relation with the aforementioned costs, in a sector in which very distinct patients and products give companies wide discretion when fixing prices (in unregulated market conditions). To avoid there being deviations from the average and supra-normal profit, they are subsequently based on public interventions currently as widespread as regulations on public funding and prices, and the evaluation of efficiency, which aims to ensure that public resources spent on medicines are justified both by the health benefits they generate and by their cost.

The third question is that, even if the benefits of the PI were justified, in terms of efficiency, there is still the issue of distribution, equity, in relation to people or countries without resources. Price discrimination on an international scale — depending on income levels — can help to distribute research costs between countries. It is also inevitable to seek solutions other than the unregulated market — universal public health insurance (as in Europe) or specific subsidies (as in the US) — to facilitate access to medicines for all who need them.

5. Innovation and sustainability: the Spanish case

In the second half of last century, the Spanish PI had limited innovative capacity. In these conditions, it was logical to prioritise access to medicines with low prices and a relatively low cost, compared to industrial innovation and development. Pharmaceutical expense reduction policies combined price regulation and patents from fairly unprotected processes. Thus, Spanish companies were able to copy the medicines developed by the foreign research industry, as developing a new process for manufacturing a known molecule is less complex and costly than developing a whole new medicine. However, at one point, the pharmaceutical bill accounted for half of public spending on health. Entry into the EU and approval of TRIPS radically changed the situation, forcing a stricter and more favourable product patent regime for research companies, which came into force in 1992.

Product patent put upward pressure on the prices of new medicines which, coupled with the progressive universalisation of the NHS and progress in innovation, generated tensions that made it hard to control pharmaceutical spending, which exploded when the economic crisis of 2008 affected the sector. From 2010-2012, heavy cuts were imposed which were not accompanied, however, by the necessary structural reforms. Since then, there has been constant concern for the financial sustainability of the NHS and for determining the level of innovation in medicines, in order to be able to set priorities when pricing them and admit them in public funding.

In any case, the financial stability of the NHS —some prefer to talk of solvency— is a concept that is vague and extremely subjective, as it depends on expectations and political choices. Without trying to put a lid on the issue, in this article we view sustainability as something related with the capacity of the NHS

to provide the services to which the population is entitled without incurring unwanted indebtedness, which could jeopardise its continuity.

In some cases, a real therapeutic innovation may reduce the costs of the treatment that it replaces but, in general, it tends to increase them, especially if the new treatment is more efficient or safer, or simply more convenient to administer, as the titular company is more likely to achieve higher prices than the competing products.

One instrument for monitoring sustainability are the budgetary impact studies of new high-cost medicines. Various types of risk-sharing agreements have also been put into place. Initially, they were limited to price-volume agreements but, recently, some contracts have been agreed with prices depending on the health outcomes obtained in real clinical practice. However, the systematic application of efficiency assessment is far from a reality.

At the macroeconomic scale, there is an agreement between the NHS and Farmaindustria to limit the increase in pharmaceutical spending to GDP growth. While this agreement puts a limit on spending on medicines, and can be seen to be a guarantee of sustainability, some critics argue that it is a privilege for the sector, as it "shields", in fact, the current level of this spending, which would be considered excessive.

6. Determining the degree of innovation

Since 1977, the General Council of Official Colleges of Pharmacists, in its publication *Panorama Actual del Medicamento (Current Medicine Overview)*, has been including evaluations of new drugs, albeit without regulatory implications on the prices or public funding.

The current legislation (reviewed text of the Law on guarantees and rational use of medicines and healthcare products approved by the Royal Legislative Decree 1/2015, of the 24th of July) includes, as criteria for the inclusion of medicines in the National Health System, the "therapeutic and social value of the medicine taking into account its cost-effectiveness" and the "medicine's level of innovation" (article 92.1, *c* i *f*). It also establishes that the "Inter-Ministerial Commission on Medicine Prices must take cost-effectiveness and budgetary impact analyses into consideration". It is subsequently clear that the evaluation of the level of innovation is required by law, directly and as an implicit element in cost-effectiveness analyses.

The main development in this sense are the Therapeutic Positioning Reports (TPRs), based on an agreement with the Permanent Pharmacy Commission of the Interterritorial Council of the NHS and Law 10/2013 (third additional provision). The basic content is a pharmacological and clinical evaluation of the comparative efficacy of the medicine, compared to the best therapies that are already available and, therefore, of its level of innovation or added therapeutic value.

The European pharmacological and clinical evaluation system for medicines traditionally focussed on the risk-benefit balance, without entering into comparisons that determine their added value. Subsequently, the marketing authorisation does not imply a recommendation for clinical use, as it may not provide advantages over those already available. This is changing and the European Medicines Agency (EMA) and the national authorities are taking steps towards comparative assessment.

Equally, the autonomous communities, responsible for management, decide the effective incorporation of medicines in healthcare practice and establish priorities and usage recommendations, something which requires a comparative assessment between the existing therapeutic options. The aim of TPRs is, precisely, to evaluate the incremental therapeutic benefit in a standardised manner which is shared by all administrations in the NHS.

Naturally, this is relevant for economic assessment and that of effectiveness, because if one of the arms on its scales represents costs, the other represents efficiency or effectiveness, and also for public funding and pricing decisions. Having a good pharmacological-clinical comparative evaluation allows progress to be made in all three directions and, if cost consideration is included, leads to a comprehensive "therapeutic positioning", which is a guide for funding, prices, prescription and use. However, the State Administration still has a long way to go in terms of regulating and establishing operational, objective, systematic, rigorous and transparent guidelines and procedures to evaluate efficiency and, therefore, only then can comprehensive therapeutic positioning be considered. Although the relationship between TPRs and economic evaluation still seems confusing in texts and in the practice of Administration, it appears that progress is being made in this direction.

On their part, the Inter-Ministerial Commission on Medicine Prices (CIMP), in a context of insufficient regulation and trans-

parency, seems to classify price requests into three levels of innovation, with the price differentials with respect to the comparator observed in Table 2.

The government of Pedro Sánchez, since June 2018, to date, has shown the capacity to manage pharmaceutical innovation and to introduce explicit and transparent criteria for evaluation, pricing and greater funding. Two of the star measures have been:

- The creation, in 2019 — eight years after being provided for by Law — of the Advisory Committee for the Funding of Pharmaceutical Provision of the NHS, which has already embarked upon its task (Ministry of Health 2019a).

- The launch of Valtermed, a patient-scale clinical micro-data information system to establish the therapeutic value of medicines (Ministry of Health 2019b).

7. Main conclusions and recommendations

- The flow of new medicines provided by the PI is of important social value, given that they undoubtedly have a positive impact on medical practice and the health of the population.

- The high cost of the new medicines is a concern for the sustainability of the NHS and its opportunity cost in terms of alternative treatments that are possibly more efficient. Orphan drugs could be considered an example of this conflict.

- The thesis of the decline in the productivity of pharmaceutical R&D, which was used to demand more protection and justify high prices, now seems to be refuted by a wave of innovation.

- In Europe and the USA, the flexibility of marketing authorisations is a concern. Reaching agreements on the definition, measurement and priorities of innovation in medicines is urgent.

- The greater profitability of the PI at enterprise level has been justified by the high risk of R&D+I and with quantifications at product level. But these are disputed by the lack of reliable data on R&D costs. Some studies conclude that it would match that of other industries and would only be slightly higher than their capital costs. However, other studies calculate a much greater profitability.

- High profitability, a symptom of market power, and the opacity of costs justify, among other reasons, the state regulation of public funding, prices and the assessment of efficiency.

- New, high-priced medicines pose equity problems. Universal health coverage is the way to put them on track in each country. Countries with fewer resources should benefit from lower prices.

- To ensure the financial sustainability of the public health systems, the governments should steer the definition, quantification and forecasting of innovation, as well as reviewing the current incentive scheme for R&D+I, which is nowadays too focussed on backing patents. In this line, non-monopolistic alternative ways of promoting bio-medical innovation should be explored.

Table 2. Innovation criteria used by the CIMP to determine the price of new medicines

Classification of the level of therapeutic innovation	Description of the therapeutic contribution	Expected improvements	Pricing scale compared to the comparator
Innovations of significant therapeutic interest	New active components that improve the aforementioned benefit/risk ratio, and increase the therapeutic arsenal	Demonstrable improvements in the efficiency of the medicine	0-15%
Medicines qualified as new with peculiarities	Those that are marketed for the first time. They do not always correspond to new molecular entities, although many of them are classified as such	Improvements in safety or in the management of some adverse effects	0-10%
Medicines of significant therapeutic interest	Those with active components that allow the risk/benefit ratio to be improved in relative terms compared to the alternatives that already exist	Improvements in compliance, in the target of patients to be treated or in the way that the medicine is administered	0-5%
Medicines of similar therapeutic utility	Innovations without significant interest. In general, they are funded because they contribute to the sustainability of the NHS	-	-

- In Spain, attempts are being made to juggle access to high-cost medicines with sustainability through price intervention, budgetary impact studies and various types of risk-sharing contracts. An agreement between the NHS and Farmaindustria limits the increase in pharmaceutical spending to GDP growth.

- With Therapeutic Positioning Reports (TPRs) and the new Valtermed tool, progress is being made in comparative assessment that tends to prioritise medicines that add therapeutic benefit.

- In times where there is a wave of innovation and new opportunities, such as those offered by mass data processing, the State must steer the definition and quantification of the NHS' needs and objectives, as well as guiding and promoting public and private investment into R&D+I.

- Anticipating the appearance of innovations and their cost through focusses such as *horizon scanning*, which is already being developed in Spain.

- The State Administration still has a long way to go in terms of regulating and establishing operational, objective, systematic, rigorous and transparent guidelines and procedures in terms of price intervention and the assessment of efficiency. ■

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THE REGULATION OF VOLUNTARY HEALTH INSURANCE

Pere Ibern
Centre for Research in Health and Economics, Pompeu Fabra University

Beyond publicly funded compulsory health insurance, the role of voluntary insurance has grown in terms of the number of users. There are many different reasons behind this duplicate coverage but, fundamentally, they manifest the incapacity of compulsory insurance to meet the preferences and needs of a quarter of the Catalan population. Subsequently, we find ourselves in a situation where what is offered by public services does not satisfy the demands of part of the population, and the private market, in parallel, is trying to resolve this, but still has inefficiencies. This article will explain the situation and put forward some fundamental and necessary regulatory measures in order to improve market efficiency.

The context of the insurance market

In Catalonia, in 2016, there were 2,057,393 citizens with private health insurance. This represents 27.4% of the Catalan population. And if we take into account the functionaries enrolled in State mutual societies and who choose private insurance (151,076), then voluntary insurance represents 25.3% of the population (table 1). The Health Survey offers slightly higher data, from 26.6% in 2016 and 28.0% in 2018[1]. And if we look at the Health Barometer from 2017[2], we find that the proportion is 33.0%. It is worth highlighting that the proportion of insured population is much higher in urban areas. In Barcelona, 35.9% of the population has voluntary insurance according to the health survey from 2016, 83.8% through an individual contract and 16.2% through their company[3].

This set of data shows us that a significant benefit is being accessed by a part of the population that is willing to pay, directly or through a company, which is duplicated because of the obligatory nature of public insurance. The OECD (Colombo, 2004) distinguishes between four types of private health insurance: primary access to insurance, duplicate coverage (when private insurance offers coverage for services already included under public protection), complimentary and supplementary. The type of voluntary insurance in Catalonia is fundamentally the duplicated type which, as well as the services already covered, seeks additional coverage for the same services and, instead of the excessive waiting lists in the public sector, facilitates access or differential aspects in terms of quality and comfort. However, we should bear in mind that the behaviour of those insured differs with regard to the use of the public or private service. Despite being voluntarily insured, usage is both public and private. A recent survey shows that 76% of those insured with duplicate coverage use both public and

1 http://salutweb.gencat.cat/web/.content/_departament/estadistiques-sanitaries/enquestes/Enquesta-de-salut-de-Catalunya/Resultats-de-lenquesta-de-salut-de-Catalunya/documents/2018-resultats/resum-executiu-esca-2018.pdf.

2 https://catsalut.gencat.cat/web/.content/minisite/catsalut/ciutadania/serveis_atencio_salut/valoracio_serveis_atencio_salut/barometre_sanitari/barometre_sanitari_catalunya_2a_onada_novembre_2017.pdf.

3 https://www.aspb.cat/documents/resultats-de-lenquesta-de-salut-2016-17-resultats-detallats-taules/.

Table 1. Insurance with double coverage in Catalonia

	2012	2013	2014	2015	2016
People with double coverage	1,842,121	1,821,179	1,872,096	1,918,787	1,906,317
Population with double coverage %	24.3	24.1	24.9	25.6	25.3
Price of healthcare policy €	708	721	734	743	710
Price of repayment policy €	968	1052	1048	1094	1081

Source: Generalitat de Catalunya. Department of Health. Free healthcare insurance entities in Catalonia 2016.

private care, 9% only use private care and 12% use public care, the remaining 3% do not use it at all (IDIS, 2018). And, for example, when the Health Barometer in Catalonia asked them where they would go in case of serious illness, 46.2% of those surveyed who have private health insurance say they would go to a public centre, while 29.6% would opt for a private one.

Within voluntary insurance there are three types: managed care policies, reimbursement policies and mixed or combined policies. In managed care policies, the insurer contracts with a health providers network and pays for the services. In reimbursement policies, the client has no restriction when choosing medical professionals or services as they assume the cost and then the insurance company reimburses them partially or fully. Mixed policies have a recommended medical network and also the option of choosing professionals freely. The cost of annual coverage is quite different; while that of reimbursement was, on average, around €1,081, that of managed care was €710 in 2016, a price similar to that of 2012 (€708). The managed care policy is the most common (93.3% of those insured). Voluntary health insurance premiums are affected by favourable tax rebates in collective contracting, which is not the case in individual contracting. The tax relief ceiling marks the threshold in price rivalry between companies. This, in turn, shifts pressure onto providers, who are affected by the bargaining power of insurers. And, in response, providers tend to focus on coping with this dynamic. This is one of the defining factors in current competitiveness.

We are in a regulated market where there are 46 companies offering their services in Catalonia. It's a highly concentrated market, where the top three companies 54.3% of the market or the top five companies, 70.6%. This concentration trend has grown in the last few years, albeit with less intensity. There are two types of entities: commercial entities and mutual societies. Currently, affiliation to mutual societies makes up only 3.3% of the total of insured parties, while commercial entities are predominant with 96.7%. They need the corresponding licence in order to operate, and commercial entities work under the supervision of the State General Insurance and Pension Funds Directorate. The Generalitat has exclusive competence over mutual societies (Law 10/2003, of the 13th of June, on social security mutual societies). The two key regulations are the one relating to the insurance contract (Law 50/1980, of the 8th of October, on insurance contracts) and the one on supervision (Law 20/2015, of the 14th of July, on regulation, supervision and solvency of insurance and reinsurance entities).

The decision of insurance coverage

Insurance protects consumers from financial risk and serves as a key intermediary for consumer access to service providers. Consumers have a wide range of insurance options to pick from and to subsequently meet their expectations. If consumers are well-informed, having a wide range of options makes it easier to adjust between supply and demand, creating greater competition at lower prices, and forcing companies to improve aspects of their products, such as supplier networks.

However, consumers generally find it hard to evaluate many characteristics of the insurance policies and to put them alongside each other in a bid to compare them (Kunreuther, 2013). There is a lot of empirical evidence that shows that consumers have difficulties in making decisions in the insurance markets, both in deciding which policy to choose and its renewal, where. Inertia plays a key role and consumers face a default option if they do not receive any news. In certain cases, they end up choosing options which, from a rational point of view, result in them losing money.

Generally speaking, these problems have two types of implications: consumers are worse off because of policies unmatched to their needs, and insurance prices and products do not improve as they would in competitive markets with frictionless and well informed consumers.

These difficulties in choosing lead to mistakes that are the fruit of inertia and can be explained by the following factors (Chandra, 2019):

1. Costs of changing: it is expensive for consumers to change of insurance companies. Beyond access to equivalent services, they need a guarantee that the new medical network will give them access to the providers they trust. If not, they will have to pay the cost of changing.

2. Costs of searching: it is expensive for consumers to search for information on insurance companies, it takes time and effort.

3. Lack of attention: consumers may be careless. They may make a "rational decision" not to take part in the search process because it is too costly compared to the expected benefits. Or they may rationally underestimate the potential benefits of the policies.

4. Bias of the current option: consumers may decide to look for new options and settle on one before their policy runs out, but then, when the time comes, they are not willing to do so or do not invest the time and effort in the task.

Beyond inertia, which results in the consumer making bad decisions, the health insurance market is characterised by the presence of adverse selection, the consumer has more prior information about their health than the insurer and can use this to their advantage. The combination of inertia in decisions and adverse selection is a challenge for the regulator in order to ensure competition in this market and, at the same time, access and well-being for consumers.

The key elements for a specific regulation

The main reason for regulating voluntary health insurance is to ensure competition in the market and to create value (better health of people). Specifically, there are two questions that must be considered: the **financial solvency** of the insurance companies and, at the same time, the **protection of the consumer and, therefore, of the quality of service,** where there are specific issues that must be monitored in the field of health (Brunner, 2012).

In terms of **financial solvency**, the State should establish frameworks that make it easier for the decisions of insurance companies not to jeopardise their ability to deal with claims. This is a simple question of risk management. To this end, most countries take measures that include minimum requirements in terms of capital, licensing, supervision and solvency control, etc. In order to minimise these risks, prudential regulation is enforced. This will not be one of the focusses of this article as it corresponds with the general insurance regulation and there is a European framework that regulates this (Solvency II) (Fuenzalida-Puelma, 2013).

In terms of **consumer protection**, there are three fundamental elements that should be considered. First, the problems surrounding information. These come in two types: before and after the contract. Before the contract, the user knows their health conditions better than the insurer and can use this information to their advantage (adverse selection). This can bring about risk selection strategies on the part of the insurer in order to counteract the impact. However, it all depends on whether it is an individual contract or a collective one through a company, and whether we are in a context where insurance is compulsory or not. Individual contracting is accompanied by a health examination and the determination of pre-existing illnesses, while this is not generally the case with collective contracting. On the other hand, in a context of duplicated voluntary insurance, adverse selection is reduced. Equally, it is important to take into account the changes that are taking place regarding access to genetic information and how this has an impact on the risk covered. From the point of view of consumer protection, care must be taken to avoid discrimination and, opportunistic behaviour.

Once contracting is completed, the user may have difficulties finding out and understanding the conditions of the contract. There may be uncertainty as to whether a service is covered or not and under which conditions, because only when a certain disease manifests itself does one realise what services are required.

According to the extent that the insurance contract becomes a subscription service and, subsequently, a long-term contract, it is necessary to manage access problems resulting

> *Regulation should avoid the relation between a place of work and the health insurance contract being an additional limitation on exibility in the job market*

from the insurers' occasional decisions (increase in prices and changes in coverage). Mechanisms must be found that protect the consumer over time.

Another element that must be taken into account to protect the consumer is that the proportion of the premium devoted to healthcare expenditure and quality healthcare must be maximised. The commercial and administrative costs should not be an excessive part in the cost of premiums. Currently, the total within the sector is made up of 80% claims ratio, 12% expenses and 8% technical results[4]. In America, the *Affordable Care Act* law specifically highlights that the acceptable ratio of spending on healthcare provision is 80%.

The **prices** for collective contracting and individual contracting tend to be quite different nowadays. The differential is notably in favour of collective contracting. The price of individual contracting can be 40% higher. The argument that justifies this difference lies in the lower commercial costs of collective contracting, bearing in mind that the claims ratio is always individual and will therefore be equivalent, regardless of the contracting. Price regulation is becoming a controversial issue and subsequently requires a detailed analysis. In any case, if the difference between individual and collective contracting is so large, one must think that there is cross-subsidisation and the regulator should assess whether it is necessary to protect the individual consumer. For example, there are other environments where that has been effective. In the case of retirement plans, a price limit has been established by law, where commissions cannot exceed, for example, a maximum of 1.5% (equity funds).

Regulation should avoid any constraint the the relationship between job and health insurance contract may represent known as *job-lock*). Some countries have responded to this issue with contract portability.

More and more frequently, consumers are using **comparators on the Internet** to consult information on prices when making their choice. While equivalent information should be shown, a framework should be established where the information is not biased and where the incentives are transparent.

Exercising choice requires access to comparable information. Beyond the generic development of products by insurers, the existence of a certified set of services by the regulatory authority would facilitate comparison.

The **guaranteed renewal of the annual** insurance contract, along with certain restrictive conditions on the updating of premiums, could help to reduce risk selection problems. The profit obtained with the guaranteed renewal criterion may be reduced if certain people face a high increase in their premium according to their risk (Patel, 2003). Subsequently, guaranteed renewal must come with a maximum increase in the premium corresponding to the risk of the whole insured population.

The certified voluntary insurance product

In a market where there are notable difficulties in terms of information and, at the same time, this is coupled with decision biases that have been sufficiently contrasted by behavioural economics, the role of the regulator must be proactive. Efforts should be made to design a market where losses resulting from the aforementioned misalignments are minimised for consumers.

In a free market context, it's worth highlighting that supply and demand stem from the independent decisions of consumers and companies. Currently, collective contracting decisions are more tax advantaged, while individual ones are not, and, therefore, taxation distorts these independent decisions while discriminating between consumers. Instead of avoiding this discrimination and promoting equal treatment, what is required is an in-depth reflection on the regulation of this market taking into account what has been implemented in others, such as with pension plans.

Barr and Diamond (2010), for example, consider, for pension plans, that the choice of options should be simple (only giving limited options is a sound and beneficial design characteris-

4 **https://www.fundacionmapfre.org/documentacion/publico/i18n/catalogo_imagenes/grupo.cmd?path=1099983.**

tic), and that low administrative costs should be achieved by disassociating the administrative functions of management. They think that choice should be simplified and a default option should be promoted.

It is precisely this default option or certified voluntary insurance policy that would encourage better competition. To achieve this, services and coverage should be considered along with the prices, access to information and the context of tax relief.

It should be noted that, beyond the market for the certified product that would allow for tax reliefs, there may be other non-certified insurance products that do not have this favourable tax treatment.

In terms of the services of the certified product, there would be a list of essential services standardised for all policies, as well as the equivalent grace periods. One of the most frequently used formulas in risk selection is establishing a grace period with exclusions in terms of pre-existing conditions. The criteria for said grace periods and exclusions should be the same for all insurers in the case of the certified product.

The certified product would be accessed through a medical network and, therefore, the patients would issue no direct payment to the providers; there would be a contract between the insurer and the provider. A shared strategy between the insurers and the providers would be necessary to establish standardised payment systems that would reduce administrative costs and encourage incentives for coordination in care.

The price of the policy is configured based on two elements: health expenditure and that of administration. Health expenditure should make up, for example, 80% of the annual premium. If a company wants to continue to offer the certified product, it must comply with this ratio, otherwise, and following a review after three years, for example, it may be excluded from certification. Given that health expenditure is individual and cross-subsidisation between consumers has to be avoided, offers on the price of the certified product would not be possible.

The decision behind choosing the certified product would be made within the framework of a comparable information platform, where there would be prices, services, a medical directory and the conditions for the various options. In order to be able to accurately monitor the basic product, the platform would be supervised by the regulatory authority.

In this product, the health information generated would receive special attention and would belong to the patient. The inclusion of data in the patient's personal folder should make it possible to add information from private and public coverage. And, in parallel, this would optimise efficient access to information for clinical decision-makers.

In order to increase the incentives of insurers to offer this certified product and encourage consumers to purchase it, a **tax relief** would be introduced, always granted individually with a percentage and a maximum limit in absolute value, applied individually through Income Tax.

In regulatory terms, a new insurance sub-branch should be opened within healthcare insurance that would allow for specific and differentiated healthcare monitoring and the repayment of expenses. This is the only way in which some of the key elements mentioned above could be contrasted.

Final comments

Generally speaking, health insurance regulation must be integrated into a specific context of insurance regulation. The singularities of this market force us to consider different specific aspects related to consumer protection, beyond conventional prudential and financial regulation. **The regulatory authority is the party responsible** for effectively enforcing **supervision, inspection and sanction** so that market competition is guaranteed along with consumer protection and the quality of service. Entities **providing** health insurance services must be **licensed** to operate in accordance with the criteria established by the standard financial regulation.

The uniqueness of the decisions regarding choosing health insurance mean that we must pay special attention to specific details. Subsequently, creating a certified **product** with homogeneous services is key. It would be a product certified by the regulatory authority and marketed through a platform that facilitates comparison. In this context, the insurance contract must be on an **individual basis** and would allow the option for a reduction in Income Tax.

Attaining a more efficient market for voluntary health insurance also forces us to consider the market for the provision of ser-

vices. The ability to choose a provider decreases for the end consumer when there is an excessive concentration. In this sense, the recent concentration in the market has been the subject of analysis in terms of its impact on prices by the Catalan Competition Authority[5]. Despite reports, this concentration has already occurred and is especially significant in the city of Barcelona.

Voluntary insurance in Catalonia covers a significant volume of people, possibly the most widely used duplicate insurance in Europe (Sagan and Thomson, 2016). Given its relevance, the regulator has to decide whether to consider the set of market misalignments shown in this article and act or, in contrast, put it to one side and watch its impact increase over time. For now, it is clear that they have opted for the second option. Considering that health is such a highly valued asset individually, surely the public deserves a satisfactory response. ■

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5 http://acco.gencat.cat/ca/detall/noticia/20190520_estudi_hospitals_2.

EVALUATION OF HEALTHCARE INTERVENTIONS

José A. Sacristán
Medical Department, Lilly España
Department of Epidemiology and Public Health, Autonomous University of Madrid

Juan Oliva
Department of Economic Analysis and Research
Seminar in Economy and Health, University Castilla La Mancha

The growing expectations of society with regards to health services, the increase in coverage —population and portfolio of services— and the continuous development of new technology have gradually increased pressure on the healthcare resources available. This has contributed to the fact that evaluating healthcare interventions has become one of the most prosperous fields in the health economy.

Logically, before being incorporated into the National Health System's (NHS) portfolio of services and used on a regular basis by healthcare professionals in their practice, the results, and the costs of all interventions, programmes and even health policies are evaluated. However, in reality, there are few components in which there is a systematic and consistent evaluation process in place. Medications and some non-pharmacological healthcare technologies are the exceptions to the norm. Each new drug undergoes a regulatory review process based on the ongoing evaluation of its risk-benefit relationship, in which random clinical trials form the cornerstone of the whole process. Regulatory agencies such as the US Food and Drug Administration (FDA), or the European Medicines Agency (EMA) set out the requirements for the development of medicines and authorise the marketing of drugs that have demonstrated adequate levels of efficacy, safety and quality.

Unfortunately, there is no similar process for most healthcare programmes and interventions that are incorporated into health systems on a daily basis (Venkataramani et al., 2019). Therefore, for this article we will use the case of medicines as a paradigm of healthcare intervention which is analysed in far greater detail and for which new evaluation proposals are being incorporated that go beyond the traditional risk-benefit assessment. The medication evaluation process may be a good model to apply to other healthcare interventions and programmes.

In a very simplified way, in the case of medicines there is a double evaluation in place. Firstly, the aforementioned regulatory evaluation, based on efficiency, safety and quality, serves as a basis for approving their launch on the market. On the other hand, following this approval, an evaluation is carried out to determine the economic impact and the possible purpose the new drug will have in therapy. In most countries, this assessment -which serves as the basis for pricing decisions, public funding, and inclusion in drug formulations- is usually conducted by health technology assessment agencies (HTAAs). (Zozaya et al., 2018). Although their objectives are different, in recent years there has been a growing dialogue between regulatory agencies and HTAAs (Eichler et al., 2010). The parallels that can be drawn are logical. The results of clinical trials that serve as a basis for regulatory approval are not always comparative studies conducted under the conditions of clinical practice with respect to the drugs in question.

Therefore, in an attempt to generate more relevant results, regulatory agencies are encouraging comparative effectiveness research, which promotes the use of comparisons with active drugs and assessment of long-term effects in heterogeneous patient populations. To this end, regulatory agencies are beginning to debate the possibility of using data from indirect drug comparisons, which would have been unthinkable a few years ago (Eichler et al., 2019).

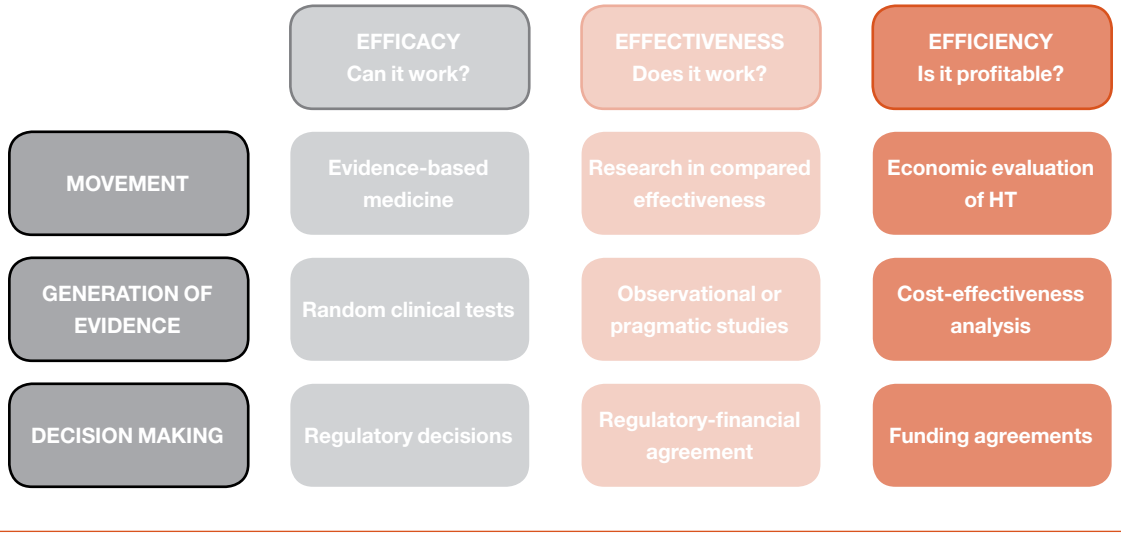
Another regulatory measure to base decisions on real-life data is to encourage the use of conditional authorisations, in which an initial approval is carried out based on the essential information on the effectiveness and safety of the new medicine. However, this approval is then subject to a subsequent demonstration of its effectiveness and/or safety in the conditions of clinical practice (Eichler et al., 2012). This strategy is leading to the development of more "pragmatic" studies, based on medical histories and patient records, the aim of which is to generate real world data that confirms or rejects the results of "explanatory" clinical trials (Sacristán, 2013). Finally, in recent years, both the FDA and the EMA have been encouraging the incorporation of variables reported by patient reported outcomes (PROs) (Basch, 2017) that gather those symptoms that have a greater impact on quality of life and can have a more direct impact on patients' functionality and social relationships, work or family.

But while we are facing a huge shift from a regulatory point of view, the changes that are taking place in the evaluations aimed at financing and the use of healthcare interventions are even more relevant. We are facing a new era of significant scientific discoveries in the biomedical field that are leading to unprecedented therapeutic progress. New drugs for the treatment of hepatitis C, targeted therapies for many types of tumours, such as T-cell therapies (Car-T), or biological drugs for autoimmune diseases are just a few examples. However, the arrival of these new drugs, often at very high prices, poses a challenge to the sustainability of the healthcare system, due to the enormous budgetary impact that, in the short term, its funding represents (Simoens et al. al., 2017). Therefore, the economic evaluation of healthcare interventions (EEHI) has become a very useful tool for decision-making with regards to the incorporation of health innovations, as well as for the good use of resources. In the same way a randomised clinical trial is the paradigm of effectiveness evaluation, cost-effectiveness studies are the paradigm of efficiency evaluation.

A look at our surroundings

While the existence of technology assessment agencies dates back a long time, it was in the early 1990s that the first countries (Australia, in 1993; the Canadian province of Ontario, in 1994) began to apply the criteria of efficiency in the process of public reimbursement of medicines. Since then, many other countries

Figure 1. From efficacy to efficiency



Source: author's own

have joined, especially European ones: Belgium, Denmark, Ireland, Portugal, the Netherlands, Sweden, Finland, France and the United Kingdom are the most prominent. The case of Spain deserves to be treated separately, so we will analyse it later. It is important to point out here that each country has developed its own agencies and formulas to integrate the information provided by the EEHI into its decision-making processes in a three-dimensional way: the inclusion of technology in publicly reimbursed benefits, price negotiation of this technology, and rational use in routine clinical practice (Zozaya et al., 2018).

The EEHI is a tool that was designed more than four decades ago The concept of *opportunity cost*, and its optimisation, is the essence of this methodology. This is made operational by considering the cost and effectiveness compared between two or more interventions (incremental cost-effectiveness ratio — ICER), a variant of cost-effectiveness analysis used in other economic fields, which makes it possible to determine the additional cost of one intervention over another for each health unit gained (Weinstein and Zeckhauser, 1973; Weinstein and Stason, 1977), in which the quality-adjusted life year (QALY), the synthetic measure that combines life expectancy and quality of life, is its top outcome measurement.

In this sense, it should be pointed out that although the EEHI has been the traditional tool used to measure the efficiency of health interventions, in recent years, the renewed interest in the concept of "value" has stimulated the development of new assessment instruments, the main objective of which was to set out the full spectrum of health effects of an intervention (beyond the survival and quality of life data given by QALYs), while also reflecting the patients' perspective (Lakdawalla et al., 2018). All these ideas can be grouped into two types of tools: *a)* value frameworks, developed mainly in the area of oncology, which incorporate in one single measure the results of the intervention on efficiency, safety, quality of life, and costs (Chandra et al., 2016), and *b)* multiple criteria decision analysis (MCDA), which aims to generate one value by weighing up the different variables that determine the value of interventions (Thokala et al., 2016). With the exception of the ICER, which compares the cost-effectiveness of interventions, the other tools have significant limitations in revealing the opportunity cost of our decisions (Neumann and Cohen, 2017; Dubois and Westrich, 2019; Sculpher et al., 2017; Baltussen et al., 2019).

If we accept the idea that financing therapeutic innovations must be linked to the value they bring to patients and society, where *value* is defined as "the improvement of health outcomes for patients for every dollar spent" (Porter, 2010), it seems logical that the EEHI, based on the concept of efficiency, and not the methods described above, should continue to be the benchmark tool for analysing the value of a health intervention (Sacristán and Dilla , 2019; Tsevat and Moriates, 2018; Campillo-Artero et al., 2018; Sacristan, 2018; Neumann, 2018). Therefore, in the following sections, the situation of the EEHI in two countries: United Kingdom and Sweden, will be analysed, with well-differentiated models, followed by an analysis of the situation in Spain.

Table 1. Efficiency thresholds for a selection of countries

Country	Initial threshold	Year	New proposals	Year
United Kingdom	20,000-30,000 pounds/QALY	2005	20,000-30,000 pounds/QALY (general reference)	2009
			50,000 pounds/QALY (end of life)	2017
			<10,000 pounds/QALY (fast evaluation)	2017
			100,000-300,000 pounds/QALY (very rare diseases)	
USA	50.000 dollars/QALY	1982	50,000-175,000 dollars/QALY	2017
Australia	42,000-76,000 Australian dollars/QALY	1998		
Canada	20,000-100,000 Canadian dollars/QALY	1992		
The Netherlands	20,000 euros/QALY	1999	20,000-80,000 euros/QALY	2015
Sweden	500,000 SEK/QALY	2001		
Spain	30,000 euros/QALY	2019	25,000-60,000 euros/QALY	2020

Source: adapted and developed by Sacristán et al. (2019)

Economic evaluation applied to decision-making: case studies on the United Kingdom and Sweden

Perhaps the most paradigmatic, but also the most atypical case in relation to the EEHI, is that of the National Institute for Health and Clinical Excellence (NICE), an independent agency -although linked to the National Health Service (NHS)- whose area of direct influence is England and Wales. NICE was founded in 1999 to guide and help promote improved health through disease prevention and treatment (Rawlins, 1999). To achieve this goal, NICE has a duty to provide healthcare professionals with tools to achieve quality care for their patients, using resources efficiently (considering the cost-effectiveness of alternatives). This involves reporting on this relationship, as well as developing clinical protocols and guidelines.

A differentiating element of NICE from other agencies is when it needs to act. Every time NICE evaluates a technology, it is already in use in the NHS and in the case of medication, it already has a price. Therefore, the initial task of NICE is to classify technology in terms of its proper use by professionals, generating information and recommendations at different levels, as follows: use of the technology for appropriate usage without any restrictions within the NHS; restricted use within the NHS for specific categories of patients; restricted use in clinical trials and product evaluations; or non-use of the technology evaluated within the NHS. Among the factors that NICE claims to consider in adopting these recommendations are the (incremental) relationship between cost and effectiveness, the degree of clinical priority for the NHS, the degree of clinical need of patients that require the consideration of technology, the effective use of available resources, the stimulus for innovation, and issues related to equity.

It is important to note that NICE audited the impact of its recommendations in its first years of existence. The studies carried out indicated a high degree of variability and also served to identify distinguishing features among the professionals as well as in the organisation and management of the centres that made it more or less likely to adhere to the NICE recommendations (Sheldon et al., 2004). Furthermore, one of the consequences of this work was the gradual increase in the NHS's commitment to link funding for healthcare centres to the follow-up to NICE recommendations. Therefore, NICE has become an indispensable part of the public health financing processes in the area in which is operates.

In addition to all the above, NICE is atypical for other reasons. Among its distinctive features is the marked independence in its operation and decisions; broad participation in the evaluation process (experts, clinicians, providers, patients, etc.); a high degree of transparency in its decisions (everything concerning the evaluation process is public, from the evaluation report itself to the minutes of the meetings of all players involved); high methodological rigour and strong political support. As a result, its vocation for evaluation has widened its scope and has become transmitted to other areas of the NHS and to other countries.

Precisely as a result of the mechanisms NICE has in place to ensure transparency, the threshold used to consider whether or not an intervention was efficient (good cost-effectiveness) was revealed, based on the analysis of its reports and public recommendations (Devlin and Parkin, 2004). This forced NICE to incorporate the revised values of these thresholds (between £20,000 and £30,000 per QALY) into its subsequent methodological documents. Although they have subsequently been revised and adapted to various specific situations (end-of-life treatments and for very low-prevalence diseases) (NICE, 2017), and although there is evidence that these thresholds are used flexibly (Dakin et al., 2015), this has made NICE the first, and so far, the only assessment agency to have made these benchmarks explicit.

The second formula, chosen by most countries, has been to develop an agency within the central services of the Ministry of Health, in order to carry out technical analyses on the efficiency of the technologies evaluated, generally medicines. While there are several experiences of unquestionable interest, such as the French Haute Autorité de Santé (HAS), as well as the same examples from Canada and Australia, the case of Sweden is particularly relevant.

In October 2002, the Läkemedelsförmånsnämnden Institute (LFN or Pharmaceutical Benefits Committee) was established. According to its statutes, the guiding principles governing this agency are: human dignity, necessity and solidarity, efficiency and marginal profit. Over time, this agency also included responsibility for dental service analyses and changed its name to the current TLV- Tandvårds och läkemedelsförmånsverket (World Health Organisation, 2017). This Swedish Agency has been very active in its role in supporting decision-making. Cost-effectiveness analyses are provided by companies wis-

hing to market new medicines, together with other elements that form part of the general dossier submitted to the Swedish Ministry of Health, and the TLV technicians evaluate the information provided. Here, there is no declared cost-effectiveness threshold, although there is evidence that special consideration is given in the case of low-prevalence diseases.

Other relevant differences are that the TLV considers above all, the social perspective (in the case of NICE, the analyses are made from the perspective of the healthcare funder), which means considering costs that are not related to healthcare, such as job losses or long-term care (professional and family); the use, from early stages, of risk-sharing schemes between the public authority and the marketing company, which leads to a strict post-marketing review process in those products financed under this formula, and more recently, the use of multicriteria decision tools. Another important element to consider is that the process of public funding of medicine in Sweden is in line with the European Union's directive on transparency. In other words, resolutions must be issued within 180 days, which speeds up the process considerably. In the case of NICE, its first evaluation processes could take two to three years before reaching a resolution, although in recent years these procedures have been significantly shortened, there is even the possibility to fast-track them, subject to certain conditions.

One last detail to consider is that the work of the TLV is part of the decision-making chain, which is not limited to ministerial level. Following the central decision on whether or not to include the medicine in the public reimbursement, a second-level control is carried out by regional and local committees, which can be much more restrictive than the national agency. So it seems that any considerations in terms of efficiency fall on the central agency, while those related to budgetary impact move to the regional, and even local, level. This division of competences, typical of the decentralisation of the health system's organisation in Sweden, and its model of National Health Service is similar to our own. Therefore, this makes it an attractive country with which to draw comparisons, as well as to take advantage of their experience, analyse their successes and failures, in order to learn from them.

The economic evaluation of healthcare interventions in Spain

Although at the turn of the century we started from a very solid position from which to include the criterion of efficiency in decision-making in the launch of new technologies in the health system (methodological documents in the line with international ones, renowned experts in the field of evaluation, assessment agencies for newly created technologies, a legal framework that favoured the incorporation of the EEHI, etc.), the truth is that this step has not been taken satisfactorily. While the political agenda has continually called for the efficient use of resources, the fact is that the leap from theory to practice has never been facilitated. Numerous professional scientific institutions have called on public authorities to implement a cost-effectiveness analysis in a regulated and transparent way into the processes of financing and pricing new technologies (Oliva, 2019; AES, 2008; SESPAS, 2017; WTO, 2014), an element that has been explicitly included in Spanish laws since 2012 (BOE, 2012). The recent creation of the National Health System's Advisory Committee for the Financing of the Pharmaceutical Provision, and the publication of the minutes of the Inter-ministerial Commission on Pharmaceutical and Health Product Prices in which its decisions are based on cost effectiveness criteria, may be a sign that the political agenda regarding this matter is changing. However, at the time of writing, it is still too early to know if this will continue over time. Some recent reviews set out the peculiarities of the AEIS in Spain (Oliva-Moreno et al., 2019; Epstein and Espín, 2019).

In the case of non-pharmacological technology, in 2012 the National Health System's Spanish Network of Agencies for the Evaluation of Health Technologies and Benefits was founded (RedETS), with the aim of generating, disseminating and facilitating the implementation of information designed to base decision-making on the National Health System, in order to contribute to increasing its quality, equity, efficiency and cohesion." Although the RedETS has produced a number of health technology assessment reports, clinical practice guidelines and methodological support documents, the use of non-pharmacological AEIS remains limited (Giménez et al., 2019).

In the area of medicines, in 2013 the Therapeutic Positioning Reports (IPT) (Ministry of Health, Social Services and Equality, 2013) were developed as an online tool (coordinated by the Spanish Agency for Medicines and Health Products, the General Directorate for the Basic Portfolio of the National Health Service and Pharmacy, and the autonomous regions). These reports, based on the available scientific evidence, were designed to help avoid redundancies and inefficiencies resulting from the multiple assessments that took place at the various decisi-

on-making levels of the NHS. The aim was, therefore, that these reports would help to boost the coherence, efficiency, integration and continuity of the different evaluations of the same medicine, guaranteeing independence and contributing to the rational use of the medicines, and equity in patient access. The initial report had to include an assessment of the effectiveness and comparative safety, the criteria for use and monitoring, and optionally, a financial assessment, so that the information could be used to decide the price and financing of new drugs. Although these IPT reports have helped to improve the consistency of evaluations conducted in the NHS, they do not include explicit information on the effectiveness of the medicines evaluated, which limits their usefulness in price decisions, financing, and use of new drugs.

Conclusions

The EEHI is a well-known and well-established tool in healthcare decision-making processes in surrounding EU countries. It provides technical elements to report on decisions aimed at incorporating the dimension of efficiency into the process, which will add to other previously considered relevant dimensions, and without losing sight of others that are subject to regulatory decisions.

In recent times, beyond the usual empty speeches, there seem to be signs of a renewed interest by politicians and healthcare managers to incorporate the criterion of efficiency into their decisions. There are several positive aspects to consider, including the continuous activity in the field of EEHI in Spain, the RedETS network with extensive experience in the EEHI (Epstein and Espín, 2019; Oliva, 2019), recent proposals have been made on what could be considered an efficient intervention in Spain (Sacristán et al., 2019), the aforementioned National Health System's Advisory Committee for Pharmaceutical Funding has been developed, and there are indications that economic evaluation could be part of future IPT reports. At the same time, we are aware of the barriers and challenges that need to be overcome, as they have already been identified and overcome in countries with health systems similar to Spain's (Zozaya et al., 2018; Epstein and Espín, 2019).

On the other hand, the field of medication and other non-drug technologies should be our initial benchmarks (as they are in other countries), as we already have information on efficiency and safety available to us. The implementation of evaluation processes that embrace the dimension of efficiency in these technologies should pave the way and be interpreted as a favourable signal to address another more complex type of evaluation in our field (organisational, management models, health policies, etc.) which is equally necessary.

Ultimately, we have the right ingredients to take this step forward, but it remains to be seen whether the top-level decision-makers who govern our NHS will want to firmly commit to a value-based funding model that helps improve predictability, consistency and the transparency of the process, leaving behind a past in which the absence of these elements has been one of our negative traits. ■

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PRECISION MEDICINE: POLICIES, PROMISES, AND PRICES[1]

Salvador Peiró
Valencia Regional Health and Biomedical Research Foundation (FISABIO), Valencia
Centre for Research in Health and Economics, Pompeu Fabra University (CRES-UPF), Barcelona

Personalised and precision medicine has become very popular in the last decade. The media shows us its friendliest face, day in and day out, showcasing pharmacological firsts that could increase survival in some types of cancer that have proven unmanageable up until now or have a positive effect on quality of life in some untreatable minority disease. Its disagreeable face is glimpsed in the difficulties in accessing these innovative therapies due to their extraordinary high prices, which put the sustainability of public health systems at risk and, most probably, that of private insurance.

This article will explore both the friendly and the disagreeable face of precision medicine, in terms of its value (often uncertain) and its price (always exact and often excessive) as well as its promises and the evidence that should back them. All this in an aim to offer a conclusion on how advantageous it is not to overlook the current priorities of health policy and management or become absorbed in the task, both chimerical and erroneous, of addressing collective problems individually, and the need to control the technological frenzy to ensure that innovation is compatible with the sustainability of healthcare systems.

From one-size-fits-all tailoring to *prêt-à-porter*

Personalised and precision medicine (PPM) is portrayed as a "individualised" medicine as opposed to a "conventional" medicine that, supposedly, would use a *one-size-fits-all* approach, common for all patients. Instead, PPM uses different approaches for different subgroups of patients who share a molecular biomarker (stratified medicine) or even individualised approaches for specific patients, either because treatment is based on a set of genomic and phenotypic characteristics specific to each patient or because therapy is developed using cells from the same patient who will receive the treatment.

This contrast is usually displayed by comparing classical cytotoxic chemotherapy (which is presumed to be uniform, based exclusively on the location of the primary cancer, not incredibly selective and with significant adverse effects) and the approach with "innovative", "targeted" therapies for molecular alterations in the tumour identified by its genomic characterisation, which is presented as a guarantee of efficiency assuming that selectivity always implies better results and lower toxicity.

However, in daily practice, both approaches coexist naturally. Cytotoxic chemotherapy has undergone significant improvements in the last few years, based not so much on the location of the tumour but on extensive empirical evidence backed — tumour by tumour, cytostatic by cytostatic — by thousands of randomised clinical trials, many of the current schemes have a manageable side effect profile with good results and,

1 This text is widely based on earlier work by the author (Peiró, 2019; Peiró and del Llano, 2019).

alone, in combination (between themselves, with radiotherapy or surgery) or in combinations with targeted therapies, still account for most of our effective arsenal against cancer, especially in solid tumours (Peiró and del Llano, 2019). Similarly, and although success stories are highly estimable, targeted medicines are not always more efficient than conventional ones, and neither are they exempt from significant adverse effects.

This absurd contraposition of precision and conventional medicine forgets that, for both varieties, **the "value" of a treatment does not lie in a general "theory" regarding its effectiveness or safety according to the "selectivity", the "individualisation" or the biological plausibility of its action mechanisms on a molecular scale, but on the empirical proof (group by group of patients, treatment by treatment) of its effectiveness in properly controlled** and implemented clinical trials that show benefits in important clinical outcomes for patients, such as survival, improved quality of life, or reduction of adverse events.

However, and although the concept of an individual approach to patients (who are always different) is nothing new in medicine, **the reductions in cost and sequencing time by** *next-generation sequencing* **methodologies and the accompanying developments in bioinformatics have made it possible to better understand intraindividual biological heterogeneity and significantly increase the possibilities of developing new therapies aimed at groups of patients who share a common biomarker**: precision medicine is not innovative because it is "individualised" or "stratified", but because it bases individualisation on omics, disciplines that have emerged from university laboratories and come to establish themselves in the daily practice of care centres.

It is worth highlighting **that the barrier between precision medicine and conventional medicine is far from rigid**. One same medicine may have untargeted uses and others guided by a biomarker; a medicine developed in and for unselected populations may nuance its use with biomarkers developed from observing the response in specific subgroups of patients or may receive a post-marketing restriction from the eligible population. Even traditional medicines that are widely used, such as oral anticoagulants, may have their dosage targeted based on the presence of genetic variants that control their metabolism.

Uncertain value at an exact price

PPM is not just "exciting" due to its potential effectiveness. Also for the exorbitant price of all new precision medicines, and the (not too distant) prospect that this phenomenon will worsen to extremes that could collapse the ability of societies to finance health systems: more than 1,000 new antineoplastics are in development, the majority associated with biomarkers. And they are not alone. There are also significant developments in minority, autoimmune and other diseases. Marketed at obscene prices, which in some cases can exceed half a million or one million euros per treatment (or per year of treatment in chronic diseases), as long as the volume of candidates continues to multiply, the budgetary impact of new therapies will be devastating for healthcare systems.

But in addition to the price and number of candidates for treatment, there is **enormous concern about the effectiveness (value) and cost-effectiveness (social value) of these new medicines in many of the indications approved** by the European Medicines Agency (EMA), the Food and Drug Administration (FDA) and other regulatory agencies for the marketing authorisation of medicines. **Precision therapies seek to find a new balance between the uncertainty surrounding the tolerable risk-benefit ratio for the regulator (the information provided by clinical trials), immediate access to promising therapies, the feasibility of clinical research in low-volume sub-populations and reducing the costs of clinical research**. In this balance, the strategies to improve competitiveness within the European Union weigh heavily which, in the extremely significant case of the pharmaceutical industry, include a reduction in R&D+I costs and much quicker market access.

In this context, both the FDA and the EMA have developed different **regulatory instruments for accelerated market access for new medicines** (*fast-track*, *breakthrough designation*, accelerated approval, priority review, conditional authorisation and authorisation under exceptional circumstances, etc.) and innovative adaptive approaches to authorisation, which aim to modify the initial authorisation in line with the provision of knowledge on the effectiveness and safety of a medicine that has come onto the market with a higher degree of uncertainty than required by previous standards. These are key mechanisms when the potential therapeutic benefit of a medicine or absence of alternative treatment in serious diseases is considered enough to justify assuming a greater degree

of uncertainty in regulatory approval to reach the market quickly but, on the other hand, it still poses a major (clinical) risk for patients and (financial) risk for health systems.

Both the FDA and the EMA have approved numerous medicines with conditional authorisations in the last few years (Martinalbo et al., 2016). These approvals have not been without controversy in terms of the incremental benefit provided by new authorised medicines and the quality of their supporting evidence: of the 48 oncological medicines approved by the FDA for 68 different uses between 2009 and 2013, 8 uses (12%) were approved with one-arm studies, prolongation of survival was not significant compared to control in 24 of the 68 (35%) authorisations, the average gain in overall survival was only 2.7 months (range: 1.0 to 5.8 months) and only 7 of the 68 uses (10%) reported improvements in quality of life (Davis et al., 2017). Of the 44 indications without evidence of improvement in survival, only 3 (7%) provided this in the post-marketing period and, for all 68 uses, and with an average monitoring time of 5.4 years, only 35 (51%) showed statistically significant improvements in survival and/or quality of life (Davis et al., 2017).

In terms of cost-effectiveness, and in the case of the Spanish National Health System (NHS), a recent study described the effectiveness and costs of the new NHS-funded schemes *versus* the comparator used in the pivotal authorisation trial (Oyagüez et al., 2013). In many cases, the contribution to survival of the new approved schemes with respect to the preliminary treatment was minimum (a few days) or even zero in some cases, while the price difference was enormous, resulting in incremental costs per quality adjusted life year (QALY) much higher than the 25,000 to 60,000 euros per QALY that is set as the availability threshold in Spain (Sacristan et al., 2019), even exceeding 3 million additional euros per extra QALY (Peiró and del Llano, 2019).

In these circumstances, it is no surprise that the increased pressure to accelerate reviews and improve accessibility to new medicines (and the major difficulties in evaluating the benefit-risk ratio for hypercomplex designs), come accompanied by great concern — of governments, but also of patients themselves and health professionals — in terms of the budgetary impact of targeted therapies and the sustainability of healthcare systems, a concern that is accentuated by the **discreet correlation between the "size" of the added therapeutic value of many of these medicines (or the high uncertainty surrounding their added value) and the "size" of the price.**

Table 1. Incremental cost per additional year of survival of some medicines for the treatment of solid tumours included in the National Health System service portfolio

Location of the tumour	New scheme	Comparator	Additional survival (in months)	Incremental cost (€)	Incremental cost (€) per additional month of survival	Incremental cost (€) per additional YLG or QALY
First line						
Colorrectal	Bevazizumab + FOLFOX4	FOLFOX4	0.9	12,846	14,274	YLG: 171,288 QALY: 856,440
Colorrectal	Cetuximab + FOLFIRI	FOLFIRI	1.3	20,305	15,619	YLG: 187,428 QALY: 937,140
Breast	Bevazizumab + Paclitaxel	Paclitaxel	1.5	49,818	33,212	YLG: 398,544 QALY: 1,992,720
Breast	Lepatinib + Letrozole	Placebo + Letrozole	1.0	22,545	22,545	YLG: 270,540 QALY: 1,352,700
Second line						
Renal cell	Everolimus + BSC	Placebo + BSC	0.4	18,878	46,680	YLG: 560,160 QALY: 2,800,800
Breast	Lapatinib + Capecitabine	Capecitabine	0.3	18,298	60,996	YLG: 731,592 QALY: 3,659,760

YLG: year of life gained; QALY: quality adjusted life year; FOLFOX4: habitual treatment for digestive cancers made up of folinic acid, fluorouracil and oxaliplatin; FOLFIRI: habitual treatment for digestive cancers made up of folinic acid, fluorouracil and irinotecan, BSC: *Best Supportive Care*. The YLGs have been calculated by multiplying the incremental cost per additional month of survival by 12 (months). The QALYs have been calculated assuming that the quality of life in the last month of an oncological patient's life is 0.20.
Source: modified from Oyagüez et al., 2013.

Establishing (and negotiating) the value and the price of innovative medicines

Almost all countries in the European Union have mechanisms, more or less direct, for regulating the prices and selective funding of medicines which, over the last few years, have been (more or less) modified to include aspects of budgetary impact, added therapeutic value and cost-effectiveness (social value). National technology assessment agencies (with no regulatory capacity for authorising medicines, which is a supranational decision in the EU), are increasing their role in assessment, in addition to the benefit-risk ratio of a treatment, its cost-effectiveness and the expected budgetary impact, with the aim to give information on: 1) the decisions behind incorporation in the public services portfolio, 2) the candidates suitable for the treatment, and 3) the price that the system will pay for the medicine for a specific use. In some countries, these agencies have been gaining in evaluative capacity and institutional weight in the decision-making behind funding for new therapies, however, in Spain they have a very limited role in evaluating and pricing medicines.

The price of medicines in different countries is fundamentally set according to three "methodologies" which can be combined with each other: 1) free price, like in the United States; 2) by internal reference to the price of other medicines with a similar prescription within a country, or external reference to the same medicine in other countries, and 3) based on the value determined by technological evaluation methods, with schemes implemented in Sweden, Canada and Australia.

Value-based pricing schemes have significant theoretical advantages: they incorporate incentives for real innovation by highlighting the social interest in effective innovative medicines, reducing delays in access and integrating objectives common to the innovative industry and the public funder. But they also have limitations, such as parallel trade if the prices vary between countries, the validity of the metrics for measuring value, extremely complex dynamics in medicines with different usages and a different value for each of them and the need for constant reassessment to incorporate new knowledge or new medicines that relocate the value of the previous ones. In practice, regardless of the pricing system used, the prices are very similar in all countries in the European Union (Young et al., 2017), largely because the industry is trying to set high initial prices in countries with unregulated prices and maintain this in the rest of the countries to avoid parallel trade.

Neither the development costs and return on investment (Picavet et al., 2013; Jayasundara et al., 2019)**, nor the complexity of manufacturing** (Picavet et al., 2013)**, the promotion and marketing costs** (Phillips, 2013)**, the added value in terms of preliminary treatment** (Onakpoya et al., 2015) **nor the formal pricing system in each country** (Young et al., 2017) **seem to explain the high prices of targeted therapies.** The market size is more capable of explaining this (with higher prices when it comes to extremely rare diseases or subgroups of tumours with very low prevalence (Onakpoya et al., 2015; Messori et al., 2010) and, above all, the absence of competition due to the patents system and poor social design from incentives to innovation (Roos et al., 2010; Cole et al., 2018; Ramsey, 2015).

Currently, **difficulties in accessing targeted therapies, beyond the uncertainty surrounding their effectiveness, begin with their high prices,** which are answered by government tactics of delaying incorporation or limitation of funded indications. Surprisingly, the added therapeutic value (the additional benefits that the new treatment scheme contributes to previous management), the key of the social value of a medicine, does not seem to weigh excessively on pricing and, beyond the size of the potential market (prevalence), there doesn't seem to be any other reason that justifies the current high prices other than an extremely distorted market (monopolistic), where "exclusivity" goes hand in hand with business pricing strategies which could be seen to summarise the maximum tolerable price and for the maximum amount of time possible, using the most expensive medicine previously included in the coverage as a reference (Peiró, 2019).

The main response to the tension between high prices and access restrictions to innovative therapies has been the partial transfer to the industry of the risks associated with the uncertainty surrounding the clinical and budgetary impact through the negotiation of discounts linked to the effectiveness of treatment. *Managed entry schemes* limit (partially) the exposure of the funder, associating discounts with certain risks, either financial (price-volume agreements, *caps*), or clinical (*coverage with evidence development*, *patient access schemes*, *risk-sharing agreements*, *conditional reimbursement* and *payment by results*). The types most frequently used are price-volume agreements (40%), agreements that include the generation of new evidence (29%) and restricted access programmes (13%) (Ferrario and Kanavos, 2015).

The advantages of these types of agreements include focussing on initial use in the sub-populations with the greatest potential benefits (linking funding with inclusion criteria), the minimisation of *off-label* use, the generation of additional evidence in real conditions, the reduction of promotional costs and offering a predictable sales framework. Among the disadvantages, practical implementation is complex with high information requirements and confidentiality issues, the transfer of some of the clinical research costs from the industry to the health system (Ferrario and Kanavos, 2015) and, above all, the fact that their real effectiveness in containing prices is very limited.

Overall, the current capacity of European countries (or the United States) to contain the prices of new therapies (if desired) is extremely precarious and, beyond the discount agreements under various formulas, access limitations are the main response from governments, creating a situation of latent confrontation between a global monopolistic industry and the health systems in each country seeking isolated solutions (and often, going against their own economy and industry departments, which tend to support high prices in an effort to maintain incentives for pharmaceutical innovation and high-skilled employment).

In this internationalised market, the negotiating position of the Spanish state is too weak to make a stand (if it has one) and, in addition to this, to date, Spain has opposed attempts to negotiate a common European price in the case of direct antivirals for the treatment of hepatitis C and, more recently, has shown a great deal of reluctance towards a common assessment of health technologies.

However, such a high and fast price increase is causing sustainability problems in all health systems, making it difficult for European countries with fiscal deficit problems to keep up with this growth in the pharmaceutical bill. Additionally, price increases are generating extensive discontent: between the American population (which has to pay much of this bill directly, plus an increase in premiums), among patient associations all over the world, traditionally linked with the industry in support of research and new medicines, and extraordinarily deteriorating the image of the pharmaceutical industry. A situation that fuels reactions (such as the authorisation of the importation of medicines from Canada to the United States) and proposals to break the current status quo, ranging from radical changes in the patent system to applying the antitrust laws to the sector. Ultimately, a very complex situation for all parties involved, in which innovation, access to new treatments and the sustainability of health systems are mutually compromised (Peiró, 2015).

Promises and realities in precision medicine

Despite its promises, and in spite of important exceptions, PPM is still gathering the empirical evidence that demonstrates its superiority in clinical outcomes over conventional approaches, and the supposed savings due to a reduction in adverse effects are difficult to identify, masked by the extremely high prices of the majority of new therapies.

In terms of diagnosis, MPP has proven useful in the diagnosis of several rare diseases, but the penetrance of pathogenic genes appears to decline as asymptomatic relatives are assessed, and the categorisation of variants as pathogens is subject to constant reclassification. On the other hand, comprehensive genome association studies have shown that health problems that carry the greatest burden in terms of disease (hypertension, diabetes, coronary heart disease, depression, most cancers, etc.) and their risk factors (obesity, smoking, sedentary lifestyle...) are linked to hundreds of genes that, together, only explain a small fraction of their varying occurrence, much less than that explained by family history, neighbourhood of residence or social-economic level (Joyner and Paneth, 2019). Proposals for the use of polygenic risk scales have not proven very useful as they carry suspicions of over-diagnosis and overuse (Janssens and Joyner, 2019).

In terms of treatments, the polyclonal and adaptive nature of most tumours is showing great resistance to targeted approaches and, despite some successes, the percentage of diseases currently addressable by actionable molecular targets is still small (Marquart et al., 2018).

In prevention, the idea that disseminating information about genetic risks would bring about life style changes has not been backed up by the studies on this topic (Hollands et al., 2016) and, additionally, some of the **proposals for the "personalisation" of preventative actions may undermine efforts among the population to protect and promote health as a way to address such issues as obesity, smoking or sedentary lifestyles, as well as lead to an increase in inequalities** (Rey-Lopez et al., 2019). On the other hand, many of the preventative approaches, combined with progress in *big*

data and developed from reductionist perspectives and with simple models of causation, have great potential for increasing over-diagnosis and diagnostic and therapeutic cascades, without this being a hindrance to molecular characterisation preventing unnecessary treatments in some tumours, such as in some types of breast cancer.

These limitations do not detract from the value of precision medicine in those cases of high-penetration variants which have proven to be extraordinarily useful in the diagnosis and stratification of some diseases (for example, BRCA variants in breast cancer) or advances in the treatment of certain actionable conditions (for example, translocation of the BCR-ABL gene, which indicates that most patients with chronic myelogenous leukemia are sensitive to Imatinib treatment, or mutation of the G551D gene in a limited percentage of patients with cystic fibrosis, in whom Ivacaftor has been shown to improve lung function).

There is no doubt that precision medicine has a lot to contribute to many patient groups, even stretching beyond its current niche in relatively rare cancer subgroups and rare diseases. But from the perspective of health policy and management, it is important to remain realistic: current evidence does not allow us to generalise the discourse of a precision medicine that will solve all our health problems, and our genes will eventually reveal our destiny and the solutions to make it live up to our dreams. The majority of the paradigms of precision medicine (Joyner et al., 2019), especially in aspects related to population health, cannot even be sustained without greatly lowering expectations.

The health policy, and without resigning to a vision of radical change in healthcare linked to genomic developments, has no reason to indulge in non-evidence-based enthusiasm. Nor can it be forgotten that precision medicine will not solve the substantial health problems associated with hypertension; obesity; a sedentary lifestyle; smoking; violence; the lack of drinking water, sanitation and food in the poorest countries; air pollution, the risks related with climate change and many other health problems that are really responsible for reducing people's lifespan and quality of life, and that, using genomic terminology, are currently "actionable" through health and non-health policies.

Conclusions

PPM is already beneficial to lots of patients and its possibilities for providing benefits for many more in the not too distant future are enormous. None of these possibilities involves the individualised approach to collective health problems, distracting the health policy and management (and precarious research funds) from their most important objectives or maintaining prices that are only justified by what would be considered abuse of a dominant position in any other sector. This is no reason to abandon the paths already taken which, in many cases, are improving results in tumours, rare diseases and in some groups of patients with chronic diseases. Quite the opposite. It is simply a matter of not neglecting the current priorities of collective health policies due to technological frenzy, not contrasting all of our hopes for a medicine with more solutions in the future with solutions that we already have, and looking for pricing systems that, as well as guaranteeing the social value of the medicine, combine the stimulus for innovation with the sustainability of the health systems. ■

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PROPHYLAXIS OF THE "CONFISCATION" OF THE NATIONAL HEALTHCARE SYSTEM

Vicente Ortún
Pompeu Fabra University

Lluís Bohigas Santasusagna
President of the Health Circle and president of the Health Commission of the Catalan Association of Economists.

We have a good health system, but with an increasingly negative prognosis. Here we will discuss, in simple terms, how to prevent the human conquest -the welfare state- from crumbling, outlining some of the actions that need to be carried out to avoid drifting towards a 21ST century version of the "confiscation": the sale of public health (and university) services.

Towards another confiscation?

Confiscation was a long historical and economic process that was initiated in Spain at the end of the 18TH century by Godoy (1798) and closed well into the 20TH century. It consisted of putting the lands and assets that had depreciated (that is, they could not be bought or sold) on the market, in the form of public auction. These lands were in the hands of the aristocracy, the Catholic Church or the religious orders, the municipalities and the state.

The sale of public health and university services can be avoided if we are aware that:

I. Our environment is abnormally fossilised.

II. The healthcare industry will no longer be "Amazon-proof".

III. No matter how much innovation and change are embraced, the public sector can come across a fast changing reality late and unprepared.

IV. Public funding of health services is a sine qua non of efficiency.

V. There is no choice but to "manage its use": first, plan what is offered and seek to attend to those areas requiring it, by fighting against both its overuse and underutilisation, (Ortún and Varela, 2017), and secondly, effectively implementing the principle of sustainability in publicly funded health services: defining an adequately prioritised portfolio of services based on democratic values and an assessment of its cost-effectiveness, including a calculation of its budgetary impact.

VI. The limitations of public management can be overcome through competition by comparison in quality and mitigation of bad governance.

I. A fossilised environment

Manel del Castillo, Manager at the Hospital de Sant Joan de Déu in Barcelona, recently outlined in Madrid, the current situation using three traits, the last of which referred to: a) Money: low income and uncontrolled expenditure (low income not adjusted to European residents, (pseudo) health tourism etc.); b) professional crisis due to low wages and inflexible offer available; poor adaptability to new emerging functions, and c) fossi-

lised management model and an exorcism of privatisation for any way out of this model. Political, trade union and professional barriers in place at any attempt to introduce responsible managerial discretion. The position of medical leaders could influence this if they felt threatened by a possible drift from our current welfare state to a welfare state for the poor —a poor welfare state—.

Table 1 illustrates several alternatives between the purely public organisation and the purely private organisation that can be adapted to the characteristics of healthcare, taking into account both its market failures and its failures concerning the role of the state. In the developed world, non-profit private organisations prevail within the healthcare sector and in Spain, purely public ones.

Table 1. Typology of organisational structures

Private appropriation of residual income	Ownership of decision rights		
	Private	Mixed	Public
Yes	Purely private (capitalist)	Regulated private	X
Partially	Non-profit commercial	Profit-making commercial with public participation	Public
No	Purely non-profit	Private trust with public funding	Purely public

Source: author's own

In Spanish healthcare, the direct management of services coexists —with a very slight incorporation of new forms of management, such as consortia, trusts or public companies— with indirect management particularly via concessions and, very much on a secondary level, construction work concessions and administrative concessions, innovative public procurement mechanisms and risk-sharing contracts. In general, it can be said that the bull has not been taken by the horns in terms of public administration reform with inadequate public right to the provision of healthcare services, when it is well-known that greater autonomy of management and a legal status of its own favour efficiency (Pérez-Romero, Ortega-Díaz, Ocaña-Riola and Martín-Martín, 2019). As José-Ramón Repullo stated, the framework statute of the National Health System —Law 55/2002— defines almost all relevant aspects of labour policy: access to employment, remuneration, negotiation of working conditions, representation, etc. This rigidity is ill-suited to the mission and needs of modern healthcare services, and paradoxically leads to a high level of unstable employment, widespread abuse of temporary contracts, and the absence of the necessary longitudinality, essential in primary healthcare.

II. Amazon-proof?

A sector such as healthcare has traditionally been protected from competition in all countries throughout the world (Rodríguez, 2019). It is therefore, an "Amazon-proof" sector, which has not prevented much innovation in the product, but some in the procedure, and a little in the organisation, although we can certainly highlight Kaiser, Geisinger, Mayo and Veterans in the United States, Aravind and Narayana Hrudayalaya in India and several organisational innovations in Spain. In terms of clinical aspects in Spain, these include infarction and stroke codes, teledermatology, *fast-track* colorectal surgery, demand management nursing, concentration of highly specialised digestive oncological surgery with half the mortality rate, etc. In Catalonia, certain association-based entities stand out for their organisational structure, while the anti-smoking law and road safety policies have been effective health measures (Garcia-Altés and Ortún, 2018).

The degree of competence is an exogenous factor that affects the quality of management. In fact, Amazon failed in its first entry into the healthcare market, as did Google and Microsoft, and its second attempt —managing the healthcare of 1,200,000 workers, the same as those in Berkshire and JP Morgan in the US— it's still very recent. It should be stressed that most disruptive companies enter a market with a product whose value is lower than that of traditional market operators, and whose cost is much lower still. This is the model for classic disruptors, such as Southwest Airlines, MP3, and Japanese car manufacturers.

Healthcare tends to be different, because consumers generally do not want to settle for a lower quality product, even if it is substantially cheaper. However, the best omen for the joint health initiative by Amazon, Berkshire and JP Morgan —a non-profit called Haven— comes under the name of Atul Gawande who became CEO in the summer of 2019. Atul Gawande (2009), surgeon and writer —who we mention exclusively in the article that Obama was so enthusiastic about— is, together with the *Gestión Clínica y Sanitaria*[1] (a journal of

1 http://iiss.es/gcs/index.htm.

secondary publications), the finest example of healthcare management aimed at improving the well-being of people with the resources available.

III. A hack of Darwin, lack of well-being on a sick planet and rising inequality that threatens democracy and development.

Long before we realise it, the genetic revolution will transform the world. Genetic technologies are designed to change the way we make babies, the nature of the babies we make, and ultimately our evolutionary trajectory as a species[2]. A moratorium has been proposed on the use of CRISPR genetic editing techniques (short, grouped and regularly interspersed palindromic repetitions), but everything will remain in a mere record for the World Health Organisation. And while we have no intention of contribute to the science fiction subgenre of "The Earth Dies," alongside prominent contenders like H.G. Wells and his *Time Machine*, we can't rule out that the Morlocks designed the Elois to suit them in an uninhabitable world[3]. In small groups, humans have been able to overcome historical situations where everyone was saved or no one was saved (hence the presence of "altruistic punishment"). With 7.8 billion of us, and continually increasing, cooperation with strangers has become as complicated as it is necessary.

Currently in healthcare, GFR, ALK, ROS/RET, BRAF, KRAS... are all biomarkers in lung cancer that enable "tailor-made" treatments; others are indicated in breast cancer or in liquid biopsies to detect blood cancer mutations, but second-generation mass sequencing clearly outweighs marker-to-marker. Both second-generation mass sequencing and artificial intelligence or precision medicine (new in that it bases the individualisation of treatments on genomics) require more specialisation, economies of scale, matrix organisation, networking, and most likely, alliances with American or Chinese technology leaders. Inertia can easily lead us to get there late and unprepared.

Furthermore, in this third section of changes, we are facing two major problems of collective action of unquestionable impact on human well-being: global warming and growing (since 1980) inequality. Both share the tragedy of being common property. Both require international cooperation. Global warming calls for action by all countries to change their paths of investment and growth, regardless of whether they are more or less rich, more or less powerful, more or less responsible. Isolated actions to reduce CO_2 emissions translate into collective action problems that are difficult to implement. Coming to an agreement on how to contain global warming may require changing our social welfare agendas and agreeing on a rate and type of growth; it could even mean considering the convergence date between the "north" and the "south," more specifically between the United States and China. Difficult. It is no coincidence that, the term that defined the year in 2018 in the *Financial Times* was the *Thucydides Trap*[4], by the historian who explains the rising power in Athens and the fear this inspired in Sparta as it saw its hegemonic position replaced and declared the Peloponnesian wars, that in 30 years would lead to the destruction of both states.

IV. Public funding

Some 87% of Spanish citizens believe that the state is responsible for providing healthcare coverage to the entire population, although they show little willingness to pay more to fund it; this figure is 70% on average for the other four countries —Germany, France, Italy and the United Kingdom— studied in the BBVA Foundation's Values Survey 2019[5].

In order for access to health services to depend on clinical and health needs, virtually all developed countries in the world choose to provide public funding in the form of a type of compulsory universal insurance, contributing according to capacity given the unfeasibility of the *Coase* solution —voluntary group insurance— given the concentration of spending on disadvantaged groups. As well as seeing to show equity, it is also justified in terms of efficiency, since to obtain the maximum quantity and quality of life with the resources available, extravagances need to be set aside in order to focus on what is clinically effective. Personal whims can always be satisfied according to the ability and willingness to pay for them individually.

The health of the population is both an instrument and an indicator of development. Its public funding will be success-

2 https://jamiemetzl.com/books/.
3 https://www.economist.com/open-future/2019/03/29/can-liberal-democracy-survive-climate-change.
4 https://www.ft.com/content/0e4ddcf4-fc78-11e8-aebf-99e208d3e521.
5 https://www.fbbva.es/wp-content/uploads/2019/09/Presentacion_Estudio_Valores_2019.pdf.

ful to the extent that action is taken on social determinants from a public health perspective and avoiding the rigidities that industrial, corporate and professional interest groups introduce. On the other hand, in Spain, greater public funding should not involve a revision of interest rates but an elimination of tax benefits (personal income tax and VAT), action on excise duties, particularly by introducing them on sugary drinks, and greater use of public prices. In addition, social harmony and on-track individualism advise -as recommended by the *World Inequality Report 2018*- tax progression, a global record that states the ownership of financial assets (antidote to money laundering, tax evasion and growing inequality), and better access to education (and well-paid jobs).

V. Usage and rationality management in establishing the portfolio of services

The human conquest —the *welfare state*— including its crown jewel —its healthcare— could be consolidated in Spain with just a few tweaks. On one hand, by making it more similar to the Nordic and central European welfare states, and on the other, by adopting measures called for by our reality and countless opinions. These include:

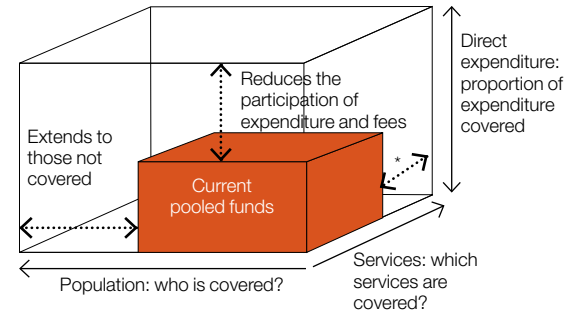
- Restoring planning (the ability to authorise openings, modifications or closings of healthcare facilities), which, when scaling the human and physical resources available, conditions future usage to a very high degree. In other words, a thorough analysis of use management is necessary.

- Fulfilling the sustainability factor that regulates the make up of the health services portfolio according to cost-effectiveness and budgetary impact, as European countries with most purchasing power do (and with a more consolidated welfare state). In fact, a portfolio that meets both scientific criteria of cost-effectiveness and social preferences is the real sustainability factor in the health component of the welfare state[6]. In the three dimensions of health coverage illustrated in Graph 1, Spain has almost universal coverage, low co-payments in a European context, and a portfolio of services that deserves to be prioritised.

- Clinical practice adapts to the supply in terms of available means and established portfolio of services, as has repeatedly been proven in the famous *History of two cities*: Boston and New Haven. Clinical practice, on the other hand, as the main allocator of health resources — in diagnostic and therapeutic decisions — contains the key to making a publicly funded health system desirable for voting citizens. This implies that it is solvent and has treatment capacity, which given its limited resources implies, firstly, eliminating unnecessary use, overuse and under-utilisation — a third of US healthcare spending, and secondly, closing the gap between efficacy (what could ideally be achieved) and effectiveness (what is really being achieved).

- Making the continuous improvement in the practice individually attractive for clinics. This entails fostering organisations with autonomous management, which should receive part of their budgets based on results —adjusted where necessary— in a scenario of competitiveness by comparisons in quality, and to do this, a better policy is needed that enables better public management.

Graph 1. The three dimensions of healthcare coverage



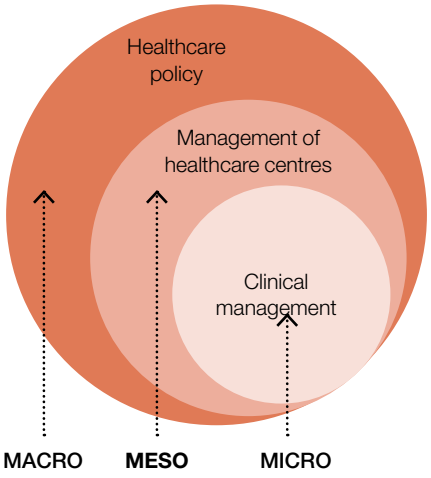
* Includes other services

VI. Mitigation of bad governance and competitiveness through comparison in quality

Management in the healthcare sector has three different areas: that of state intervention (regulating, financing, informing and even producing) which translates into health policy, that of health centre management and that of clinical management (Figure 2).

6 https://nadaesgratis.es/sergi-jimenez/la-evaluacion-economica-de-medicamentos-como-factor-de-sostenibilidad-de-la-sanidad-publica.

Graph 2. The three spheres of healthcare management



Source: Ortún, V. "Presentation of the 5th Congress of the Spanish Society for Public Health and Healthcare Administration." *Gaceta Sanitaria* 1993; 7(38S): 1-2.

The quality of hospitals improves when they compete through comparison in quality. The aforementioned management quality assessment survey, validated in other sectors of the economy and in other countries, was applied to two-thirds of acute care hospitals in England. A total of 18 practices were grouped into four dimensions: a) *lean* operations, such as admission, protocolisation, inter-consultations, discharge and follow-up, etc.; b) gauging action based on the use of technology, error prevention, continuous improvement, etc.; c) goal setting, and d) incentives: attracting and retaining talent, expelling non-compliance, etc. It turned out that best management practices were associated with better outcomes, including lower mortality after acute myocardial infarction, better financial results, higher staff satisfaction, and higher scores by the quality monitoring agency. Incorporating an instrumental variable of a political nature makes it possible to establish causality and its meaning:more competition between hospitals leads to better quality management. While there may be other ways to improve quality, such as encouraging informed choice by users, the study's findings support the policies of countries such as the Netherlands, Germany, UK or Norway, which aim to promote competition through comparison.

We know that the guarantee of immortality in organisations and individuals is a sure recipe for stagnation and a sticking point. Innovation is born, in part, from necessity. Rights must be guaranteed, with the appropriate social security networks, but privileges are not.

It is not a question of competing on price (sacrificing qualities that the user does not perceive) or doing error-proof experiments, in the interest of the political promoter, but of gradually introducing the idea that resources received by healthcare organisations will depend, minimally at the outset, on the quality it offers in relation to its equivalents. The greater integration —even if it is virtual— needed to care for poly-pathological patients who are greatly limited in daily activities will reduce the number of healthcare providers, and the resulting greater concentration will sometimes force them to look for comparators farther away.

The key influencing factors in the improvement of clinical and financial results and staff satisfaction, as well as competition through comparison in quality, are related to the clinical and management size and skills. The relationship between size (volume of surgery, procedures, etc.) and quality is well established. This is the clinical expression of economies of scale and reflects the obvious point that expertise in a trade is acquired through practice, although it cannot yet be ruled out that selective referral also plays a role. Clinical and managerial skills (better communication, more credibility and authority) —in that order— explain better performance in healthcare organisations.

Bad governance will not combat global warming or inequality, nor will it sustain the welfare state. The population needs to believe in the impartiality of public administrations in order for the welfare state to become consolidated. In Spain, especially from 2011 onwards, there was a growing awareness of institutional deterioration and abundant proposals to improve the quality of government, all of which are now on the back shelf of memories, possibly due to the monothematic desire to resolve *whatever it takes*, where Catalonia fits in the puzzle.

Corrupt capitalism, friends and influences, ruins this confidence in the impartiality of public administrations. All countries face a huge but very familiar challenge: how to balance capitalism, the government of a few, with democracy, the government of many? How will democratic capitalism work? We should pay attention to the institutional trend referred to in Novoa, Gérvas and Ponte (2014): poor regulation, or growing individualism. The rise of populist plutocracies in the world rai-

ses the question of determining which is stronger: a certain desire for social harmony or the polarisation of income in an environment of growing individualism. Evidence of the negative effects of inequality on future growth or global warming on world health does not necessarily need to affect the direction societies take.

Democracy alone is not enough to build good government. According to Charron et al. (2015), the three factors that seem to weigh greatest in understanding differences in the quality of governance between countries are: 1) professional public management with a strict separation between politicians and civil servants. 2) decentralisation and autonomy in human resource management, and 3) transparency, which is understood as access to public information (without publicity or concealing poor results), and freedom of the press.

Interestingly, paradoxically, almost the greatest difficulty, according to Ricard Meneu (2019), does not lie in the articulation of political responses, but in undertaking the seemingly colossal task of convincing citizens of the need to demand what is essential for the benefit of all[7]. ■

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