

## 'Prioritising Health Services or Muddling Through'

Solvency and the endurance of public health systems in developed countries is not guaranteed in its current incarnation.

Aging, chronic diseases with epidemics (e.g. obesity, mental illness, all types of addictions), chronic unemployment, a reduction in the percentage of the active population due to the introduction of labour-substitute technologies, dizzying biomedical innovation, wrong public expectations regarding the capacity of the system – and a long etcetera – cause an excess of demand, unapproachable for the supply of services, and costs that are difficult to assume with current and possibly future economic growth. In this context, the establishment of priorities becomes an imperative for those responsible for health policy and management.

In this book we pursue some answers for the following questions: What procedures are used to determine whether new technologies should be publicly funded? What is the role of each stakeholder in the prioritisation process? What type of evidence is necessary to decide priorities? When setting priorities, are trade-offs between the different objectives, plans and values of the system taken into account? Does debate and transparency exist in the process? What can be learned from worthwhile international experiences? How does the architecture of our system influence the prioritisation of the publicly funded basic benefits package? And finally, how does health technology assessment help in all of this?



*Prioritising Health Services or Muddling Through*

Juan E del Llano-Señarís and Salvador Peiró Moreno (Dir.)

Juan E del Llano-Señarís  
and Salvador Peiró Moreno (Dir.)

# Prioritising Health Services or Muddling Through



Series *Economía de la salud y gestión sanitaria*  
Edited by *Vicente Ortún, CRES-UPF*



**Springer Healthcare Ibérica S.L.**

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Depósito Legal: M-31432-2017

ISBN: 978-84-940118-9-4

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This book was supported by an unrestricted educational grant from Celgene.

Depósito Legal: M-31432-2017

ISBN: 978-84-940118-9-4

ASE7SB9893

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# Foreword

Jordi M. Gol-Freixa

To set priorities is part of life. It is also a core element of medical practice since time immemorial – and arguably, even ‘the core element’ of medicine. At the bedside, which, by the way, may be a reasonable place to start this comment, the physician has to sort out what to consider from the patient during the clinical encounter; namely signs, symptoms, context and personal history, one item at a time, and importantly, in what order. This was the essence of the *clinical assessment* and therefore of the ‘*clinical judgement*’.

‘Priority setting’ as a distinct issue in medicine or healthcare was not raised as such until late 20th century. Notionally, maybe when the “Problem Oriented Medical Record” was introduced, circa early 1970s clinicians had to work themselves up, and by that time began the first attempts to conceptualise medical decision making as such. At first glance we can see that *prioritisation* at this clinical level already implies the existence of options, explicit and known ones, an element of discernment and of judgement, and an element of assessing preferences, or choice in short. Some of those may be time-sensitive, their sequencing may be also sensitive, sometimes critical. In other words, the complete gamut of decision making. Also, it is the origin of practice guidelines.

At some point of history, the issue of priority setting became something beyond the mere competent practice of medicine at the individual level and entered the realms of societal discussion, of early academic scrutiny and of health policy analysis. Arguably, by the early 1960s [1], a paper on market failures in health insurance from 1964 [2] may be considered still relevant today [1].

As the diagnostic means of increasing complexity became available and the means of increasing usefulness evolved, therapeutics – both pharmacological and surgical – also developed. To make choices at the point of care thus became more difficult precisely because of the gamut of options available. At some point it became a social issue, which was broadly when the demand for medical care was unbalanced with the availability of means. To handle demand became an issue: resources appeared limited, and the bad word was rationing. Was medicine challenged from its success? In a way, yes.

We can jump from the individual clinical encounter to a system-wide, or even,

nation-wide focus. What are the goods healthcare should deliver at large? How does it? Let's introduce the rule-of-thumb: the four 'Ds': reduction of death, disease, disability and distress. The understanding of the parameters and the development of its metrics is a story on its own, and not a trivial one at that. Without these, the first explicit exercises, such as Oregon's (1990 reorganisation of state Medicaid) would not have been thinkable. Seen retrospectively, the donabedian distinction of 1966 vintage between 'structure', 'process' and 'outcome' may appear as not a particularly big deal [3]. However, it did set the proper framework; hence the focus on outcomes was something worth making explicit and measurable. In other words, the question of effectiveness. Now, we already have something.

It can be argued – and indeed this will be the case in all chapters of this book – that by 2017 there is a solid body of knowledge available to handle priority setting at all levels of health policy, ranging from the basic clinical encounter to 'Global Health' in capital letters. This body of knowledge is more than adequate to enable a comprehensive rational approach, again at all levels. Is this the case? Well, *'yes and no'*. This is a balanced assessment, an honest one – even a politically savvy expression. In the affirmative, there are a myriad of initiatives, well thought-out ones, going on. Some areas are at the highest level, robust, explicit and comprehensive, like the recent White Paper that was considered by the Norwegian Parliament [4]. Many other initiatives are close to the bedside or the quite 'micro' level, such as the triage processes to sort out patients queuing at emergency rooms. Current knowledge on the comparative effectiveness of most interventions is reasonably known and is on the research agenda. However, more importantly, there are accepted criteria and systems to generate this knowledge and to make it readily available. The evidence-based medicine *movement* has had a substantial contribution here. Many examples can be found in all chapters. Importantly, there is substantial consistency on a surprisingly vast amount of issues and criteria (or principles, if you wish). But the dissatisfaction concerning the status quo is quite real. There is a gap between the body of knowledge and daily reality. This concern is shared by all the authors as you will see.

Nevertheless, the notion of priority setting has something intrinsically elusive. In a way it is a moving target of sorts. Each progress, conceptual, methodological, organisational, is a significant step forward, and there have been many. For instance, patient–clinician joint decision making has been developed and usable tools are available. Or the nature of the variations of clinical practice can be measured, understood and addressed. However, the feeling that something is missing stays – independent of the difficulties of and resistance to implementation, which are normally significant.

Then, there is the possibility of a rational approach – a thorough and systematic one. Currently, to foster a decent **stewardship of resources** could be regarded as part of the societal consensus. Nobody will disagree. This is a basic element of good governance (GG), but the fact is that GG is inadequate in most health systems, and is usually the conclusion of most analysts. Furthermore, discussions on GG in health are usually intermeshed with partisan politics, and there is the underlying presence of philosophical and ideological elements, which are considered legitimate by society at large. Good health is both a private good and a semi-private good for the citizen at the same time. Simplifying and excluding population and public health considerations, we can say: 'your good health is mainly your issue, but also affects my interests somehow'.

There is no clear line here, and the debate is, again, politically legitimate, while demarcation has a substantial impact. Issues like personal autonomy, or dependence, can be quite

philosophical and at the same time have practical implications, thus they become more than controversial. There is an emotional dimension that limits rational modelling. Let's mention the 2017 Economics Nobel Prize awarded to Richard Thaler as the relative new field of 'behavioural economics' comes of age, and recall the controversies surrounding the field because they are relevant here. The rational models have been shown to be insufficient, and this is indeed the case with health as well.

An old and often forgotten subject on bioethics is the tension between 'rescue' and 'viability'. In short, apparently humans are hard-wired to come to the rescue of fellows in peril; that is, when there is a case, 'a call for mobilisation' seems to be in order. Consideration of resource consumption becomes secondary or even distracting. This is known by neuroscientists, and by the mass media. The public wants immediate rescue and wants to see it. The viability here is to consider mainly the potential benefits of intervention – the ability to make a difference. It is, at best, a challenge to articulate both approaches – viability and rescue – properly. On a different octave – or clef – is the issue of cost/quality-adjusted life year considerations, or the use of simple, gross cost-consequence analysis for basic priority setting. Crudely, there is a stratification of diseases on costs levels, and economic analysis works within a level but not across all levels, which is considered in several chapters.

The current challenge is again to make ends meet; in other (and coarse) words: rationing. Yes, there is a known possibility to 'invest to save'; there is waste to be reduced, compliance to be improved and iatrogenia to be avoided. However, as Relman said – as early as 1988 – the challenge is rationalisation [5]. Now we have tools and a volume of information that was unthinkable at that time; furthermore, the standard 'evidence-based' is considered the bottom-line. The pressure for rationing is indeed linked to society's situation of economic prosperity and therefore this pressure is cyclic; however, it can be said that it has come to stay forever. The same Relman warned that a 'medical-industrial complex' was in development [6]. Labelling could be debatable, but the supply of increasingly expensive high tech is here, and sustainability is already an issue – arguably for all health systems.

Considerations on the politics and philosophy of equity are relevant, and are made, but their full consideration may be out of the scope of this monograph; equity as value on health is apparently a societal consensus in most western countries, but not all.

There is an external dimension to priority setting, and politics is part of it, as are other vested interests. In any changes – and rationing obviously is one – there are winners and losers, and the latter tend to resist and obstruct. The case for the rational approach may be felt as not completely satisfactory, and even as a cold shower of sorts, but it has the virtue of a wake-up call. This book attempts to be an honest collection of essays critically examining its elements and mapping the issues on rationality and its limitations. Therefore, it occasionally has a tone of urgency and of some gravitas, and makes the case in an almost compelling manner. I hope you will enjoy reading it as much as I did.

## BIBLIOGRAPHY

1. Norheim OF. The elusive challenge of priority setting in health and health care. *Global Challenges*. 2018;1:28-9.
2. Arrow KJ. Uncertainty and the welfare economics of medical care. *Am Econ Rev*. 1963;53:941-68.

3. Donabedian A. Evaluating the quality of medical care. *Milbank Mem Fund Q.* 1966;44(3): Suppl:166-206.
4. Norwegian Ministry of Health and Care Services. Principles for priority setting in health care. Oslo: Norwegian Ministry of Health and Care Services, 2017. Available from: <https://www.regjeringen.no/contentassets/439a420e01914a18b21f351143ccc6af/en-gb/pdfs/stm201520160034000eng-pdfs.pdf>
5. Relman SR. Assessment and accountability. The third revolution in medical care. *N Engl J Med.* 1988;319:1220-2.
6. Relman AS. The new medical-industrial complex. *N Engl J Med.* 1980;303:963-70.



## CHAPTER 1

# Deciding on Public Programs: Prioritisation and Governance - An Inseparable Whole

M Callejón, C Campillo-Artero, V Ortún

### Summary

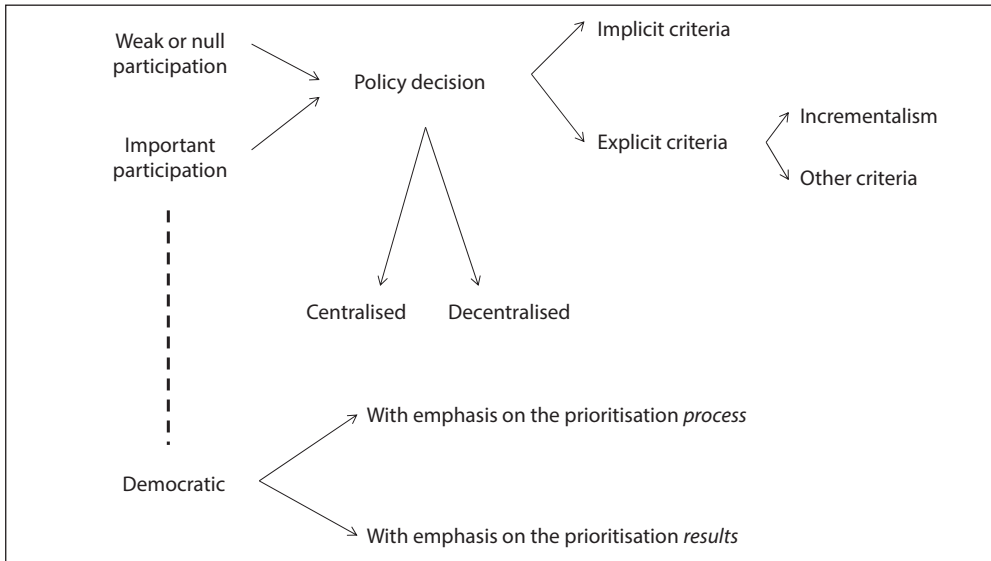
The prioritisation of tasks and programmes occurs in any field, public or private, collective or individual, and is always done, better or worse, explicitly or implicitly. The prioritisation of interventions by the State is justified both to correct market failures and to favour a certain redistribution (the tandem efficiency–equity of public policy). This can be addressed within the context of the limitations of public action and from the Political Economy–Public Choice theory’s perspective. Regardless of whether recommendations for prioritisation are evidence-based or not, we should not be so naive as to believe that the best ‘Economy’ will necessarily translate into the best ‘Policy’; for this to happen governance should prevail, and this holds true for all social realms.

### Who Shall Live? Health Services: Only a Part of the Whole

The prioritisation of tasks and programmes occurs in any field, public or private, collective or individual, and is always done, better or worse, explicitly or implicitly.

Certainly, it has been in the health field where the criteria of prioritisation have been discussed the most. For this reason, it is a very appropriate sector to take the analysis beyond the criterion of efficiency, and to determine what other elements influence the decisions.

The classic work by Victor Fuchs *Who Shall Live?* was organized in three parts: (i) health or other objectives; (ii) health services or other forms of getting health; and (iii) which combination of health services? Too often, attention is only paid to this last part. It is assumed that the answers are exclusively technical in nature. Thus, when we study the effects of the crisis on health in Spain, which is non-existent in the short-term [1], we try to associate them with cuts in public expenditure on health services when other factors are involved, such as unemployment or the loss of social mobility – the main culprits for what happens in the medium and long term [2].



**Figure 1.** Public Services Prioritisation. A typology.

Something similar occurs when the evaluation of oncological treatments at the end of life is refined: despite the fact that their cost-effectiveness ratios are very unfavourable, they are experiencing an exponential expansion, and another end-of-life crucial intervention – palliative care – is being relegated. Palliative care knows a much slower diffusion than drug treatments despite their clear contribution to the quality of death. It can be erroneously perceived that palliative care competes with chemotherapy treatments with their strong economic and professional incentives to prevail [3].

In both cases the technical–professional discourse faces results not quite compatible with what was expected.

The prioritisation of interventions by the State is justified by its intervention both to correct market failures and to favour a certain redistribution – the tandem efficiency-equity of public policy (see next section). Following that, the basic aspects of this logic will be recalled in the context of the limitations of public action analysed by Public Choice theory. Regardless of whether recommendations for prioritisation are based on evidence or not, one cannot maintain the naivety of believing that the best ‘Economy’ will necessarily translate into the best ‘Policy’, a topic which is addressed in the section on Governance Quality, where the quality of the institutions of particular countries is taken into consideration. The last heading concludes.

## Limited Resources, Unlimited Needs, Efficiency in Resource Allocation, Market Failures

Government intervention in economic and social affairs aims to achieve the maximum possible welfare for citizens. The analysis of policy making includes two complementary approaches: (i) the analysis of efficiency or welfare maximization in resource allocation

– the normative approach; and (ii) the analysis of Political Economy or its close approach Public Choice [4] – the positive approach.

The basic issue is that society has limited resources to meet needs and demands that are practically unlimited. The efficiency conditions in the allocation of resources between alternative uses – or partial equilibrium – has been developed by the branch of Welfare Economics in the context of market systems. According to the normative approach, first, a perfect market with free competition should allocate resources efficiently; and second, in instances where the result derived from free competition is not efficient (i.e. is not socially optimal) the market failures model is applied. There are several types of market failure and the main categories for which elaborated analytic models exist are: public goods, externalities, lack of competition, and incomplete and asymmetric information among agents. When any of those circumstances are present in a given activity, market interaction alone will not reach the optimum allocation of resources. Inequalities between individuals and groups are also considered market failures that must be corrected in order to achieve better levels of efficiency according to the welfare maximization model.

To correct market failures, policymakers can use a set of instruments under the form of regulations, incentives or fines, or direct control and provision. Since the different productive sectors of goods and services, by their very nature, are affected by different types of market failures, each type of sector or activity (electricity, education, mining, industry, airlines, health) usually develops its own regulatory strategies, procedures, rules, processes, standards, principles, benchmarks, lines of analysis, and enforcement mechanisms. This is also the case for the health care sector [5-6].

At given crucial historical moments, after wars or deep crises, when citizens were traumatized and ready to undergo radical reforms, systemic policy decisions have been made to simultaneously address all or most of the problems of social and economic life. The clearest example of a massive correction of market failures (before the concept was theoretically identified and formalized in economics) took place in the Western European countries following the Second World War. The devastating impact of the conflict on population and institutions gave way to the explicit manifestation of the social demand for collective goods and services that were needed after the conflict. This recognition of the need to organize the provision of collective goods and services resulted in the election of political parties with audacious social–democratic platforms, and in the adoption of the set of policies known as Welfare State. This happened in a highly sensitive social context in which the population was willing to cede part of its income to the state under the form of taxes, so that the government could organize and guarantee the universal provision or broad coverage of collective services, such as health care, education at all levels, retirement pensions, housing, and a social safety net.

The social contract to protect and maintain the Welfare State system has been and still is a valued systemic arrangement, perceived as a social enlightened advance. In most European countries, few political groups dare to be against it, despite recent justified concerns about the willingness of the wealthier segments of society to pay for it.

The first experiment with a welfare scheme happened before the Second World War in the 1880s: Prussia's Chancellor Otto von Bismarck introduced a powerful and innovative welfare programme. The scheme was not intended to address pure social justice issues; it was mostly aimed at improving the productivity of workers and their living standards, and thus prevent the advance of socialism. The programme comprised sickness insurance,

- Welfare state affirms the role of the state in the protection against life risks: A big public insurance company (Social Security) , which also owns, or contracts with, a service provision company/ies (e.g. the British National Health Service).
- It usually includes:
  - Cash benefits: Old age, unemployment, sick leave, maternity pensions...
  - In-kind benefits or welfare services: Healthcare, social care, education...
- But when is protection against risks extensive enough for a state to be called a welfare state?
  - Initially: Only states with universal, free – at the point of use – programs
  - Later: Most civil servants work for the welfare state
  - Nowadays: At least three nearly universal programmes

**Figure 2.** The Spirit of 1945.

accident insurance, disability insurance, and a retirement pension. The acceptance of the programme among the German population was so wide and strong that there was a sharp drop in emigration to America. Workers preferred the indirect wages of the German State insurance, to the higher direct wage, without any insurance, which they would get in the USA. The workers preferred, in short, to have their main personal and family risks covered.

Precisely in the health sector, many of the characteristics that give rise to market failures are observed: it is largely a collective good (a service collectively consumed but with individual impact), it generates important externalities in the population, asymmetries of information are relevant issues, and health is very sensitive to income inequalities.

The widespread existence of market failures, both in the health sector and in other sectors that deal with collective goods or services, has led to the elaboration of a powerful set of theoretical and applied models aimed to generate instruments to identify and measure gaps between actual policies and the expected efficient outcome, and to offer solutions to correct those gaps. We find models that identify the existence of market power and its extent, anticompetitive behaviour in specific sectors, and efficiency evaluation tools, such as distance to frontier in technology; benefit–cost analysis (BCA) used in project evaluation; cost-effectiveness analysis (CEA) widely used in health; inequality measures to determine access to health care by different income groups; and others.

**Table 1.** Main world regulatory agencies aimed at health services market corrections.

Region/ Country	Pharmaceutical Regulatory Authority	Ministry	Medical Device Regulatory Authority
<b>EU Member States</b>			
EU	European Medicines Agency (EMA), European Commission (EC)	DG Health and Food Safety	Notified Bodies, European Commission
Austria	Federal Office for Safety in Health Care (BASG), Austrian Medicines and Medical Devices Agency (AGES MEA)	Federal Ministry of Health	Austrian Medicines and Medical Devices Agency (AGES MEA)

Belgium	Federal Agency for Medicines and Health Products (FAGG)	Federal Public Service Health, Food Chain Safety and Environment	Federal Agency for Medicines and Health Products (FAGG)
Bulgaria	Bulgarian Drug Agency (BDA)	Ministry of Healthcare	Bulgarian Drug Agency (BDA)
Croatia	Agency for Medicinal Products and Medical Devices of Croatia (HALMED)	Republic of Croatia Ministry of Health	Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
Cyprus	Ministry of Health – Pharmaceutical Services	Ministry of Health	Cyprus Medical Devices Competent Authority
Czech Republic	State Institute for Drug Control (SUKL)	Ministry of Health of the Czech Republic	Ministry of Health of the Czech Republic
Denmark	Danish Health and Medicines Authority (SST)	Ministry of Health	Danish Health and Medicines Authority (SST)
Estonia	State Agency of Medicines (SAM) RAVIMIAMET	Ministry of Social Affairs	Ministry of Health – The Health Board
Finland	Finish Medicines Agency (Fimea)	Ministry of Social Affairs and Health	National Supervisory Authority for Welfare and Health
France	French National Agency of Medicine and Health Products Safety (ANSM)	Ministry of Health and Social Affairs	French National Agency of Medicine and Health Products Safety (ANSM)
Germany	Federal Institute for Drugs and Medical Devices (BfArM)	Federal Ministry of Health	Federal Institute for Drugs and Medical Devices (BfArM)
Greece	National Organization for Medicines (EOF)	Ministry of Health and Welfare	National Organization for Medicines (EOF)
Hungary	National Institute of Pharmacy (NIP)	Ministry of Human Resources	Office of Health Authorization and Administrative Procedures
Ireland	The Health Products Regulatory Authority (HRPA)	Department of Health	The Health Products Regulatory Authority (HRPA)
Italy	Italian Medicines Agency (AIFA)	Ministry of Health	Ministry of Health
Latvia	State Agency of Medicines (ZVA)	Ministry of Health	State Agency of Medicines (ZVA)
Lithuania	State Medicines Control Agency (VVKT)	Ministry of Health	State Health Care Accreditation Agency
Luxembourg	Ministry of Health	Ministry of Health	Ministry of Health

Malta	Medicines Authority	Ministry of Energy and Health	Malta Competition and Consumer Affairs Authority
The Netherlands	Medicines Evaluation Board	Ministry of Health, Welfare and Sport	Ministry of Health – CIBG
Poland	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Main Pharmaceutical Inspectorate	Ministry of Health	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Portugal	National Authority of Medicines and Health Products	Ministry of Health	National Authority of Medicines and Health Products
Romania	National Agency for Medicines and Medical Devices	Ministry of Health	National Agency for Medicines and Medical Devices
Slovakia	State Institute for Drug Control (SUKL/SIDC)	Ministry of Health	State Institute for Drug Control (SUKL/SIDC)
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	Ministry of Health	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
Spain	Spanish Agency for Medicines and Medical Devices	Ministry of Health, Social Services and Equality	Spanish Agency for Medicines and Medical Devices
Sweden	Medical Products Agency	Ministry of Health and Social Affairs	Medical Products Agency
UK	Medicines & Healthcare Products Regulatory Agency	Department of Health	Medicines & Healthcare Products Regulatory Agency
<b>America</b>			
Brazil	National Health Surveillance Agency	Ministry of Health	National Health Surveillance Agency
Canada	Health Canada	Minister of Health	Health Canada
USA	Food and Drug Administration	Dept. Health Human Services	Food and Drug Administration
<b>Asia</b>			
China	China Food and Drug Administration	Ministry of Health	China Food and Drug Administration
India	Central Drugs Standard Control Organization	Ministry of Health and Family Welfare	Central Drugs Standard Control Organization

Japan	Pharmaceutical and Medical Device Agency	Ministry of Health, Labour and Welfare	Pharmaceutical and Medical Device Agency
South Korea	Ministry of Food and Drug Safety	Ministry of Health and Welfare	Ministry of Food and Drug Safety
<b>Oceania</b>			
Australia	Therapeutic Goods Administration	Department of Health	Therapeutic Goods Administration
New Zealand	Medicines and Medical Devices Safety Authority	Ministry of Health	Medicines and Medical Devices Safety Authority
<b>Africa</b>			
South Africa	South African Health Products Regulatory Agency	Department of Health	South African Health Products Regulatory Agency

## Political Economy, Government Failures

The refinement, variety, and abundance of the available models, as well as the quality of the many evaluation analyses produced in all the countries – in many instances under the supervision and sponsorship of prestigious international organizations – has not always given place to the implementation by governments (at least with reasonable success) of those recommendations issued from the application of the principles of economic evaluation in efficient priority setting.

In the health policy context, the relevant question would be why ‘is it often difficult to obtain political backing for highly cost-effective interventions such as vaccinations treatment against diarrheal disease in children, and preventive policies such as improved access to clean water, or policies curtailing tobacco consumption?’ [7]. The long-known competitive advantages of curative over preventive interventions are a case in point. Decision makers’ preferences for prioritising prevention are weak, which is most likely because prevention has no identifiable beneficiaries; costs are immediate and benefits mid and long term; the expected returns on investments are low; and because the evidence collated on the effectiveness and cost-effectiveness of health prevention and health promotion interventions is scanty compared with that of medical treatments [8-11].

To understand this lack of correspondence between well-founded normative analysis of efficiency and the current decisions in policy making, it is useful to turn to the Political Economy analytical approach. If market failures are not addressed and corrected in spite of the knowledge of how to do it, one may think that something is probably wrong inside the policy-making process, and this situation can be called a government failure (such as intensity of individual preferences not reflected in a yes/no vote or rent-seeking behaviour because control over politicians and civil servants – a public good – will tend to be carried out through groups of concentrated interests with very intense economic or ideological preferences).

According to the models of Political Economy, agencies and institutions in charge of carrying out public policy do not always adopt the decisions that seek to maximize social welfare. Policy-making instances are not always, or are only in part, the benevolent agents

that try to optimize the social preferences represented in the Social Welfare Function. [12] The Political Economy approach follows the classical economics assumption that all agents – public and private – confront their own set of incentives and, thus, their choices and decisions seek to maximize their own individual preference function. Of course, this is a strong hypothesis, but it is useful for the construction of the stylized simple models that help to capture the deep forces behind some observed phenomena. To soften the self-interest hypothesis and improve relevance, some models maximize a policy maker's preference function, which includes both individual and social variables.

To give a proper context to the abrupt economic assumption of self-interested individuals and organizations, the highly complex political environment has to be considered, namely an environment with multiple stakeholders (consumers, firms and diverse organisations), with many different interest groups, with political parties that need to attract votes to stay in power, and with a growing body of career bureaucrats and high civil service positions whose status is not dependent on electoral votes, but whose prestige and associated perks are dependent on their influence on programme design and management. Policy making operates very often in an intricate network of relationships than makes it very difficult, and it can be very difficult to optimize a set of objectives.

Policy makers, thus, take decisions and operate in a highly-constrained environment, under pressures from interest and stakeholder's groups affected by or willing to influence the government decisions. At the same time, the political parties that need the support of constituency votes, and public bureaucratic agencies that wish to gain power and prestige, interact among them and with other external pressure groups. In some instances, policy makers will unwillingly give up the best solution in favour of a second best if the opposing forces, or any other hurdle, block the optimal alternative.

### **Tobacco's Long March**

Although campaigns against smoking already had been implemented in the 1930s, s. XX, the first solid epidemiological evidence on the link between tobacco and lung cancer could be considered to be the British doctors' cohort study of Doll and Hill, published in 1954. The first public recommendation for quitting tobacco was produced in 1964 in the USA. Since this first Surgeon's General Report on smoking and health, there have been more than 20 million premature deaths attributable to smoking, with millions more living with smoking-related diseases. Tobacco continues to be the leading preventable cause of death in the USA and many countries of the world.

More than half a century later, the battle of rationality with vested interests is far from over. A little over a year ago the European Union (EU) won one of the latest skirmishes with the industry: It successfully opposed the legal offensive of four large tobacco companies and got into effect the directive, which means that 65% of the front and the back of a cigarette and roll-your-own tobacco pack.

Hollywood contributed to the global tobacco epidemic, later aggravated by the tobacco industry, which has been linked to the suppressed evidence of the health risks posed by cigarettes; its role in smuggling its products around the world; the routine bribery of governments and officials not to legislate against tobacco; and the way it identified developing countries as lucrative markets for exploitation.

Millions of deaths later: For decades, tobacco has been the risk factor for which most premature mortality can be attributed (around 12% of all world deaths in adults). Wealthy people in developed countries have the lowest smoking rates, and the middle class has increasingly quit; however, smoking has become a burden of the poor, the less educated and the marginalized. Developing countries are the new markets for the 'deadly business' where threats, bullying and lawsuits are the tools of the tobacco industry's dirty war for the African and Asian markets.



Political economy models differ among them depending on the relevant interest under their focus. From the supply side of public policies, political parties may try to increase support from voters by including in their electoral platforms policies that benefit large groups of people, such as pensioners or women. From the demand side of public policies, the most successful are usually organized pressure groups with enough resources and capacity to ensure the adoption of programmes or schemes that favour their interests as a group.

One basic reason why government policy making may systematically deviate from the socially efficient solution is that in democratic societies political equilibrium tends towards the preferences of the 'medium voter' with the risk of leaving large groups of people less protected than other groups.

## Pressure groups and interest groups

In his well-known work *The Logic of Collective Action* [13], Mancur Olson defined pressure groups as well-organized social minorities with very specific common interests capable of effectively exerting pressure on the government to take public decisions that, eventually, channel resources towards them. The pressure groups achieve their objectives because their interests are specific and well delimited, and their members form a cohesive group. The social costs they may inflict to non-members are usually largely spread between an amorphous mass of uninformed taxpayers who are not willing to incur relevant transaction costs of effectively opposing the programme.

Pressure groups can materialize in *lobbies*. Lobbyists, usually representatives of sectoral private interests, are legally recognized and subject to some type of regulation in the USA and in several EU countries, such as France, the UK and Germany, or the European Commission itself. The regulation of pressure groups is based on the premise that, since they objectively exist, it is preferable to make their activities transparent.

Not without some audacity, Gary Becker [14], a University of Chicago professor and Nobel laureate, argued that, in aggregate terms, lobbying activities promote the adoption of more efficient policies by the government; the reason being that competition between pressure groups for alternative resource-consuming policies has the effect that those programmes with greater net social benefits will go ahead.

According to Becker's thesis, the formation of a significantly powerful group, capable of gaining important benefits, automatically encourages the formation of opposing alliances among other disadvantaged groups. By rational logic, the intensity of the effort undertaken by any pressure groups will be determined by the net benefits expected from the government programme. Members of a lobbying group have incentives to carry out activism to the extent that the benefits they expect to gain from the programme are larger than the cost of its lobbying activities (contributions to political parties, academic and expert reports, meetings and symposiums, advertising campaigns, persuasion to the media).

It is not obvious how general Becker's model is, despite its clear internal logic. In the food industry, for example, in which well-publicized products sometimes have unwanted consequences on people's health, critical groups have lacked the strength to limit or change the composition of production, despite having enough research evidence about consumption undesirability. It is quite clear that there is not always an opposition group with the capacity to neutralize bad politics.

In the regulatory arena, pressure groups are often successfully organized to achieve legislation to protect their benefits. The Nobel laureate and Chicago School economist, George Stigler [15], developed the theory that powerful business monopolies manage to convince governments to enact regulations whose effect is to limit or deter the entry of new competitors in the market, or to protect them from international competitors. The protection of the profits of monopolies comes with the social cost of reducing competition, rising prices and inflicting harm on consumers. Therefore, Stigler's theory is about the demand to governments of legal regulations that benefit a given agent, while consumers, taxpayers and other politically weaker sectors entirely bear the social costs of the regulation. This situation is known as *regulatory capture*, and has been widely implemented and studied. Actually, the process of regulatory capture affects many sectors of economic and social activity, not only monopolies.

### Regulatory Capture

Adam Smith was the first to formulate the main 'virtue' of markets: making social welfare possible by pursuing a particular interest. With property rights protected by an impartial State, the entrepreneur could also have an interest in investing the surplus to expand his business. Later, already in the mid-20<sup>th</sup> century, Hayek emphasized the importance of prices as a readily available signal that facilitates the coordination of many decentralized decisions.

However, a review of history shows how markets offer no protection against fraud, theft or violence. Indonesia was ruled by the Dutch West India Company for 200 years until the Dutch state took control in 1800 to make it a colony for the next 150 years. Similarly, the Indian subcontinent was ruled for nearly a century by the British East India Company until the British crown nationalized India in 1858. A few years earlier, in 1840, the British government – fulfilling the mandate of money – had declared war on China, the first opium war, in the name of 'free trade' as traders did not want to obey China's ban on dealing with drugs.

Under very strict conditions, the market has its virtues: to stimulate efficiency and innovation in addition to compensating the risk; however, it also has its great failures: a tendency towards oligopoly, corruption and cronyism. Only powerful and independent competition watchdogs and anti-trust courts can prevent failures from overcoming virtues. Hence the importance of dealing with regulatory capture phenomenon.

From the end of the First World War to the early 1980s, the West has experienced a period of prosperity with a very significant reduction of inequalities, a possible result of the protagonism shared by an increasingly regulated market and a State which, in many countries, has been operating satisfactorily.

The need to continue to regulate the functioning of markets in the presence of global multinationals is compounded by the need to achieve flexible welfare states (such as those of Germany or Sweden) without losing sight of the growing inequality and the 'new Indies companies': The world's technological leaders.

According to Evgeny Morozov, a distinguished researcher who studies the social and political implications of technology it seems that democratic capitalism – this odd institutional creature that has tried to marry a capitalist economic system (the implicit rule by the few) to a democratic political one (the explicit rule by the many) – has run into yet another legitimization crisis. Technology firms are rapidly becoming the default background condition in which our politics itself is conducted. Once Google and Facebook take over the management of essential services, Margaret Thatcher's famous dictum that 'there is no alternative' would no longer be a mere slogan but an accurate description of reality.

In 1985, the Swedish economist Assar Lindbeck suggested an equilibrium limit for the quantity of programmes that government platform can effectively carry out. Applying the logic of economic decisions, the supply of public policies will grow to the point where the increase of votes, by those that benefit from the programme, is equal to the loss of votes due to the unpopularity of these measures among non-beneficiaries. Nevertheless,

Lindbeck does not predict that equilibrium will be rapidly reached. Given the asymmetry of information between voters and policy makers, and the fact that most voters do not know the details of each public programme, it will probably take some time before voters perceive the tax burden of so many programmes, and the popularity of the government starts to fall.

### Regulatory Capture in the Medical Devices Market

It has long been known that regulation is not strongly associated with the existence of market failures. In light of the theories of regulation (public interest, special interest, bootleggers and Baptists, normative analysis as a positive theory, capture theory, economic theory, and Stiglerian/Peltzman and Becker models, money-for-nothing), we have been witnessing the effects of severe regulation failures, such as the health negatives externalities of the current regulation of medical devices.

According to the regulatory capture theory, politicians and regulators face an information and agency problem. From this view, the definition of public interest is ambiguous, and requires advice and recommendations from experts on how to address the issues. Such advice is formalized under the 'rent-seeking' behaviour, where finally the politician decides on a certain approach that favours one part over another. The maintenance in Europe of a fragmented, privatized and opaque regulation of devices by means of *Notified Bodies* in lieu of a central, independent, and strictly transparent and public regulator could be a case in point.

The fragmented medical device industry is noticeably plagued with externalities. It seems that regulation is being supplied more in response to the industry's demand than for redistributing health and wealth. Severe adverse events and lack of data on the efficacy and safety associated with medical devices have long been spurring demand for regulation, both in the US and the EU. Governments have been urged to promote risk-based, cost-effective regulations, those that pursue the interests of individuals affected, by using public and unbiased estimates of their costs and benefits, maximizing net health gains through legislation, applying clear rules of the game, being transparent and accountable, and breaking up the effects of the influence of interest groups. It is indisputable that medical devices, like drugs, diagnostic tests, surgical innovations and other medical technologies, should require high overall quality of evidence of efficacy and safety before being licensed.

On 5 April 2017, two new regulations on medical devices were adopted in the EU, one of them (Regulation (EU) 2017/745) on medical devices amending directives and regulations adopted in 1993, 2002 and 2009, and the other (Regulation (EU) 2017/746) on in vitro diagnostic medical devices repealing a Directive adopted in 1990 and a Commission Decision adopted in 2010.

Suspensions of regulatory capture in the medical device market are reportedly attributed to, first, the delay in the regulatory overhaul and the adoption of new regulations, and second, the fact that the new rulings will apply 3 years after the entry into force for the Regulation on medical devices (Spring 2020) and 5 years after entry into force (Spring 2022) for the Regulation on in vitro diagnostic medical devices [5,16].

With the proliferation and segmentation of programmes linked to the search of voter's pools, the net benefit derived from public activity for each interest group ends up being very small. In the end, each citizen benefits from a given programme but pays taxes on all of them. The maximum number of programmes a government can undertake is reached when net social benefits are zero. It is something like a zero-sum game. Each citizen gains from a given programme – for example, pensioners with free medicines – but contributes with his taxes to programmes targeted to other groups – for example, costly prophylaxis for risky sexual practices.

Despite the reduced aggregate effectiveness of the multiplication of programmes, some of which are even contradictory, the electoral interests of political parties generate incentives to spend resources inefficiently. At the same time, the whole process gives

way to growing bureaucracy. The diversity of programmes also provides incentives to the emergence of private operators that expect to make profits from the management of programmes. In political economy language, one part of those would be rent-seeking activities. The generation of incentives for private involvement may give rise to new pressure groups and, ultimately, hinder the reversibility of programmes with proven inefficiency.

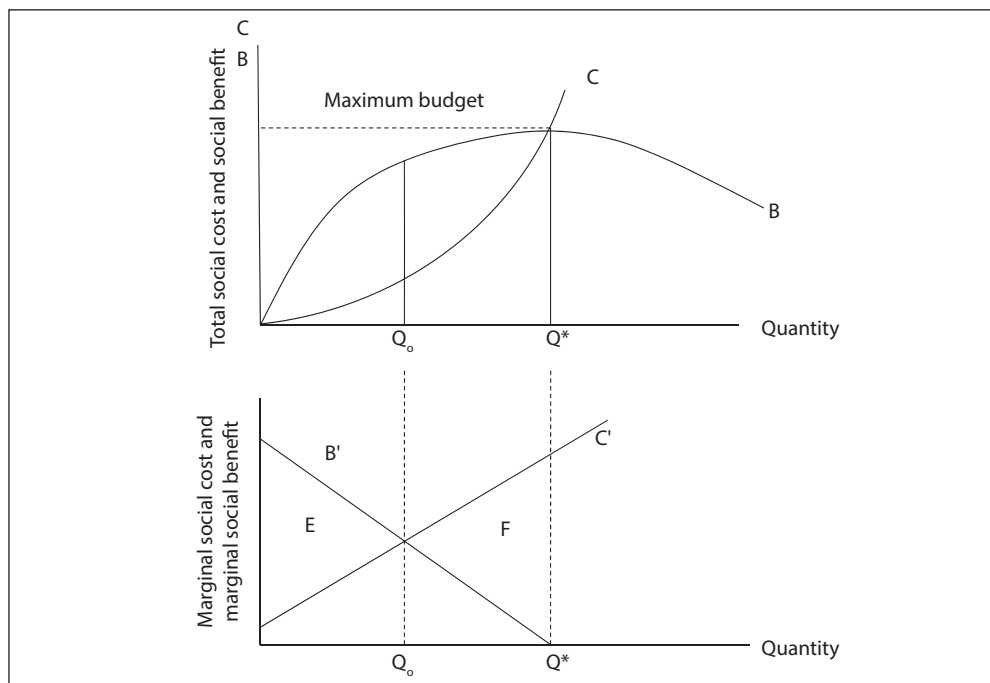
## Bureaucrats' interests

In 1971, William Niskanen [17] produced the best-known and most used model of bureaucratic behaviour in relation to government expenditure. Niskanen was a valued expert in military efficiency, thanks to his command of linear programming. He worked for the Ford Motor Company and, as a professor at Berkeley, founded the Graduate School of Public Policy there. Later he was economic adviser to President Reagan. Thanks to his wide experience in the private sector, academia and government, he succeeded in producing an elegant model of the behaviour of high-ranked civil servants and their influence on public policy programmes and in the growth of public spending. Niskanen's economic model assumes that bureaucrats maximize their own preference function in their activity as public agency managers of policy programmes. One crucial feature of the model is the assumption of the existence of information asymmetry between the senior bureaucrats that manage the programmes, and the government departments that select and decide on the public programmes to be implemented.

Since bureaucrats do not depend on the outcome of elections and do not seek to maximize votes, the preference function they do maximize contains arguments such as prestige, gratuities, rank, salary and promotion possibilities. These variables are linked to the size of the budget of the bureaucrat agency, which measures the relative importance of the programme. Therefore, the objective bureaucrats will be to maximize the budget of their agency. The outcome of this model is that each agency or department will produce more quantity of its service than the efficient quantity.

Because of asymmetric information the government – or its budgetary department – does not know the cost function (the cost at each quantity produced) and only decides about the total budget allocated to the bureaucratic agency. As long as the total budget does not exceed the expected total social benefit, the government will approve the budget required by the bureaucratic agency.

The equilibrium condition of the Niskanen model requires that the total cost of the service produced ( $C$ ) does not exceed the total social benefits of the service ( $B$ ) (Figure 3). That is, the social cost cannot exceed the value of the service to taxpayers to be accepted by the government budget office. For quantities larger than ( $Q^*$ ) the cost of production of the service would exceed its social benefit.  $Q^*$  is the maximum production possible. The socially optimal production would be ( $Q_0$ ), the amount for which the social marginal cost ( $C'$ ) equals the marginal social benefit ( $B'$ ). For quantities larger than  $Q_0$ , each additional unit produced has a higher marginal social cost ( $C'$ ) than its marginal social benefit ( $B'$ ). Another feature of  $Q_0$  is that the social surplus ( $E$ ) – the area depicting total social benefit minus total social cost – is maximum. On the other hand, if the quantity produced is brought to  $Q^*$  – using the maximum budget that the bureaucrat would be able to get – the social surplus disappears because between  $Q_0$  and  $Q^*$  the marginal social cost is higher



**Figure 3.** Niskanen's bureaucratic production model.

than the marginal social benefit for each unit produced. The positive area E equals the negative area F and the social surplus is zero.

The above process would explain the frequently observed fact that many public services have structures that are too large with high budget consumption.

When public policy faces sectors as complex in diversity and size as health, there are also multiple instances in which decisions must be taken systematically and continuously by public employees. Lipsky's [18] concept of *street level bureaucracy* differentiates between the incentives of high-level civil servants and the direct and ongoing tasks and decisions that are implemented by public employees in direct contact with the public, with citizens. These types of decisions are of paramount importance for health services, and of enormous impact for individuals who use the services. The definition of the autonomy and influence in the health policy of those professionals who deal directly with the public is of an importance that is difficult to exaggerate.

## Democracy and efficiency

Hotelling's [19] model of the median voter has major implications for the Political Economy approach, and represents a methodological and consistency challenge for certain formulations of democratic prioritisation. This means that if one programme or political platform defeats the other platforms by rule of a simple majority, politicians will have to adopt that programme if they wish to be elected. There will be a natural tendency

of the party's political platforms – two in the case of bipartisanship – towards the same set of public policies that are those preferred by the median voter. The big implication is that the goal of maximizing votes leads all opponents to the same or similar political platform, not to public programmes that correct market failures and improve efficiency. Political equilibrium will not necessarily maximize social efficiency.

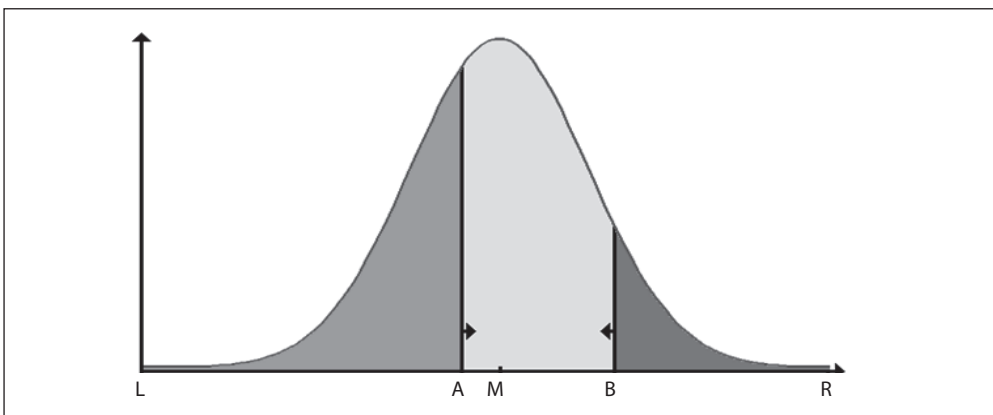
The median voter theory counts as great predecessor Alexis de Tocqueville, with his work *De la Démocratie en Amérique*, published in 1835. In that historical period, the right to vote in the USA was being progressively extended from the rich to the poorer groups. Tocqueville observed that the greater the inequality among voters, the greater the demand for public policy to be redistributive. In a democratic election by majority rule among the citizens with the right to vote, the median voter is the citizen that is positioned in the middle when all individuals are ordered according to their income. With 50% of voters on either side, the median voter determines the winning majority. If the median voter belongs to the group whose income is below the average income of voters, there will be a majority in favour of a redistributive government platform. If the median voter belongs to the group whose income is above the average income of voters, the winning majority will vote against redistributive policy.

Therefore, if ruling or aspiring parties wish to maximize their votes, they will have to adopt proposals that are near the median voter preferences as illustrated in Figure 4.

Voter preferences are plotted on the abscissa in a continuous dimension from left (L) to right (R) according to a normal frequency distribution. In the ordinates axis the frequencies or the number of voters in each political positioning are measured. Most voters opt for positions around the median voter (M), with half the voters positioned to its right and the other half to its left. The most extreme positions at left and right are minoritarian.

If the political programme of the party on the left is in A, and the one on the right is in B, both will have incentives to bring their programmes closer to M, where the bulk of voters are. Even if they lose support at the extremes if they move away from these, they can expect a larger number of new votes than lost votes at the extremes.

The criterion of the median voter can be a general analysis tool at all levels and types of programmes that are voted by majority rule and a one-dimensional issue, such as how much quantity, or how much quality, or the budget size for a given programme.



**Figure 4.** The median voter model.

Because of the implications of the median voter model, there have been discussions about the risk of implementing a dictatorship of the uninformed in particularly complex issues. In fact, there are some examples of democratic procedures, especially referendums or other binary elections that reach very questionable or clearly suboptimal solutions. The inability or even the impossibility of majority rule democracy to ensure consistent results has already been demonstrated by Arrow [20], and it certainly constitutes a limitation for real-life decision making, as we often see when people vote among three or more platforms or alternatives.

## **Political economy of the private provision of public goods**

The healthcare sector has been under strong growth tensions over recent decades, not only because of growing demand due to rising incomes combined with large demand elasticity, but also mainly because of the rapid advances in the use of technologies and sophisticated knowledge it continuously incorporates under the forms of drug treatments, medical instruments and equipment, and improved surgery and healing procedures. Healthcare is the sector with the largest expenditure in research, which is also provided in part by a growing number of physicians and an even faster growing number of administrators, especially in the USA – the health system with the largest share of administrative expenditures in total health expenditures. The health sector uses and develops a considerable number of intensive knowledge activities: robots and physics-based instruments and machines, software, chemical and biology labs, a set of services for hospitals, residential facilities and more. Many of these activities are provided by specialized private operators, which are also business partners that negotiate with the public sector quantities, prices, quality and innovation, and are stakeholders of the public health policy decisions that are taken. There is a tight private–public association in these activities.

With different conditions depending on the extent of the welfare system in each country – small in the USA, big in the EU – important areas of healthcare are exclusively run by private companies and institutions. In sum, the network of connected interests of private organizations, policymakers, high bureaucracy and strong professional associations, make the health sector a privileged area of study for the analytic approach of political economy. This issue still needs to be developed considerably in terms of the political economy approach. It is reasonable to expect that more and better co-analysis simultaneously based on the efficiency approach and the political economy approach may improve both the understanding of facts and the design of programmes.

## **Political economy and the institutional approach: more than self-interest**

Although the political economy approach stresses that policy makers are also rational self-interested agents and their preferences influence their policy decisions, the main objective of public institutions is the maximization of social welfare. Even private institutions may pursue, in part, collective welfare. The branch of Institutional Economics, unlike Political Economy or Public Choice, argues that what is considered rational depends on



the prevalent institutions. The individual rationality of self-interest coexists with social, cooperative and reciprocal rationality. Otherwise it would be difficult to explain why individuals form groups with cooperative rules, and impose punishments to those that free-ride or cheat.

For sensitive issues, such as health programmes and health provision, the use of consensus and participation of all those involved is a possible useful proposition. To avoid uninformed decisions, given the expertise needed in many topics, it would be good to incur adequate levels of investment in expertise, public education, information and teams with the capability to reach democratic, fair and beneficial decisions. ‘This involves rewarding civil service motivations, addressing public value failure and regulating obnoxious markets. Public goods require multilevel governance, policy interdependence and integration with national and global development policies. Divergence can be addressed by well-designed public policies that incentivize public goods. A theory of public goods that effectively balances democratic participation, fair access to essential goods and public benefit offers an important alternative to the conventional paradigm of free-rider individualism and cynical government, thus recovering possibilities for the public value of public things’ [21].

## Governance Quality

The quality of governance between different countries translates into very different capacities for setting priorities that reflect social preferences, not just power and influence. As we have just seen, the popular theory of democracy says that informed citizens choose their leaders at the polls, who govern and represent them. Active citizens will control the actions of their governments and will eliminate the abuses of power. It is a pity that it is not so: political decisions are made by professional politicians influenced much more by those who hold power and influence than by ordinary citizens; however, the quality of government differs greatly among countries, and it is convenient to try to learn from those who do best.

There seems to be sufficient consensus on the central importance of the quality of institutions in the explanation of – as the seminal Acemoglu and Robinson title their book – ‘Why Nations Fail’. Data such as the World Bank’s Worldwide Governance Indicators help quantify various dimensions of good governance.

It is necessary that the population believes in the impartiality of the administrations so that the welfare state is consolidated. The corrupt capitalism of buddies and influences ruins that confidence. All countries face a huge but well-known challenge: how to reconcile capitalism – the government of a few, with democracy – the government of many. How will democratic capitalism work?

Good institutional quality even helps society in the markets–government failures issue, since market and politics not only fail, they also interact: politics can be used to get more of markets, and markets can be used to get more of politics. Further, market failures do not always require government intervention: Under some conditions – provided that transaction costs aren’t too high – negotiation among the parts can solve the market failure, as shown in the examples of contracting bees for pollination and the private building and operation of lighthouses.



### Government Failures and Economic Growth

Nations with a higher level of corruption and red tape have slower growth rates, but differences can be attributable to other factors. One way of surmounting this problem has been the use of the historical perspective that enables a comparison between ‘treatment’ nations with high-quality government and ‘control’ nations with low-quality government. This has been the approach used by Acemoglu, Johnson and Robinson.

The treatment nations in Africa, Central America and the Caribbean were governed from afar; their European colonizers focused solely on extracting from these countries as many natural resources (such as diamonds, silver and copper) as possible. The colonizers were not interested in setting up institutions in these nations to foster economic success (e.g. effective property rights or bureaucratic institutions). The control nations were governed from within: the European colonizers moved to these nations in large numbers and installed in them permanently.

The weaker institutional development related to the mortality of the settlers in the middle of the c. XIX is clearly seen in the Congo where the annual mortality of 280 per 1,000 between the Belgian settlers prevented their settlement, but they did not renounce the exploitation – through slavery at gunpoint – of the country’s natural wealth. At the port of Antwerp, the ships went in loaded with coffee or cocoa and came out with ammunition and troops. This unequal exchange caused 5 million deaths only in the Congo, especially between 1885 and 1908, as Adam Hochschild in ‘King Leopold’s Ghost’ excellently describes. In contrast, significantly fewer mortalities among settlers in Australia or Canada led to the establishment and subsequent development of welfare-enhancing institutions.

Democracy is not enough to build good governance. According to Nicholas Charron et al. [22], the three factors that seem to have the most empirical support for understanding the differences in governance quality between countries are: (i) a professional public management with a strict separation between the careers of politicians and civil servants; (ii) decentralization and autonomy in the management of human resources; and (iii) transparency, which is understood as access to public information (neither advertising nor hiding the bad results) and freedom of the press.

Good public governance must ensure fair action by means of *impartial* government institutions [23]. When public resources are heavily assigned to corruption and cronyism, instead of using objective criteria (e.g. improvement in the air quality or literacy and numeracy scores attained by students in different schools), citizens become more reluctant to act by the State and even undermine support for welfare policies no matter how much they benefit from them.

A consensus among academics and international organizations has crystallized on the determinant quality of governance, which is measured by instruments, such as the World-wide Governance Indicators of the World Bank, the Global Competitiveness Index of the World Economic Forum, the Index from Transparency International, or the Rule of Law Index, to explain the success or failure of nations.

## Conclusions: Credit to the God of Science but without forgetting the Caesar of the essential improvements in institutional quality needed to prioritise according to informed social preferences

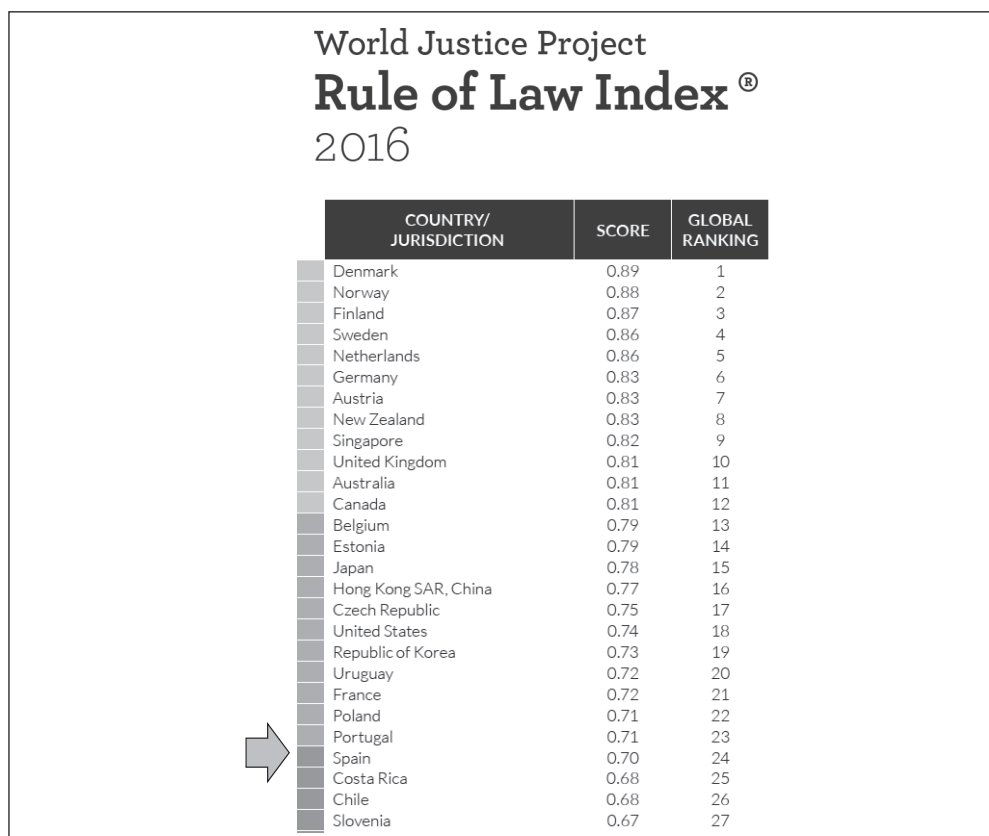
It is good that scientific articles tend to include in their discussion the need for additional research; at the very least it should be useful for authors. But just as there is non-scientifically based innovation (e.g. container, palette, surgical check-list), the correct

measurement of social values and preferences also can be made by means of the responsible participation of the citizenship – all of us, not just the beneficiary segment – when it comes to establishing priorities for the allocation of publicly funded resources. The threshold of social willingness to pay per year of quality-adjusted life based on ratios of incremental cost effectiveness cannot be the sole criterion governing public decisions. First, because decision makers are concerned about other objectives besides maximizing health (whether equity, the impact on public opinion or the trade deficit) and second, because we citizens are also concerned about other objectives. It is worth trying to collect, weigh and scientifically assess other objectives, such as preventing further damage in the future, encouraging scientific and technical innovation, treating the socially disadvantaged, looking after the ‘end of life’ or being sensitive to rare diseases. The advancement of science should be welcomed, but advances must be complemented, or even replaced, with an institutional change promoting the legitimacy of the decision-making process to arouse a wider social agreement as the results of the economic evaluation are perceived as a reflection of social preferences. Considering the lability and time-inconsistency of preferences, the role of emotions and the relative ignorance about how such preferences are generated, plus, on the other hand, the knowledge about the framing effect (choices depending on how the problem is formulated) and the important limits to rationality, credit is due to Science’s God but we must render unto the social functioning Caesar the practical measures for its improvement [24].

It seems that participating in social decision-making processes affects people’s well-being, and that it affects more the participation itself in the process than enjoying the results of this process: Immigrants without the right to vote in Switzerland, for example, benefit from the results, but not from the participation in the process.

Vicens Vives, whose work on *La Mesta* was disseminated by the Nobel North, is one of the first to explain the role of institutions (the ‘rules of the game’, the formal and informal restrictions created by the man who structured the economic, political and social interactions, as well as its safeguard mechanisms) exemplified with the role that *Mesta* has played in the secular backwardness of Spain. World Bank reports – in 1995 and 1996 – prompted by Stiglitz, helped to restore the importance of the State and to correct the ideological trap created by a completely mistaken interpretation of the fall of the Berlin Wall. The huge failures of the transition from planned economies to market economies in Central and Eastern Europe revealed that the correct functioning of markets is just a necessary but inefficient condition: without an effective State, countries fail. Reality and academic work have helped to make the institutional approach widely accepted today. In short, it can be said that in order for a society to develop, it is necessary for its institutions to make individually attractive what is socially convenient.

An increasing viscosity in several governance indicators of Spain has been observed: The Global Competitiveness Index of the World Economic Forum, Worldwide Governance Indicators of the World Bank, Transparency International or the Rule of Law Index (Figure 5), all have highly concordant results. The institutional deterioration in Spain has partially been an unexpected result of the 1999 monetary union (the Euro), which was supposed to bring structural adjustments and institutional reforms of less competitive economies when neither currency devaluation nor public deficits above 3% of the gross domestic product were allowed any longer. The expansion from 1999 to 2007 at a 3.6% annual growth rate, with real estate and financial bubbles, without increasing productivity,



**Figure 5.** Rule of Law Index.

and a postponement of reforms (education, labour market) allowed incompetent managers to make money and politicians to satisfy citizens at the same time. Spain has already incurred in investments and unproductive expenses, has suffered the Dutch disease, the debt is causing hangover and it will take a while to renew Spanish institutions [25]. Spanish growth during the 1994–2007 expansion was based on factor accumulation rather than productivity gains. In particular, annual total factor productivity growth was  $-0.7\%$ , which is low in comparison to other developed economies such as the US or the EU. The source of negative total factor productivity growth seems to have been the increase in the within-sector misallocation of production factors across firms, especially in industries in which the influence of the public sector is larger (e.g. through licensing or regulations). These industries closer to the public sector experienced significantly larger increases in misallocation [26].

Spain has a problem with its public management. It will be very difficult to improve public management or introduce reforms that significantly increase our productivity without an improvement in the quality of the politics and the institutions that are conditioning it. The requirements for a better government of the State are as well-known as ignored: (i) hedging the financing of political parties by limiting expenses and controlling

private contributions; (ii) streamlining the electoral regulations to approach the beginning of a person, one vote; and (iii) allowing the independence of the public communication media. Only an effective State that facilitates the type of transparent and impartial institutions of countries, such as the Scandinavian or many Central European countries will allow Spain to become stronger after the crisis. There will be no better public management without a better government – a complex concept that includes, among others, the need for transparency, accountability, appropriate regulation of conflicts of interest, and the professionalization and independence of the executive functions of the public administration.

Political parties play an irreplaceable role in every democratic system. Unlike what happens in other advanced democracies, in Spain the legal framework in force does not facilitate the debugging of the parties, although this has long been revealed as necessary. The Spanish parties are self-regulated: the congresses and governing bodies meet when it is advisable for their leaders; the usual method of selecting internal positions and candidates for representative positions is co-optation; and the control of the accounts is entrusted to an organism, the *Tribunal de Cuentas* (Court of Public Auditors), which is strongly politicized and whose members accede to the charge by political quota. In constitutionally more advanced democracies, parties are strongly regulated by law or, as in the British case, by custom. In all countries there is political corruption, but internal democracy in the political parties, the competition between those who are leaders and those who aspire to be so, and the obligation of transparency imposed by the law allow corrupt politicians to be quickly removed from office. In Spain, this does not happen, and corruption grows; it weakens government action at a critical juncture, causes citizens' disaffection and ends up causing a serious crisis for the politicization and loss of efficiency of state institutions, such as the General Council of the Judiciary, the Supreme Courts, the Court of Auditors, the Tax Authority, etc. There is even more. The co-option method, repeated over and over again, is an adverse selection method that ends up promoting the least critical and the less capable to places of responsibility. It seems urgent to develop a new law of political parties in order to regulate their activity, and ensure their internal democracy, transparency and control of funding, and bring the politics closer to the citizens. This is a necessary condition to be able to launch a much broader institutional reform with reasonable assurance that should include, among other things, the reform of Justice, the regulation of lobbies and the strict separation of political and administrative positions to ensure the independence and professionalism of the public function. The basic rules that this new law should collect are very common in European democracies.

In Spain, the time has come for the introduction of the idea and practice of competence for comparison in quality (e.g. universities, educational centres, health centres) without the need for markets, with a horizon of 30 years. There will be no better public management without a better policy and better governance – a concept that includes reviewing political party financing, accountability, resolution of conflicts of interest, and professionalization and independence of the executive functions of the system.

Certainly, the social values in Spain – based on the BBVA Foundation Survey – support the notions of merit or competition far less than in other European countries, and something will have to be done so that Spain matures as a society. Policy makers could inform the public about the costs, performance and quality of publicly funded services and encourage people's awareness of the taxes and quotes that are paid (which are quite

hidden today) to see if people are interested in collective issues at least as much as they are interested in the neighbourhood associations that exist in any building with shared property (an interest that is not excessive either).

## BIBLIOGRAPHY

1. Regidor E, Vallejo F, Granados JAT, Viciano-Fernández FJ, de la Fuente L, Barrio G. Faster mortality decline in low socioeconomic groups during the economic crisis in Spain: A cohort study of 36 million people. *Lancet*. 2016;388:2642-52.
2. González López-Valcárcel B, Barber P. Economic crisis, austerity policies, health and fairness: lessons learned from Spain. *Appl Health Econ Health Pol*. 2017;15:13-21.
3. González López-Valcárcel B, Zozaya N. Tecnologías para nacer y tecnologías para morir. ¿Cuál es el papel de los incentivos en la velocidad del proceso de adopción de las innovaciones? En Juan del Llano (dir): *Innovación y regulación en Biomedicina*. Madrid: Fundación Gaspar Casal; 2017. p.187-212.
4. Buchanan J, Tullock G. *the calculus of consent: logical foundations of constitutional democracy*. Indianapolis: Liberty Fund; 1962.
5. Campillo C, Ibern P. Framing an integrated and adaptive regulatory overhaul of medical technologies: A regulatory science and health economics perspective. Barcelona: Center for Research in Health and Economics, Universitat Pompeu Fabra; 2015. (Working Paper No. 201512-87.)
6. Baldwin R, Cave M, Lodge M. *Understanding regulation: theory, strategy, and practice*. Oxford: Oxford University Press; 2012.
7. Hauck K, Smith P. The politics of priority setting in health: a political economy perspective. *CGD Working Paper 414*, Washington, DC: Center of Global Development, 2015. Available from: <http://www.cgdev.org/publication/politics-priority-setting-health-political-economyperspective-working-paper-414>.
8. Campillo-Artero C. Sesgos de publicación, valor de la información y su efecto en las políticas de salud. *Rev Cubana Salud Publica*. 2012;38(5):714-24.
9. Faggiano F, Vigna-Taglianti F. Systematic reviews of effectiveness of Public Health practice. *Ital J Public Health*. 2006;4(3):29-33.
10. Waters E, Priest N, Armstrong R. The role of a prospective public health intervention study register in building public health evidence: proposal for content and use. *J Public Health*. 2007;29:322-7.
11. Schwappach DLB, Boluarte TA, Suhrcke M. The economics of primary prevention of cardiovascular disease - a systematic review of economic evaluations. *Cost Effect Resource Alloc*. 2007;5:5.
12. Samuelson P. *Foundations of economic analysis*. Cambridge, MA: Harvard University Press; 1947.
13. Olson M. *The logic of collective action*. Cambridge, MA: Harvard University Press; 1965.
14. Becker G. A theory of competition among pressure groups for political influence. *Q J Econ*. 1983;98(3):371-400.
15. Stigler G. The theory of economic regulation. *Bell J Econ Manag Sci*. 1971;2(1):3-21.
16. Campillo-Artero C. A full-fledged overhaul is needed for a risk and value-based regulation of medical devices in Europe. *Health Policy*. 2013;113:38-44.
17. Niskanen W. *Bureaucracy and representative government*. Chicago: Aldine-Atherton; 1971.
18. Lipsky M. *Street Level Bureaucracy*. New York: Russell Sage Foundation, 1979.
19. Hotelling H. Stability in competition. *Economic Journal*. 1929; 39(153): 41-57.
20. Arrow KJ. A difficulty in the concept of social welfare. *J Polit Econ*. 1950;58(4):328-46.
21. Su-ming Khoo. Public goods: from market efficiency to democratic effectiveness. In: Robertson A, ed. *Commonwealth governance handbook 2013/14*. Galway, Ireland.
22. Charron N, Dijkstra L, Lapuente V. Mapping the regional divide in Europe: A measure for assessing quality of government in 206 European regions. *Soc Indic Res*. 2015;122:315-46.

23. Holmberg S, Rothstein B (dir): Good government: The relevance of political science. Cheltenham, UK: Edgar Elgar, 2012.
24. González López-Valcárcel B, Ortún V. Pals don't evaluate pals...or do they? *Rev Esp Salud Pública*. 2015;89:119-23.
25. Fernández-Villaverde J; Garicano, L; Santos, T. Political credit cycles. The case of the Eurozone. *J Econ Perspect*. 2013;27(3):145-66.
26. García-Santana M, Moral-Benito E, Pijoan-Mas J, Ramos R. Growing like Spain: 1995-2007. Madrid: Banco de España. Working Paper No. 1609.