

'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?



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

Prioritising Health Services or Muddling Through

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

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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.

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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].

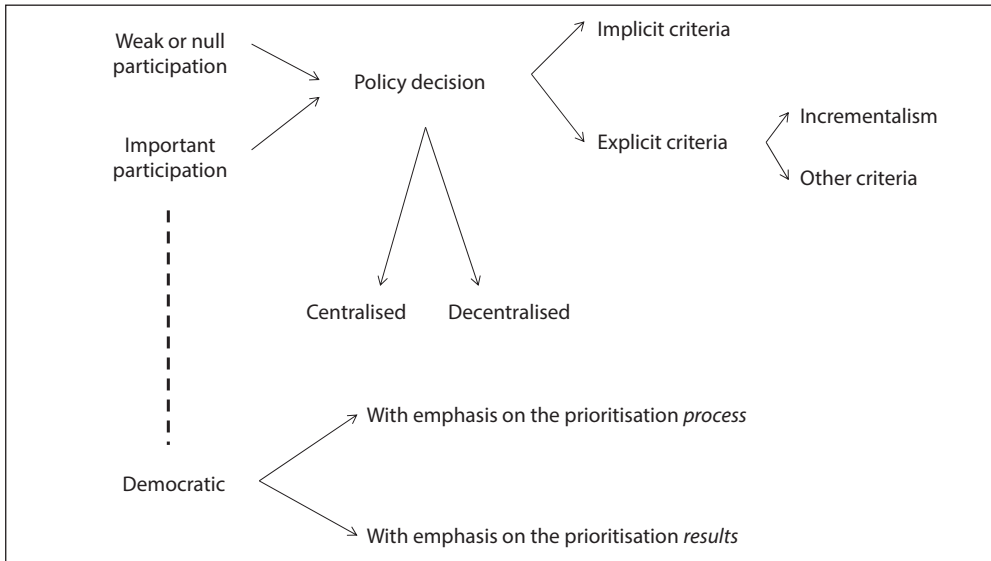


Figure 1. Public Services Prioritisation. A typology.

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
EU Member States			
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
America			
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
Asia			
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
Oceania			
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
Africa			
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-20th 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

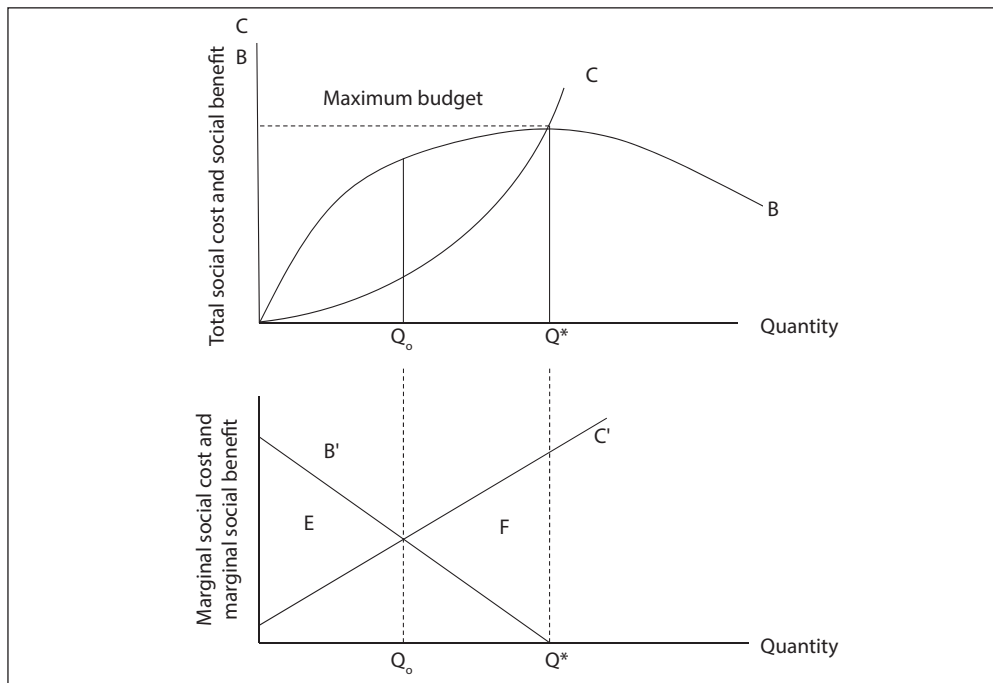


Figure 3. Niskanen's bureaucratic production model.

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.

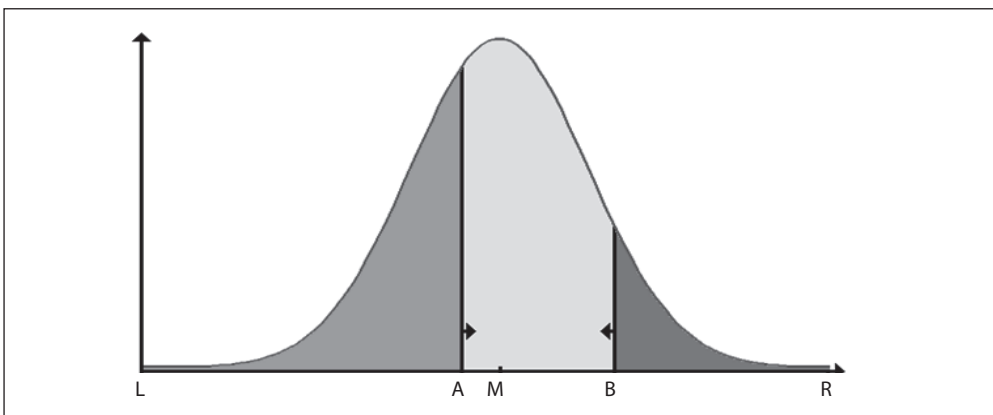


Figure 4. The median voter model.

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,

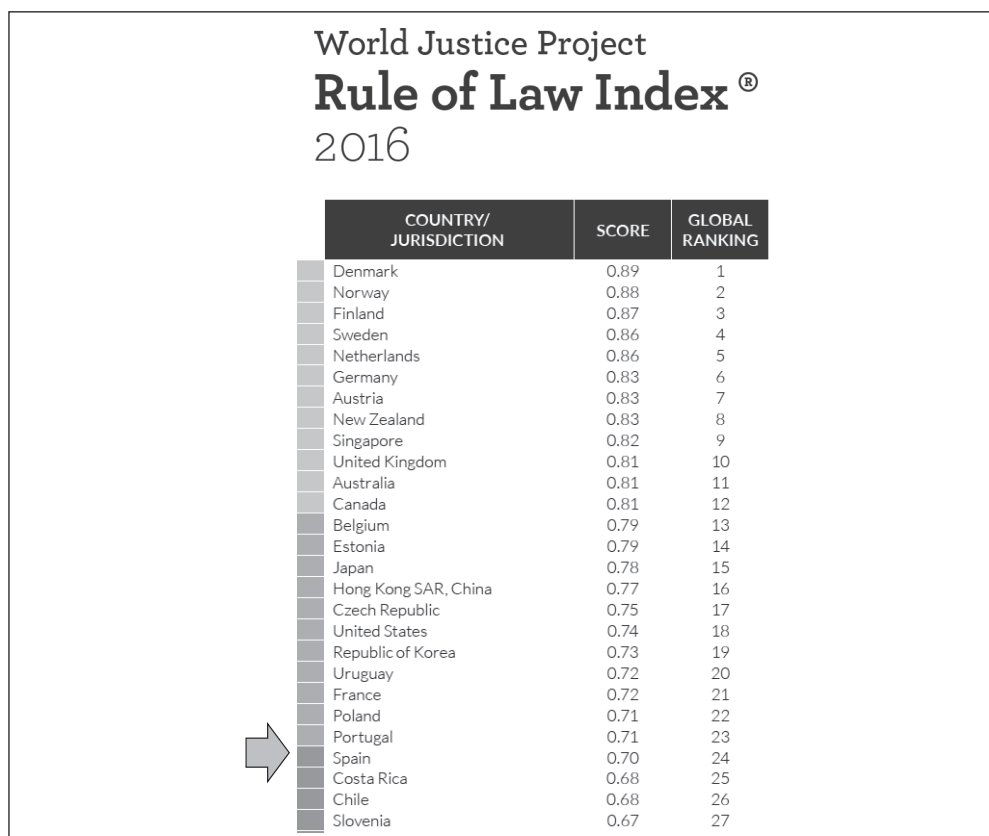


Figure 5. Rule of Law Index.

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).

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CHAPTER 2

Prioritisation in Public Health: Aims, Methods, Problems and Practical Experiences

Beatriz G Lopez-Valcarcel

Summary

Prioritisation in public health is more complex than in health services, with permanent tension between ‘purists and pragmatists.’ Two types of difficulties are encountered: first, that of unravelling and measuring the values of the society; second, the technical difficulties in determining the expected or probable consequences of different actions. The problem is not only technical, but also it requires us to address conflicts of interest between organisations, and thus to consider problems of implementation and organisational reforms. As health is not the sole aim of social welfare policies, the framework in public health prioritisation should be wide. Ultimately, the decision must be taken as to whether prioritisation should be limited to health, or rather, should address more ambitious – and more difficult – targets in the field of social welfare.

By performing prioritisation we fuel the culture of prioritisation, which is essential for its social acceptance. Just as there are orphan drugs, there are also orphan policies, the evaluation of which no organisation is willing to pay.

The two most commonly used explicit prioritisation methods are Programme Budgeting and Marginal Analysis (PBMA) and Multi-Criteria Decision Analysis (MCDA). The dimensions that are most frequently applied to health problems or programmes form a long and varied list, and the weights or values assigned to each of these dimensions are of crucial importance in the final ranking obtained.

Health plans are well-intentioned attempts at prioritisation, but they are generally unsuccessful because of the technical and political problems outlined above. In general, these initiatives tend to prioritise problems more than solutions, and have evolved towards plans based on the interdepartmental paradigm and towards ‘Health in All Policies’.

A checklist for pragmatic considerations in priority setting should include four aspects: (i) clear, well-structured objectives with a clearly-defined time horizon; (ii) an organisation equipped for change; (iii) selecting appropriate people to carry out change;

and (iv) the financial and organisational feasibility of change. From a review of practical experiences, we conclude that in many cases, public health exercises continue to be more didactic than pragmatic.

Introduction

Terms such as prioritisation, choice and trade-off are inseparable from the genome of the economy. Prioritisation in public health is more complex than in health services, and there is permanent tension between ‘purists and pragmatists’ [1], with the risk that it may be restricted to a mere academic exercise or an excessively narrow, health-focused framework may be adopted in which health is the sole objective of actions and policies, which, in fact, extend beyond the departmental barriers of healthcare.

Any prioritisation responds to a system or set of interests and values, and there are no exclusively technical solutions. Two types of difficulties are encountered in any prioritisation process: (i) unravelling and measuring the values of a social system; (ii) the technical difficulties in determining the expected or probable consequences of different actions. The more general the **prioritisation framework**, the more difficult it will be to compile evidence on causes and effects, and to obtain a common measure of social benefits: personal health versus social welfare; extending life versus improving its quality; programmes to benefit a few identifiable members of society or to benefit diffuse population groups. Moreover, the more general the prioritisation framework, the more refractory are both types of difficulties. The allocation of resources on the basis of ‘silos’; that is, reserving specific funds for certain programmes or policies, which is one way to avoid or to minimise these problems. Indeed, in practice, **narrow-frame prioritisations** tend to prevail (e.g. between different treatments for stomach cancer, according to the funds allocated from a silo). However, the public health policy makers should not resign themselves to such a narrow framework, because its fundamental goal is a generality: the population’s overall health.

In this field, there are two types of prioritisation: **health problems** and **interventions** (in order to address a given problem there may be alternative, complementary or substitutive interventions). In other words, either **problems or solutions** may be prioritised¹.

It is also useful to differentiate between formal and informal prioritisation. Prioritising helps managers make decisions about funding public programmes in a systematic, transparent way; ultimately, it responds to an ethical principle. Thus, ‘Accountability for reasonableness (A4R) is an ethics approach that focuses on ensuring fair priority-setting processes’ [2].

In public health, prioritisation is often eluded by denying the greatest priority; that is, the need to prioritise, by asserting that *everything* is important, essential and cannot be renounced [3]. But prioritisation is intrinsic to action, and when it is not performed with explicit criteria and methods, it is done implicitly. Thus, in Spain, tobacco is evidently assigned a higher level of priority than alcohol, according to the evidence available in regulations and public interventions regarding both drugs; nevertheless, no laws or public statements have been passed clearly stating such a ranking.

Prioritisation can be **explicit or tacit**. In the latter case, it is based on not questioning consolidated spending patterns and on renewing budgets only within the narrow margins

1 For a conceptualisation and typology of public services prioritisation, see Chapter 1 in this book by Callejon, Campillo and Ortun.

of available funding. Under **inertial budgeting**, priorities do not change; since last year's budgets reflected certain priorities, maintaining the same spending figures is deemed reasonable. In practice, economic evaluations are not usually conducted of consolidated programmes as they are assumed to be necessary and cost effective.

But between zero-based budgeting (starting from scratch and assigning everything afresh, according to prioritisation criteria) and the incrementalists, there is an extensive spectrum of more or less disruptive alternatives, which need to be prioritised.

The framework of prioritisation is defined by its intra- or inter-departmental nature and by the intra- or inter-level of government involved. A framework for public health prioritisation should ideally be comprehensive, also taking into account policies that are not directly related to health but which reduce the burden of preventable disease, as well as the health care organisation and management and the assessment of technologies. However, in practice, explicit prioritisation is generally limited to healthcare, without addressing wider considerations of public health, let alone inter-sectoral actions.

The following sections of this chapter set out a framework for the prioritisation of public health (Section 2); review the methods most commonly used in explicit prioritisation (Section 3); identify the technical difficulties that may be encountered (Section 4); discuss other problems (Section 5); review some interesting practical experiences of prioritisation in public health (Section 6); and finally, present the main conclusions drawn from this analysis (Section 7).

Framework: The Aims of Prioritisation in Public Health

One of the first difficulties encountered in public health prioritisation is that of defining its framework and objectives. Many of the policies and interventions conducted are inter-departmental, as are the outcomes achieved. However, economic considerations frequently fail to rise above the academic outlook by which social welfare is measured and valued. Although population health is a major component, and health is a requisite, or necessary 'capability' [4], it is not the sole aim of social welfare policies. In addition, other areas of social importance, such as economic well-being, education, security and the environment, compete with health for the attention of policymakers. Public health authorities have managed to win acceptance for the ideal of Health in All Policies (HiAP), with institutional success, at least on paper, since HiAP has become established as official European Union (EU) policy. Accordingly, perhaps the same progress could be achieved via the impulse of Education in All Policies, advocating a knowledge society as a strategic route towards people's economic well-being, happiness and health. Moreover, such a trade-off among social objectives implies a corresponding one between efficiency and fairness. Society must decide whether it prefers to maximise social achievements – in the field of health, for example, as the sum of years of life gained, or by enhancing the health of the most vulnerable, needy and abandoned. Another trade-off must be made between short- and long-term outlooks.

In academic economics, significant progress has been made in defining social welfare functions and in advances such as proposals for a healthy equivalent income (comparing the incomes of two persons in good health) [5]. A study conducted in 40 countries with a sample of 634,951 people [6] explored the determinants of life satisfaction between 1990

and 2011, and the extent to which restrictions on smoking influenced this satisfaction. The most striking result obtained is that the maximum difference between levels of life satisfaction occurs between employed and unemployed people, not between those who have better or worse health. Thus, between health and income there is a trade-off (we give up something in one respect to obtain an improvement in the other). Moreover, people are heterogeneous, and individuals, too, present changes throughout their lives. As we get older and richer, health becomes a higher priority and is assigned greater value [7].

Ultimately, the decision must be taken as to whether prioritisation should be limited to health or rather, should address more ambitious – and more difficult – targets in the field of social welfare. In the latter case, we would need an operative measure of social welfare with which to compare quality-adjusted life years (QALY) gained with health interventions and their determinants with the ‘satisfaction’ gained, for example, through increased income from pensions.

Let us focus on the (generic) target of health, setting aside for the moment others, such as education, income or happiness. By doing so, we avoid making comparisons that are, if not impossible, at least politically paralysing, such as having to decide between ‘vaccinating against pneumococcal disease or reinforcing environmental policies in order to reduce the planet’s temperature by one degree’.

Furthermore, by performing prioritisation we fuel the culture of prioritisation, which is essential for its social acceptance. For this reason, whenever prioritisation takes place, the active participation of the population is an essential ingredient, to provide both input and output to the process; on the one hand, to reveal values and preferences (input), and on the other, to socially assimilate the act of prioritisation, which is increasingly accepted (output). Participatory prioritisation is a resource that the EU regularly uses, even for technical issues, such as endocrine disruptors², and the Global Health Alliance (EU and World Health Organisation) has launched consultations to prioritise socially sensitive problems, such as those associated with climate change³.

Even so, the problem is complex to such a degree that the Centers for Disease Control and Prevention (CDC) provides specific courses⁴ and instruments⁵ with which to learn to prioritise public health problems. Nevertheless, wolves dressed as sheep remain wolves under the skin, and although prioritisation may take the guise of a technical exercise⁶ (in fact, the technique is quite simple), it is essentially evaluative, incorporating a predefined framework implemented via weighting criteria and based on pre-selected problems or interventions. The dimensions or criteria that are most frequently applied to health problems or interventions (programmes) in prioritisation exercises in the field of public health form a long and varied list (see Table 1), and the weights or values assigned to each of these dimensions are of crucial importance in the final ordering of the problems to be addressed and/or the order of interventions in the final ranking.

2 <http://www.usda-eu.org/wp-content/uploads/2015/01/United-States-Submission-Endocrine-Disrupters-2015-01-20.pdf>

3 <http://www.epha.org/spip.php?article5776>

4 https://www.cdc.gov/globalhealth/healthprotection/fetp/training_modules/4/prioritize-problems_fg_final_09262013.pdf

5 <https://www.cdc.gov/nphpsp/documents/prioritization-section-from-apexph-in-practice.pdf>

6 <http://www.health.state.mn.us/divs/opi/qi/toolbox/prioritizationmatrix.html>

Table 1. Prioritisation dimensions or criteria in the context of public health.

Health-related problems	<ul style="list-style-type: none"> • Number of persons affected • Lethality • Degree of disability • Impact on activities of daily life • Costs of the disease • Possibility of contagion
Interventions and programmes	<ul style="list-style-type: none"> • Effectiveness • Fairness in the distribution of the benefits (with special attention to the least-advantaged) • Affordability (budget required to fund the intervention) • Cost-effectiveness • Number of beneficiaries • Appropriateness • Sustainability • System integration • Cost per QALY gained • Certainty (quality of the method and data used in the evaluation)

Source: Devised by the authors.
 QALY = quality-adjusted life years.

Methods of Prioritisation in Public Health

The two most commonly used explicit prioritisation methods are Programme Budgeting and Marginal Analysis (PBMA) and Multi-Criteria Decision Analysis (MCDA). Other methods have been proposed, although some are mere variants of the above.

In PBMA, a panel of experts is consulted to help decision makers maximise the impact of budgetary changes on the health needs of a local population. Programme budgeting is the appraisal of past resource allocation in specified programmes, while marginal analysis is the appraisal of the consequences of investments and disinvestments in specific programmes. This approach is used to determine the expected impact on one programme of spending changes in others. PBMA consists of eight steps [8]. 1. Choose a set of meaningful programmes/initiatives; 2. Identify current activity and expenditure in those programmes/initiatives; 3. Think of improvements; 4. Weigh up incremental costs and incremental benefits and prioritise a list; 5. Consult widely; 6. Decide on changes; 7. Effect the changes; 8. Evaluate progress..

MCDA is a procedure in which weighted criteria are integrated into the assessment of health problems or programmes. It consists of the following critical steps: (i) identifying interventions; (ii) identifying evaluation criteria; (iii) measuring the interventions against the criteria; and (iv) combining the criteria scores using weights to produce an overall assessment of each intervention [9]. In practice, these four steps require value judgements from experts and/or the population. Thus, stage 1 defines the framework, which, in turn, establishes the ground rules for the assessment and bears a strong influence on the results eventually obtained: will this exercise prioritise problems or solutions? Will it be narrow or wide in scope? And, above all, who will compile the list? In stage 2, which generally involves discrete choice experiments, the criteria are weighted from a

pre-selected initial list. Again, the question arises: who provides this initial list? The 'technical' part of obtaining and modelling results to obtain the weights is straightforward, and carrying out step 3 is a simple task, but the legitimacy of the exercise is based on selecting a valid sample of persons: should these be politicians, decision makers, experts, patients or the population at large? In practice, criteria weights are usually generated using discrete choice experiments based on the opinions of decision makers or of the general population.

MCDA is increasingly used because it incorporates both health and non-health economic outcomes into the prioritisation of public health interventions, and because it overcomes the limitation of QALY as a single homogeneous measure of results. Furthermore, it incorporates a broader spectrum of values, and addresses them more systematically than under economic evaluation [9].

Among other proposals (less widely accepted than PBMA and MCDA) is macro-marginal analysis, described as an 'explicit process for setting priorities across major service areas within a regional health authority, based on both evidence and local expert opinion' [1]. Its proponents claim it overcomes limitations of non-comparability of rankings for different health problems and patient groups, and that it provides a zero-sum means of identifying 'margins for change', such as investing in certain problems and areas with resources derived from others. A budgetary experiment [10] has also been proposed and used in a participatory health system priority setting.

Technical Problems in the Procedures and Methods of Prioritisation in Public Health

The problematic incorporation of values into interdepartmental and intersectoral actions

Transversal prioritisation within a context of intersectoral collaboration can make a major contribution to health improvements, but the problem of accurately measuring and evaluating outcomes may be irresolvable and paralysing, with each department involved valuing achievements in terms of its own perspective and interest. How can a common measure of value in healthcare be used to compare activities as disparate as agricultural production, industrial externalities, trade controls and incentives or rates of taxation? [3]. Furthermore, the problem is not only technical, but also it requires us to address conflicts of interest between organisations, and thus to consider problems of implementation and organisational reforms.

The inadequacy of the methods

As observed above, prioritisation in public health requires a broader framework than in health care services. Additional problems must be overcome in order to determine society's willingness to pay, which is an essential input, when there exist externalities and public goods: the two fundamental characteristics that define public health. The lack of a market that could relate costs and benefits is a much more disturbing handicap in public health than in health services. The QALY approach is clearly inadequate, but there is a dearth of measures of social welfare that are sufficiently generic and inclusive, but at the

same time reliable, with which to assess the consequences of interdepartmental policies in wide-ranging prioritisation exercises. In short, traditional prioritisation methods fall short of requirements.

Uncertainty about cause-and-effect relations

Knowledge can only be provisional. It is continually subject to revision, and sometimes prior beliefs must be discarded. Scant evidence is available on the effectiveness of public health policies compared to that concerning medicines. In the absence of evidence, managers must fall back on guidelines citing the desirability of certain strategies or programmes, although they may never have been rigorously evaluated, or if they have, with surprising results. Thus, the 'walking bus' programme to prevent childhood obesity has proved ineffective, as have many health education programmes in Australia [11].

Nevertheless, methods to perform policy evaluation and health impact assessment are essential in the prioritisation of public health, and any progress in this regard is welcome.

Moreover, there is a need to identify knowledge gaps regarding health-related cause-and-effect relationships; therefore, research efforts regarding effectiveness, cost-effectiveness and policy impact must also be prioritised [12,13].

Beyond Technical Difficulties

Unlike uncertainty, which refers to a lack of knowledge because science has not yet advanced sufficiently, **ignorance** consists in disregarding the evidence due to limitations of the person and/or of the organisation. Kahneman [14] proposes an example from the field of public health to illustrate heuristics and bias in decision making (to which politicians and decision-makers, among others, are also subject). When a public health programme is formulated positively, by presenting the gains to be achieved (lives saved), it is much more likely to be preferred and chosen than if the same programme were presented in negative terms (the number or rate of deaths).

The bias of immediacy is also strongly present in political decisions, and is often supplied by the media, which remind society of the (fashionable) issues that opinion makers wish to highlight, implicitly imposing their own agendas and priorities. Accordingly, it is essential for good public health data to be provided, so that tainted sources may be avoided.

When there is ignorance about the expected effects of causes, this may be due not only to technical problems, but also to the presence of bias in publications and scientific studies.

In addition to technical problems, there may be a lack of incentives to obtain evidence on the effect of health policies, as opposed to that of medicines and medical devices (behind which there are always sellers seeking a favourable evaluation), and of finance for studies of cost-effectiveness. Just as there are orphan drugs, there are also **orphan policies**, the evaluation of which no organisation is willing to pay.

Many public policies belong to various areas of decision, from global or multinational down to the local, and (in Spain, for example) passing through the EU, the State and the Autonomous Community (region). Decisions and actions frequently correspond to

one level of government while their consequences affect others. For example, measures against pollution and climate change are taken locally but their effects are global. The same problem that may arise with interdepartmental plans can also appear between levels of government. In other words, there are **political externalities** that are difficult to internalise. In this respect, consider taxes on health-damaging products; for example, on the sugar added to drinks. Real success in this area would be if such taxes brought in very little revenue (i.e. if consumption were diverted towards healthy substitutes). For this reason, tax-raising departments do not find them attractive, because administration and management costs would be incurred without producing corresponding economic benefits. Thus, it is the health authorities that must lead the way and convince society of the worth of this tax for social well-being.

Difficulties in resolving intragovernmental conflicts and, especially, the formidable influence of corporations are serious obstacles to the implementation of public health policies. But failures also provide lessons for the future. Accounts of flawed attempts in this field, such as alcohol restrictions in Spain, the taxation of fatty foods in Denmark and sugary drinks in Mexico, are all valuable sources of knowledge.

Social, cultural and economic globalisation imposes restrictions on local public health policies. For example, patterns of human nutrition and obesity respond to cultural globalisation rather than international free trade [15], while economic globalisation, through structures such as the Transatlantic Trade and Investment Partnership (TTIP) can impose restraints on government action⁷.

Another question, partly related to the above observations, is that of who should assess and perform the prioritisation exercise. Following the principle of 'he who pays the piper calls the tune', international development cooperation agencies, in practice, define the health priorities of developing countries. In developed countries, the question is whether government or society should pull the strings of prioritisation, and how government can turn social values into policies without their becoming 'lost in translation'. The sensitivity of governments to corporations that have private interests and often exercise undue influence, and the mechanisms by which these corporations interfere and define political agendas, are real problems [16] and institutional architecture is a factor of crucial importance. In this book, the chapter by Ana Garcia addresses these questions in detail. Another problem is that gaps in institutional coordination (e.g. between public health, occupational health and environmental health) in turn generate gaps in citizen participation in processes of health prioritisation [17].

Practical Experiences of Prioritisation in Public Health

Health plans are well-intentioned attempts at prioritisation, but they are generally unsuccessful because of the technical and political problems outlined above. In general, these initiatives tend to prioritise problems more than solutions, and have evolved towards plans based on the interdepartmental paradigm and towards 'Health in All Policies', such as the Interdepartmental and Intersectoral Plan for Public Health (PINSAP) devised in Catalonia. In Spain, some health plans include the participative exercise of prioritising

⁷ <http://sespas.es/2015/11/20/posicionamiento-sespas-ttip-y-salud/>

problems with explicit criteria, for example the Asturias Health Plan 2004–2007 (2003) was based on an evaluation conducted with the participation of experts, healthcare professionals and the general public, in which the prioritisation criteria adopted were those of the foreseeable benefits to health, the effectiveness of the intervention, citizens’ opinions and the social burden of the problem⁸. The 4th Andalusian Health Plan decentralised prioritisation towards the provinces, and referred the final coordination to a central technical committee⁹. Until the mid-2000s, the health plans issued in Spain made little mention of social inequalities in health [18], with just a few exceptions, such as the Basque Country Health Plan.

Prioritisation in public health is a matter of concern to academics, and has been the subject of reports by scientific societies, such as the Spanish Public Health Service Administration (SESPAS) [19-21].

Peacock et al. [22] published a checklist for pragmatic considerations in priority setting (Table 2), in which four types of aspects were distinguished: (i) clear, well-structured objectives with a clearly-defined time horizon; (ii) an organisation equipped for change; (iii) selecting appropriate people to carry out change; and (iv) the financial and organisational feasibility of change.

Table 2. Checklist for pragmatic considerations in priority setting.

1. Establish the organisational objectives
<ul style="list-style-type: none"> • Multiple objectives (effectiveness, equity etc.; trade-offs between objectives) • Hierarchical objectives (provider, local, regional and national levels) • Inter-temporal objectives (short and long term)
2. Ensure the organisation is ready for change
<ul style="list-style-type: none"> • Develop leadership and ownership (managers, providers, consumers, community) • Consider timing and stability (organisational reforms) • Identify institutional boundaries (budgetary, service fragmentation or integration) • Establish incentive and sanction mechanisms (financial, managerial)
3. Establish an appropriate advisory panel structure
<ul style="list-style-type: none"> • Recruit members representing all stakeholders (service managers, providers, consumers, community) • Identify roles and responsibilities (values, decision-making criteria, evaluation of services) • Train key stakeholders • Community participation (community values, specific needs)
4. Ensure that implementation of results is feasible
<ul style="list-style-type: none"> • Is there a desire to reallocate resources? (ownership) • Will institutional boundaries allow reallocation? • How well are funding and priority setting mechanisms integrated?

Source: Peacock et al. [22]. Reproduced with permission.

Although there have been many experiences of prioritisation in public health, in health policies and in healthcare in general, most of these have been informal, without explicit criteria being established. Traditional consensus techniques, such as nominal groups or

8 http://tematico.asturias.es/salud/plan/plan/documento/plan_salud.pdf

9 http://www.andaluciasana.es/PAS/links/IV_PAS_v9.pdf

Delphi techniques, are often used. But in very few cases have explicit prioritisation criteria been employed, leading to reassignments in real-life situations. According to a recent literature review [23], the most commonly-used relational-life methods (sometimes in combination) are PBMA and MCDA. It is noteworthy that these authors, who are well versed in the field of prioritisation worldwide, in compiling real-life experiences of prioritisation published between 2000 and 2013 (including grey literature), only managed to locate 33 such prioritisation exercises. However, what is most striking is that although ‘Health Priorities’ and ‘Community Health Planning’ were included in the search terms, broad-scope terms were notably absent. Very few studies extended their research focus beyond health services, and some even restricted their attention to a specific health problem, such as diabetes, respiratory disease, growth hormone or HIV. There have also been specific exercises examining the service rather than the health problem (in areas such as spending on medicines, or health services for chronic diseases). A considerable number of studies have addressed investment/divestment/reinvestment decisions, but examinations of the use of budget increases for decisions at the leading edge of allocations are less commonly observed. According to this review, the most frequently used criteria are effectiveness, fairness, affordability, cost effectiveness and the number of beneficiaries.

An interesting pragmatic case is that of the Calgary (Canada) healthcare region [1], where Macro Marginal Analysis identified redundant activities, accounting for 3% of the total budget (over CAN\$40 m), which could be redeployed to other areas.

Another instructive experience is that of the prioritisation carried out in primary healthcare trusts in the UK [24]. The ground rules for this prioritisation are made apparent in the scoring tool, which establishes the maximum weight (from 0 to 100) to be assigned, a priori, to each of the different criteria: National priorities (maximum 20 points), local priorities (maximum 10 points), risk assessment (maximum 20 points), local needs (maximum 20 points), effectiveness (maximum 10 points), and cost considerations (maximum 20 points) [24]. The end result of the exercise, obviously, is strongly influenced by the design of this scoring tool. Over 100 initial proposals were made, with a total cost of £44 m. Of these, 66 (valued at £26 m) were evaluated. The budget available was £5 m. The top-scoring programmes resulting from this exercise were clinical ones aimed at individual patients, while community health and disease prevention programmes were assigned low priorities. In practice, it seems that ‘funding of the locally driven priorities took precedence over some of the nationally driven priorities, such as funding of specific NICE guidance in the primary care setting in the UK’ [24].

A prioritisation exercise that was noteworthy for addressing both public health and population health was carried out in Ghana [25]. Among the 10 activities prioritised were the regulation of tobacco advertising and the obligatory use of safety belts in vehicles.

However, in many cases, public health exercises continue to be more didactic than pragmatic. Thus, one such exercise was intended to ‘demonstrate the feasibility of developing and applying a method for prioritising preventive health interventions in the UK’ [9]. A multi-criteria decision analysis was employed to prioritise 14 public health interventions, using weighted criteria in a discrete-choice experiment. Taxation was ranked at the highest priority; mass-media campaigns and brief interventions were ranked in the top half of the scale; and schools-based educational interventions, statins and interventions to address mental health problems were placed at the bottom of the list. The aim of this exercise was to establish a benchmark for public health prioritisation, by including five

major areas of health-related problems (alcohol, mental health, obesity, tobacco and sexually transmitted infections) and a wide spectrum of health interventions and non-health-related prevention, ranging from taxation to screening and pharmacological treatments. The list of interventions assessed by Marsh et al. in their public health prioritisation exercise in the United Kingdom includes interventions in the areas of alcohol, mental health, obesity, smoking and sexual transmitted infections.

In this exercise, five criteria were applied to determine incremental cost effectiveness: (i) cost per QALY gained; (ii) proportion of the population eligible for the intervention; (iii) fairness in the distribution of benefits to the most disadvantaged 20% of the eligible population; (iv) affordability (budget required to fund the intervention); and (v) certainty (based on the quality of the method and the data used in the evaluation). Feasibility and acceptability criteria were excluded due to lack of means with which to measure them.

Conclusion

Canada is a good source of experiences in health prioritisation. In an article based on three empirical exercises with international participation [26], 10 key aspects, associated with both the process and the results obtained, are proposed as fundamental to the success of a health prioritisation exercise: (i) stakeholder understanding; (ii) shifted priorities/reallocation of resources; (iii) decision-making quality; (iv) stakeholder acceptance and satisfaction; (v) positive externalities; (vi) stakeholder engagement; (vii) use of explicit process; (viii) information management; (ix) consideration of values and context; and (x) revision or appeals mechanism.

Despite lip service being paid to the ideal, few institutions actually listen to what the population has to say. This 'attention gap' remains to be addressed, although in line with '*sauve qui peut*' ad hoc solutions are often proposed; for example, via reviews of healthcare plans. Citizen participation is an essential component of public health, which the Spanish Public Health Act defines as 'the set of activities organised by public administrations, **with the participation of society**, to prevent disease and to protect, promote and recover personal health, both individually and collectively, through health service, sectoral and cross-cutting actions'.

It is important not to allow the potential for change to be worn down – and acting inappropriately or ineffectively is worse than doing nothing. Raising false hopes and proclaiming tired slogans will eventually erode, disrupt, destroy and distort ideas that are fundamentally good. Planners must learn from the mistakes of the past and reconsider traditional health plans. Why weren't options prioritised? Were these plans just examples of wishful thinking? Obviously, resources are limited and there are no superheroes around with powers to grant our every wish. Did planners count on the input of others, but without them knowing? Plans drafted in health department offices set out measures to be adopted by other branches of government, but these other offices may not be made aware of them. Did they seek to ignore the quantification of funding and its sources? Did they define measurable indicators to determine the degree of compliance? How many health plans in Spain have ultimately resulted in a transparent, well-weighted evaluation?

Health plans in Spain are all too often simulations of prioritisation, which ultimately come to nothing, but which ensure that all problems, sectors and population subgroups

are given their turn in the spotlight. It is like a family photo, with something for everyone, which fails to prioritise but rather legitimises the politician who is willing to tackle anything and everything. Prioritising, in contrast, means making a decision, selecting, concentrating on the essential and setting the rest aside.

Finally, let us remember that prioritising, in itself, is not enough. Measures must then be implemented. When the prioritisation exercise ends, the real work of putting proposals into practice begins.

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CHAPTER 3

Value-based Prioritisation in Healthcare

Juan M. Cabasés

Summary

Setting priorities in health decision making is a practice that incorporates the value to society of competing interventions in health and wellbeing, both inside and outside the healthcare system. This may result in denying an individual or a group something that could be of benefit to them. In economic terms, this means taking into account the opportunity cost; that is, benefits forgone as a consequence of choice. It may have an important distributive impact and effect on efficiency, which calls for an explicit mechanism where all potential affected stakeholders should have their voice. Prioritisation requires first defining a framework; second, establishing explicit criteria weighted against each other; and third, choosing methods for implementation. Our aim in this chapter is to look at (i) the state of the methods used; (ii) their potential and limitations; and (iii) the agents involved in this value-laden exercise. We concentrate on methods and criteria used in efficiency and equity measurement. Also, recognising that setting priorities requires a deliberation process where several stakeholders are involved, we emphasize the crucial role of patients and the general public.

Introduction

In a world of scarce resources, setting priorities is inescapable. It is not possible to offer all the interventions that could benefit everyone in need. How should we allocate scarce resources in an area as important as people's health? What services should be publicly funded? How should we rank patients' access to health interventions? This is a complex task that entails at least ethical, legal, social and economic implications. Setting priorities is to implement a mechanism that ultimately selects who will receive and who will not receive services that provide some benefit to the recipient. In other words, it means to deny someone something that could be of benefit to them. In economic terms, this means

taking into account the opportunity cost; that is, benefits forgone as a consequence of choice. However, this has always been done implicitly in all health systems. Its relevance lies in the recognised need to do so explicitly, as well as in the expectation of its contribution to reducing the gap between health demand and supply, improving efficiency and being equitable in resource allocation [1].

The rationale for prioritisation is the scarcity of resources to provide unlimited healthcare for all in a world of moral hazard in patients' behaviour and lack of incentives for providers to be cost conscious. They are usually focussed on effectiveness but not efficiency. Moral hazard responses, such as price and waiting times, are not sufficient or might be undesirable in our healthcare systems. Also, providers' incentives – usually monetary – have some limitations in terms of crowding out intrinsic motivation, and non-monetary incentives are still in their infancy [2]. It is in this context where setting priorities makes sense to improve efficiency. Rationing mechanisms have the potential of delimitating benefits through the elaboration of a package of services or the use of different variables to order the waiting lists other than the traditional order of arrival.

The scope of new actions for investment (or disinvestment) in health that needs priority setting is widening nowadays: prevention, predictive medicine, individualisation of treatments, new forms of organisation imposed by changes in diseases, e-health and information systems to increase transparency. Also, the scope for prioritisation is broadening beyond healthcare interventions to the wider set of variables of the production of health. Intersectoral policy, from sectors outside healthcare, includes prevention, healthy life style promotion, healthy environment at the workplace and at leisure, etc., all producing health gains together and usually in competition with the interventions of the healthcare sector. Moreover, the broader concept of wellbeing is now more appealing than health itself, plus happiness and a broader view of quality of life are conceptually even more attractive. These wider views of outcomes have stimulated recent research on priorities. There is also a trade-off between the above concepts and other areas of social interest, such as dependency, education, social services and poverty [3].

Prioritisation requires (i) defining the framework for decisions; (ii) creating explicit criteria; and (iii) choosing methods for implementation. Looking at the criteria, here we concentrate on the economic approach: being efficient and equitable. Our aim in this paper is to look at the state of the methods used, their potential and limitations, and the agents involved in this value-laden, deliberative exercise of setting priorities in health and wellbeing.

Health Technology Assessment (HTA)

The current method for priority setting on efficiency grounds is health technology assessment mostly through cost-effectiveness analysis (CEA), with the main objective of maximising health gain. Research has focused on measuring health to devise health indexes as effectiveness measures, with the quality-adjusted life year (QALY), which combines quantity and quality of life, as the preferred index. Comparing effectiveness with costs, results are presented in terms of incremental cost effectiveness ratios (ICER) that allow comparing and ranking interventions in homogeneous terms. A further step is to give a monetary value to QALYs, and to calculate the incremental net benefit, so

that it is possible to know the efficiency of each alternative being evaluated. If there is uncertainty in some of the variables, probabilistic sensitivity analysis allows results to be obtained through confidence ellipses and acceptability curves, which show the probability of the intervention to be efficient against the comparator intervention. This is a field in permanent improvement with some recent new insights [4,5].

Outcomes Limitations in HTA

The above cost-effectiveness framework, however useful, poses multiple methodological issues. Looking at the outcomes, to get a QALY requires having an operational definition of health, and a health-related quality of life (HRQoL) instrument, which weights diverse dimensions of health with several levels in each of the dimensions giving a set of mutually exclusive health states. The final step is to give a relative value to the health states using appropriate techniques. We shall comment briefly on some of the problems of these issues.

The operational definition of health refers to functional health, one's ability to perform the usual activities of normal life, which is far from conceptually perfect health as defined by the World Health Organisation. This is what most HRQoL instruments try to capture. For the purpose of obtaining QALYs, a generic instrument, as opposed to a condition-specific instrument, would be preferred. Among the best known, SF-36 and EQ-5D, SF-36 [6] was not designed as an index but as a comprehensive descriptive system of health, although a short version, SF-6D, was created to produce a QALY [7]. The Health Utilities Index [8] is also an index of health based on preferences, but its use has not expanded worldwide. EQ-5D was created with the aim of attaining a health index [9], and has become the HRQoL instrument most used in CEA. We shall concentrate here on its features as an instrument to help setting priorities in HTA.

EQ-5D is a standardised HRQoL questionnaire developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal [10]. It provides a simple descriptive profile of five dimensions that are supposedly exhaustive of society's views of health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression, with three-level and five-level response options, EQ-5D-3L and EQ-5D-5L, respectively, and a youth version, EQ-5D-Y. It also provides a self-report visual analogue scale (EQ-VAS) and an index value (utility) for health status that can be used in the clinical and economic evaluation of healthcare as well as in population health surveys.

However, the suitability of the EQ-5D descriptive profile has been questioned because it may not capture all the aspects of quality of life that matter to patients with certain conditions. Among them, cognition, sensory-related dimensions (particularly vision and hearing), and mental health have been recently recognised by the general public in England as relevant dimensions of health not captured by EQ-5D [11]. Finch et al. [12] also assessed the importance of hearing, sleeping, cognition, energy and relationship as relevant dimensions. One way to consider additional dimensions of the EQ-5D would be to bolt on; that is, adding those dimensions considered relevant for the purpose of evaluation. This cannot be done without problems: a lack of clear direction on the basis for the development of bolt-ons, how to score them, the potential to undermine the core EQ-5D product, and the investment costs.

Perhaps the most challenging step in getting a health index is the choice of the appropriate preference-based method for giving a single value to each of the health states. One problem any technique should avoid is the presence of logical inconsistencies; that is, giving lower value to an objectively better health state. The most used valuation method has been the Time Trade Off [13], which is well-rooted in multi-attribute utility theory but showing slight problems of inconsistency in its application. The appearance of the EQ-5D-5L, with considerable increase in the health states (from 243 in EQ-5D-3L to 3125 in EQ-5D-5L), has stimulated interest to find the most suitable techniques for obtaining preferences. After conducting pilot studies in several countries, the EuroQol Group has developed a valuation protocol that includes a composite-time trade off (C-TTO) method and a discrete choice (DC) method as information in order to be able to estimate the health states with greater precision [14]. The combination of both techniques in a hybrid model also solves the problem of logical inconsistencies that techniques applied individually cannot. This common protocol has already been applied in a few countries with a pioneering character in Spain to a sample of the general population [15].

There are several index techniques leading to value sets of different HRQoL instruments. Every building technique has its own theoretical and empirical basis, and gives different values for the same health states. For the purpose of setting priorities in a constituency, be it a country, a region, or even in a hospital or clinic, it is important to get an agreement on the variables involved and the choice of HRQoL instrument, plus the preferred technique, and to guarantee the representativeness of the values for the relevant population. Indexes are usually estimated as mean values that produce QALYs when quantity of life is added. Mean values are useful for efficiency studies, but they hide values when distributive aspects matter. We go further on these issues in the equity section of the chapter.

An additional problem in setting priorities based on CEA is the difficulty to count with outcome measures from generic instruments in many healthcare interventions. Most interventions use clinical indicators in patient follow-up and do not always use HRQoL instruments; however when they do, they are usually condition-specific, not generic or, when they are being generic, they are not preference based. This creates important problems of comparison between interventions. In those cases, one way to obtain an index is the use of statistical techniques of association or mapping that allow the prediction of utility values of health status of the generic instrument from specific measures, or non-preference-based generic instruments [16-19]. These methods are not exempt from methodological problems, such as uncertainty and possible estimation errors. The incorporation of a common generic preference-based HRQoL, such as the EQ-5D to the battery of clinical indicators of patients in all services and interventions, would facilitate the comparison and prioritisation exercises.

This suggests developing patient-reported outcomes (PRO) measures, so the voice of patients and families is taken into account in all interventions. The UK Department of Health introduced the routine collection of PRO to measure the performance of healthcare providers. From April 2009, generic (EQ-5D) and condition-specific PRO have been collected from patients before and after four surgical procedures; eventually this will be extended to include a wide range of other National Health Service (NHS) services. This is a significant development for the NHS. For the first time, the NHS will seek to measure what it produces in terms of health, rather than in terms of the production of healthcare [20].

CEA compares the additional costs of one technology versus another, which serves as a comparator, with the additional QALYs. The result is an ICER, which is expressed in terms of cost per QALY gained. This is a useful ratio to rank technologies that achieve improvements in health according to the efficiency criterion, but does not allow knowing if the gain in effectiveness overcomes the cost. This information is increasingly needed in a world where pricing decisions for new technologies (including medicines) are being set in terms of value-based pricing. For this it is necessary to know the monetary value that the society assigns to the QALY. There are very few studies of monetary valuation of QALYs with the notable exception of the UK and Spain [21].

In the absence of studies on monetary valuation, it is common for decision makers to use cost-effectiveness thresholds to accept (or not) a technology as being efficient. The National Institute for Health and Care Excellence (NICE) in the UK has made explicit cost-utility threshold values for its recommendations on whether or not to authorise a new health technology, with ranges between £20,000 and £30,000 – the latter being the upper value for investment decisions with added benefits, such as innovation. In the USA, the figure of \$50,000 has been used, understanding that it is only a reference as a lower bound: below \$50,000 per QALY should be approved, but this is not considered a ceiling. However, the USA does not accept the use of a threshold. The ACA (Obamacare law) specifically forbids the use of cost per QALY as a threshold [22].

In Spain, the figure of 30,000 euros became a reference and was proposed as a threshold for the cost per year of life (not per QALY) [23], but soon became a reference in the evaluation studies in Spain interpreted as Cost per QALY. Recently, a group of researchers advanced the debate about the CE threshold in Spain [24]. In summary, they raise two possible perspectives on what the threshold should represent: (i) the monetary valuation of society on health benefits; that is, how much society is willing to pay for health; and (ii) the calculation of the opportunity cost of introducing new technologies; that is, health losses resulting from diverting health funds to finance new interventions.

The aim of the abovementioned report was to explore the second perspective, to estimate the average opportunity cost of health financing decisions in the Spanish context. The cost per QALY currently operated by the Spanish National Health System (SNS) offers an approximation of this opportunity cost and serves as a guide to setting the cost-effectiveness threshold in fixed budget contexts. The results show that the average cost per QALY in the SNS is approximately €21,000 to €24,000 [24]. The interpretation of these figures is that the SNS should not approve the introduction of any intervention with a cost/QALY above them. However, this value does not incorporate the preferences of the population, an aspect that is derived from the estimation of the monetary valuation of health by society. Currently, the group is carrying out a study of the 'willingness to pay' (WTP) for health using DC modelling.

In England, since 2009, some exceptions have been established that violate the cost/QALY threshold by applying a rescue rule; that is, a weighting for end-of-life treatments: selected terminal patients according to evidence of survival of at least 3 months compared with alternative treatments. The weighting can reach up to 2.5 times the threshold; that is, up to £50,000/QALY. Regardless of this weighting, this prioritisation criterion still results in low access to new, expensive drugs in the UK. In particular, the use of cancer drugs approved after 2004 in the UK reached only 41% of the average use in five countries (France, Germany, Italy, Spain and the UK).

At that time, the UK Government considered going one step further and applying the value-based pricing (VBP) criterion, whereby the prices of new drugs should better reflect the clinical and therapeutic value for patients throughout the UK [25,26]. Thus, a higher cost/QALY could be applied for drugs that treat burden of illness in terms of quality and quantity of life, and/or demonstrate broader social benefits (wider societal impact), such as the ability to return to work or contribute to society, which will be a function of age, sex, disease and quality of life. After appraisal for these new criteria, NICE kept the weighted threshold unchanged, which remained at £50,000/QALY.

In 2010, the UK government, aware of the problem of access to new, expensive drugs, decided to temporarily establish a separate fund to specifically finance cancer drugs not yet evaluated or not recommended because they were not cost effective from the NICE point of view: the cancer drugs fund (CDF). Its endowment: £50m in 2010/2011, rose to £200m over the next 3 years and went up to £280m in 2014/2015 and £340m in 2015/2016, the expected completion date and replacement by a new method of establishing VBP [27]. Despite this, the CDF has exceeded its allocated budget each year since 2013/2014. Furthermore, even though two reprioritisation exercises were undertaken, the final outturn position for 2015/2016 was £466m, an overspend of £126m (37%).

A new CDF came into operation in June 2016. From then, all new systemic anti-cancer therapy drug indications expected to receive a marketing authorisation will be appraised by NICE following Ministerial referral. The NICE recommendation of a new cancer drug to be used within CDF will happen when NICE considers there to be plausible potential for a drug to satisfy the criteria for routine commissioning (the usual NICE weighted threshold), but where there is significant remaining clinical uncertainty [28].

The above examples of end-of-life weighting and CDF assume that society values some health situations differently from others. But this might not be true. A recent study was carried out in England regarding preferences about funding life-extending end-of-life treatments that would not meet the reimbursement criteria used for other treatments. The choice tasks involved asking respondents which of two hypothetical patients they would prefer to treat, in case the resources only allowed treating one. Results showed that choices were more influenced by the size of treatment gains than by a patient's life expectancy without treatment. Overall, the authors found little evidence that members of the general public prefer to give higher priority to life-extending end-of-life treatments than to other types of treatment [29]. If this result were representative, then it would show a clash of views between the general public and the regulators, which is somewhat against the principle of CEA's respect for individual preference. A study conducted in Spain [30] suggests that QALYs for end-of-life treatments are more valued than those affecting temporal health problems, and that people discriminate between different health gains in treatments at the end of life, giving greater value to palliative care than to the extension of life.

Beyond Quality-Adjusted Life Years

A QALY is a measure of effectiveness where the quality adjustment is based on health-related aspects of quality of life. However, some people feel that the existing measures of HRQoL might not capture important benefits of treatments beyond HRQoL, such as independence or improved relationships with friends, family and carers [31].

Moreover, there is an increasing recognition of the need to make decisions that may impact on a number of sectors, such as social care and public health, where interventions may have outcomes and effects other than on health. However, different measures are used in healthcare, social care and public health, making it difficult to compare across these sectors, which is important when thinking about the wider health and social care budget. Research is needed to develop new tools to assess quality of life that are equally relevant across these sectors, and to capture the key things – not just health – that are important to people [31].

There are a number of proposed sector-specific tools available in social care, such as the Adult Social Care Outcome Tool (ASCOT) [32]. The ASCOT measure is designed to capture information about an individual's social care-related quality of life (SCRQoL). The aim is for the measure to be applicable across as wide a range of user groups and care and support settings as possible. The problems of integrating HRQoL from different perspectives can be illustrated by looking at the domains of ASCOT. There are two types, for user and carer perceptions: (i) the user SCRQoL domain: control over daily life; personal cleanliness and comfort; food and drink; personal safety; social participation and involvement; occupation; accommodation cleanliness and comfort; dignity; and (ii) the carer SCRQoL domain: occupation; control over daily life; self-care; personal safety; social participation and involvement; space and time to be yourself; feeling encouraged and supported.

In public health there is no single measure, but there are a number of broader measures that could be used. These include measures of wellbeing, such as the preference-weighted ICECAP capability index [33], and Personal Wellbeing, such as the ONS-4 [34]. However, the use of wellbeing measures is currently limited: They rarely produce a cardinal measure of output, and they are not anchored on the 'zero to one' scale so the relationship between dimensions cannot be modelled. This is a crucial limitation as a scale since covering death and good health/wellbeing is essential for quality-adjusting survival duration whether it is health or wellbeing.

The above problems of integrating outcome measures are encouraging new research in the development of new measures in a conceptual framework where a broader notion of quality of life is considered. Subjective wellbeing, that is, happiness and life satisfaction, can be of great value to patients and should be included in the economic evaluation of interventions, especially when there is not an expected improvement in health. This would mean moving towards measures of experienced utility (as described by the patients) from the usual measures, such as QALYs, obtained from the general public.

Recently, 10 main approaches for future research have been explored as alternatives to the health-related QALY to address the problem of using multiple outcome measures to inform resource allocation within and between sectors [35]. These have been classified under three headings going from minor adjustments to current methods to options that depart in more radical ways from the health-based QALY: those looking to extend the existing health-related QALYs, those using wellbeing and those using money to value outcomes.

The first line would be to extend the QALY beyond health, which could be approached in three ways: (i) statistical mapping to EQ-5D; (ii) bolting on to EQ-5D; and (iii) valuing on a common scale using preferences. We have already commented on the first two. The third way – valuing on a common scale using preferences – would mean working out a

common yardstick from a choice-based valuation technique where the upper anchor is not instrument specific. Time trade-off (TTO) has been used to get values for EQ-5D and ASCOT, but the upper end is not comparable: EQ-5D best state (no health problems) and ASCOT best state (meeting social-care-related needs). To get a common measure using TTO, one possibility would be to describe the upper end of the scale in more general terms such as ‘best imaginable state’ [35].

The second line, which uses wellbeing to value outcomes across sectors, could be approached by valuing by association with wellbeing measures, developing a wellbeing-adjusted life-year (WELBY) and through direct valuation of one’s own health or wellbeing states. Again, there is a problem with the metrics to be used in the term ‘wellbeing’. Several measures of wellbeing are used but do not map easily onto QALY measures. For example, in mental health, Johnson et al. [36], using the Warwick-Edinburgh Mental Well-being Scale and the EQ-5D-3L, conclude that the earlier maps onto the later, but only to a limited extent. The levels of mental wellbeing varied greatly amongst participants who had the maximum score on the EQ-5D-3L. As a result, they propose a measure – Wellbeing Adjusted Life Year – to evaluate the relative effectiveness of interventions that impact on mental wellbeing.

Finally, the third line would be to use money to value outcomes with several options, such as public sector implied WTP, contingent valuation using WTP (welfarist) and societal WTP (non-welfarist) and also monetarise health and other outcomes using experience. As the authors note, any choice between this list of approaches involves important political decisions about what counts in measuring the benefits of interventions. One way to incorporate public WTP in CEA under uncertainty is through the acceptability curves, which show the probability for the intervention under the evaluation of getting an incremental net benefit as a function of the public WTP for the effectiveness (QALY) [37]. Individual and societal WTP from contingent valuation studies would capture the whole value of health gains; however, they may be biased by the ability to pay.

Equity Criteria Not Captured by Cost-Effectiveness Analysis

CEA, the main approach to establishing a health priority setting, addresses only the objective of health maximising, but equity and financial protection have no doubt important implications in prioritisation in healthcare. There is a rich literature on the incorporation of equity in economic evaluation in healthcare (see, e.g., Johri and Norheim) [38]. However, there is still a lack of a systematic consideration of which normative criteria of equity should be included, and how to deal with the multiplicity of concepts and values involved in equity.

A group of academics from diverse disciplines, and decision makers, elaborated a guide on priority setting in healthcare to consider equity criteria not captured by CEA that could be relevant in addition to CEA [39]. The idea concerning distribution is that every person in society should have a fair chance to live a long and healthy life, following the fair innings definition by Williams [40]. The purpose is that decision makers consider these equity criteria alongside CEA when making decisions on funding and refusal interventions. Although the original purpose was to help in low- and middle-income countries, the guidance is relevant in all settings once it is aligned with the social values of the

specific country. It is an explicit view of the efficiency equity trade-off and a good example of the interdisciplinary task of prioritisation.

The Guide (Guidance for Priority Setting in Health Care) adopts the form of a checklist and proposes three main groups of criteria that capture the social values concerning health maximisation, health distribution and financial protection. These are summarised in Table 1: Group 1 refers to the disease-related criteria; Group 2 are criteria related to the characteristics of social groups; and Group 3 incorporates criteria related to protection against the financial and social effects of ill health.

Looking at disease-related criteria, diverse methods have been applied in recommendations by agencies such as NICE, for example, adjusting CEA ratios by severity of disease, present and future, and giving an extra value to interventions for particularly severe health conditions as the abovementioned end-of-life weighting in the UK. Limited potential for improvement that CEA would not consider, given its utilitarian basis, might be an important additional variable. It would probably be considered unfair not to take into account that some patients with a severe chronic disease will never be prioritised in interventions for acute processes that affect them and other people without the chronic conditions. An example could be the assignment of a kidney to two end-stage renal failure patients, one with a chronic comorbidity, say schizophrenia, and the other one without the chronic condition. CEA would propose giving the kidney to the patient without comorbidity since, on utilitarian grounds, this assignment would get more QALYs. This is a probable outcome in our developed societies that seem to be more utilitarian than egalitarian. However, a more egalitarian society would give – *ceteris paribus* – a similar chance of receiving the organ to both patients. The important question here is to know the values of the society implied in the prioritisation and being explicit in showing the effects of the alternative decisions. Our classroom and pilot exercises on this shows that people in our society are basically utilitarian.

Criteria related to characteristics of social groups concentrate on equity weighting of the results of CEA that proposes that society sometimes is willing to sacrifice QALYs to benefit some social groups to reduce inequalities. Group 3 refers to some specific costs and effects in CEA and offers a note of caution when incorporating them into the analysis: changes in productivity, informal care and catastrophic illness. Interestingly, these are three items usually contemplated in CEA.

Concerning changes in productivity, the Guide reminds the ethical problem of introducing market productivity that discriminates against those who are out of the market, such as the retired and the disabled. The introduction of lost productivity in CEA has been always challenged not only for these ethical considerations, but also for the possibility of double counting if preference assessments techniques to derive QALYs already contain productivity losses. A recent revision of the issue has recommended incorporating lost productivity in the numerator of the cost effectiveness as a cost [4]. The authors argue that current measures of preference do not capture the impact on productivity losses, so they should be treated as a cost in CEA.

The informal care costs constitute a relevant element of costs in societal perspective in CEA. The Guide reminds the analyst and the decision makers that affected people could also be carers (parents, etc.) so there is an additional benefit of the interventions over these people.

Finally, that catastrophic illness can lead to poverty is a reality in healthcare systems without universal healthcare coverage, and this should be taken into account since financial protection does matter.

This important guide can be of great help as an aid to decision makers' deliberations in their need to prioritise what matters most. However, relying only on a set of criteria does not help to measure the extent of inequities and the weighting procedure to consider them. We need to go a step further and design methods to jointly incorporate criteria. Multiple criteria models try to solve this problem.

Table 1. Guidance for priority setting in healthcare (Norheim et al. 2014 [39]).

Group 1: Disease and intervention criteria	
Criteria	Question
Severity	Have you considered whether the intervention has special value because of the severity of the health condition (present and future health gap) that the intervention targets?
Realisation of potential	Have you considered whether the intervention has more value than the effect size alone suggests on the grounds that it does the best possible for a patient group for whom restoration to full health is not possible?
Past health loss	Have you considered whether the intervention has special value because it targets a group that has suffered significant past health loss (e.g. chronic disability)?
Group 2: Criteria related to characteristics of social groups	
Criteria	Question
Socioeconomic status	Have you considered whether the intervention has special value because it can reduce disparities in health associated with unfair inequalities in wealth, income or level of education?
Area of living	Have you considered whether the intervention has special value because it can reduce disparities in health associated with the area of living?
Gender	Have you considered whether the intervention will reduce disparities in health associated with gender?
Race, ethnicity, religion and sexual orientation	Have you considered whether the intervention may disproportionately affect groups characterised by race, ethnicity, religion and sexual orientation?
Group 3: Criteria related to protection against the financial and social effects of ill health	
Criteria	Question
Economic productivity	Have you considered whether the intervention has special value because it enhances welfare to the individual and society by protecting the target population's productivity?
Care for others	Have you considered whether the intervention has special value because it enhances welfare by protecting the target population's ability to take care of others?
Catastrophic health expenditures	Have you considered whether the intervention has special value because it reduces catastrophic health expenditures for the target population?

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Multiple Criteria Decision Analysis

In 2014, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) established an Emerging Good Practices Task Force, charged with the objectives of establishing a common definition for multiple criteria decision analysis (MCDA)

in healthcare decision making and developing good practice guidelines for conducting MCDA to aid healthcare decision making [41,42].

MCDA is a set of methods and approaches to aid decision making, where decisions are based on more than one criterion, which makes clear the impact on the decision of all the criteria applied and the relative importance attached to them. Examples of criteria relevant for decision making in healthcare include incidence, prevalence, severity of disease, the population group affected, the availability of alternative technologies, the quality of available evidence and the contribution of the technology to innovation [43,44].

MCDA makes the criteria and its relative importance clear in priority setting and admits multiple approaches, both technical and non-technical, with different levels of sophistication. However, common to all of them, is to reach replicability (i.e. in identical situations of evidence and social value judgments, the same decision would be made) and transparency (i.e. all factors taken into account are evident to observers outside the process).

Concerning the methods used, there are two possible final outcomes of MCDA: the aggregation of information on criteria into a single expression of value, a summary index, and a wider view allowing criteria to be assembled in a 'performance matrix' to support deliberation without the need for aggregation.

Weighted-sum or value measurement models involve constructing and comparing numerical scores to identify the degree to which one decision alternative is preferred over another. 'They most frequently involve additive models which multiply a numerical score for each alternative on a given criterion by the relative weight for the criterion and then sum these weighted scores to get a "total score" for each alternative' [41]. Most of the applications of MCDA in healthcare are of this type. They allow alternative decisions to be ranked from most to least preferred as a function of the value achieved for the policy objectives.

Different theories support model building in the measurement models. Among them are: multi-attribute utility theory, multi-attribute value theory, outranking, weighted goal and lexicographic goal programming (for a description of the theoretical foundations, see Regier and Peacock) [45]. These authors conclude that there is a paucity of theory-related research in healthcare and encourage further research on MCDA methods that best address stakeholders' needs.

Although there are many differences in the ways in which these models are used and applied, there are several main elements of the process that are common among these methods: defining the decision problem being addressed, selecting the criteria, measuring alternatives' performance, scoring alternatives and weighting criteria, aggregation, uncertainty analysis and the interpretation of results. Table 2 shows the eight steps in a value measurement MCDA process and their description.

Of these steps, scoring and weighting are the ones that try to capture priorities and preferences for criteria of the involved stakeholders; weights capture preferences between criteria, while scores capture preferences in a criterion. DC analysis and direct rating (DR) are some of the methods used in healthcare.

To illustrate with an example, we comment on a pilot study we ran on priorities in a surgical waiting list through the voice of the general population (stakeholders). To identify which clinical and social characteristics should be used to prioritise patients on the waiting list for elective surgical procedures, a DC experiment was conducted using

Table 2. Steps in a value measurement MCDA process (Thokala et al., 2016 [41]).

1. Defining the decision problem: identify objectives, type of decision, alternatives, stakeholders and output required
2. Selecting and structuring criteria: identify criteria relevant for evaluating alternatives
3. Measuring performance: gather data about the alternatives' performance on the criteria and summarise this in a 'performance matrix'
4. Scoring alternatives: elicit stakeholders' preferences for changes within criteria
5. Weighting criteria: elicit stakeholders' preferences between criteria
6. Calculating aggregate scores: use the alternatives' scores on the criteria and the weights for the criteria to get 'total value' by which the alternatives are ranked
7. Dealing with uncertainty: perform uncertainty analysis to understand the level of robustness of the MCDA results
8. Reporting and examination of findings: interpret the MCDA outputs, including uncertainty analysis, to support decision making

MCDA = multiple criteria decision analysis.
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a representative sample of the general population in Navarre (Spain) (Step 1). After revision of the literature, an initial list of 12 criteria or attributes was built and 5 were selected as a result of a survey to colleagues in our department: (i) problems in the patient's current health status before the intervention; (ii) improvement in health that the patient can obtain due to the intervention; (iii) costs borne by the Health Service for the intervention; (iv) age in patient years; and (v) waiting time for surgical intervention (Step 2). Each attribute had five levels. Respondents had to make choices between pairs of a combination of attributes and levels (1024 possible combinations) and 16 hypothetical patients (choice sets) were selected for the direct elicitation (DE) exercise (Steps 3 to 5). Data were analysed using Bayesian methods (Step 6). The relative weights of attributes showed that the most important attributes when prioritising patients were the disease relevance, the cost of the intervention and the waiting time. Severity of illness was the most important attribute and, contrary to prior expectations, improvements in health were considered less important. These findings showed that prioritisation according to waiting time alone may not take into account other issues that matter to the general public. An interesting finding was that cost was considered an important prioritisation criterion. This study provided a further example of the potential of discrete choice experiments (DCE) in prioritising in healthcare. Although DC has several limitations, this tool may be useful to develop prioritisation scoring systems for patients on waiting lists [46].

DR scores and weights by DE, lead to an interval scale. EVIDEM is a framework for direct elicitation used in HTA. EVIDEM is an open-source framework resulting from a collaboration of experts and stakeholders, which comprises a broad range of decision criteria, allowing the capture all elements of value relevant to patients, health-care systems and society [42,47]. Criteria can be weighted to reflect their relative importance from different perspectives, can be used for scoring the intervention, and can be combined to derive a composite measure of the intervention's value.

The framework includes a set of 13 “core” criteria grouped into five domains: (i) need; (ii) comparative outcomes; (iii) type of benefit; (iv) economic consequences; and (v) knowledge about the intervention.

(i) Criteria for need domain are three: disease severity; size of affected population; unmet needs, with scoring scales each ranking from 5 (very severe, very common disease and serious unmet needs, respectively) to 0 (not severe, very rare disease and no unmet needs, respectively).

(ii) Criteria for comparative outcomes are also three: effectiveness, safety/tolerability, and patient-perceived health, with scorings between 5 and < 5 (5 much better than comparator, < 5 much worse than comparator).

(iii) Criteria for type of benefit are two: type of preventive benefit and type of therapeutic benefit, scoring from 5 (elimination of disease, cure/lifesaving, respectively) to 0 (no reduction of risk of disease; no therapeutic benefit, respectively).

(iv) Criteria for economic consequences are three: cost of intervention, other medical costs, and non medical costs, with scoring from 5, substantial savings, to < 5 substantial additional expenditures.

(v) Criteria for knowledge about the intervention are two: quality of evidence and expert consensus, with scores ranking from 5 (high relevant and valid, and strong recommendation vs other alternatives, respectively) to 0 (not relevant or invalid, and not recommended, respectively).

The EVIDEM framework also comprises seven qualitative criteria to capture contextual factors: (i) mandate and scope of healthcare system; (ii) population priorities and access of healthcare system/plan; (iii) common goal and specific interests; (iv) environmental impact; (v) opportunity costs and affordability; (vi) system capacity and appropriate use of intervention; and (vii) political, historical and cultural context.

EVIDEM is recognised as a useful tool in healthcare decision making, but has some notable limitations: anchoring using categorical scales might result in loss of information if the relationship between criteria and scores is continuous; also, criteria weights are elicited independently of the performance being evaluated [48].

EVIDEM has been applied and tested in the context of HTA decision making in a number of jurisdictions, including Canada [49] and, more recently, Spain [50], where the HTA body in Catalonia has been exploring the framework for the appraisal of orphan drugs.

The process of selecting criteria for priority setting in healthcare in practice: The case of Sweden

Some countries start the process for priority setting in healthcare by establishing a set of principles as the foundation of priorities in the philosophical, medical and economic spheres. Some try with only one criterion, such as that of severity of illness in the case of Norway; however, in general, combinations of criteria are used. Sweden’s current model – the National Model for Transparent Prioritisation – illustrates these processes well. It begins with the parliamentary task of ensuring that a greater proportion of resources are allocated in an appropriate and efficient way to the attention of those who need it most, enabling and facilitating transparency in prioritisation. Next, an ethical platform consisting of the principles of human dignity, need-solidarity and cost effectiveness is defined.

The first principle – the broadest – states that all individuals have the same value and the same rights, regardless of their personal characteristics and role in society. The personal characteristics that could affect the specific needs or the effects of the interventions will be considered in the prioritisation between groups. The principle of need takes into account the severity and expected outcome of the interventions. The severity level is based on the current state of health, the risk of disease and the duration of illness. The effectiveness of interventions includes both positive and negative effects (e.g. the risk of complications). The combinations of severity and effectiveness are ranked on a scale of values: very high, high, moderate and low. The criterion of cost effectiveness is inserted in this scale: cost per unit of very high, high, moderate and low effect. This exercise is performed in each of the selected priority areas (organisation, patient groups, etc.) depending on the objective pursued, be it rationing, the introduction of new technologies or the disinvestment of ineffective methods. The next step is to establish an order based on a qualitative weighting of severity, the benefit to the patient, the cost effectiveness and the quality of information, establishing up to 10 levels. Pairs of morbid conditions – highest priority intervention (1 on the scale) – indicate that health services should allocate more resources to them and ensure that action is taken. Those of lower priority in the scale should only receive resources if the ones with the highest priority are covered, and certain interventions should cease to be offered if they do not show effectiveness, a high level of risk or incidences of adverse effects in relation to expected benefits, independent of the availability of resources [51].

Deliberation, one way to value-based priority setting

Priority setting in healthcare is a value-laden activity. Decision makers have different sets of values and objectives, plus conflicting criteria that force them to trade off efficiency, equity, social sensitivity and social opportunity. Input for decisions can come from multiple stakeholders. Belton and Stewart [52] offer a list of possible stakeholders: Representatives from government, key decision makers at institutions, clinicians, healthcare professionals, patients, the lay public or drug (technologies) developers. The inclusion of stakeholders and their role is at the discretion of the decision makers.

Stakeholders often justifiably disagree about the relative importance of criteria. Baltussen et al. [53] propose the use of ‘evidence-informed deliberative processes’ to explicitly recognise priority setting as a political process and an intrinsically complex task. ‘In these processes, deliberation between stakeholders is crucial to identify, reflect and learn about the meaning and importance of values, informed by evidence on these values.’

Patients and the lay public as potential or experienced patients are, in the end, the protagonists of the prioritisation exercise, and their role cannot be underestimated. It is worth noting the creation of discussion groups in the UK, in the form of citizen juries and citizen councils, to give opinions on the definition of the need for treatment or in the role of age in clinical decisions. Based on the assumption that, with enough time and information, any person can be competent in decision making, these representative groups of the population in their geographic scope were created; they receive evidence from people who are knowledgeable about the subject and make recommendations for the authorities who must reason their refusal not to follow them, if any. Also, the routine

incorporation to the clinical records of the Patients Reported Outcomes will allow the voice of patients to emerge. The healthcare system needs informed patients, which will clearly add experience and value to the priority-setting process.

Conclusion

Evidence that the establishment of a framework of values for prioritisation has had an impact on health policy and that prioritisation exercises have led to the ideal of participation in decision making is still scarce. Principles in abstract do not have much influence on policy. Occasionally there is a conflict between criteria; the resulting rankings are not always operational at the individual level; there are conceptual and practical problems in defining need; and there is resistance to removing services from the guaranteed care package. Cases of success occur in countries that developed recommendations for clinical guidelines, such as the UK with NICE. The future of prioritisation in times of budgetary constraint lies in ensuring that these processes are solidly evidence-based and transparent [54,55].

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CHAPTER 4

Which Evidence from Health Technology Assessment Analysis is Required for Prioritisation and Decision Making?

Iñaki Gutiérrez-Ibarluzea

Summary

Since its inception, health technology assessment (HTA) has been a multidisciplinary and multidimensional approach to help health decision makers choose where to invest or disinvest when different alternatives are available and rational use of resources is crucial. Obviously, HTA has evolved and refined its methods to try to answer complex questions in which other compounds that are different to clinical aspects have even greater impacts on health and wealth outcomes. On many occasions, evidence on organisational, ethical, legal or social aspects related to the context in which the technology will be implemented is critical to recommend or not the implementation or deletion of that technology, or to prioritise where to spend the budget within a concrete healthcare system. In recent decades, different models have been proposed to determine the value of, and compare, different health technologies in order to prioritise them. While in most cases decisions are taken on the basis of non-explicit criteria, different models or methodologies have been proposed to supersede this. Transparency, replicability and robustness are the pillars of those models. Even so, the authors of those models admit that context determines preferences and priorities, and thus, models should be adjusted accordingly, while ensuring transparency and evidence-based decision making. Although they are not widely implemented, economic models, and in particular, the incremental cost-effectiveness ratios, have been the best known and discussed. These models are attractive by themselves as they include two components of the equation: On the one side the benefits (measured in different ways) and on the other side, the costs. Furthermore, they offer a quantitative approach to the problem. In this regard, health systems and international organisations, including the World Health Organisation (WHO), have proposed thresholds to determine what is fair to pay for a concrete technology and what is not. Nevertheless, these models have been criticized by different authors as they fail to capture all the dimensions of value. Other proposals have gained importance over the last decade to overcome these issues and include the preferences and priorities of the different systems and contexts. Among

them, the multi criteria decision analysis and the INTEGRATE-HTA project's suggested methodologies have been the last to be proposed and debated. Within this chapter, the difference between the prioritisation of topics to be evaluated and the prioritisation of technologies to finance will be addressed. Finally, methods to measure value and their relation to HTA evidence generation will be discussed.

Health Technology Assessment, Definition and Role in Decision-Making Processes

Health technology assessment (HTA) is a multidisciplinary political analysis that tries to assist decision makers by providing information on health technologies and their value. HTA by definition is *'the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies'* (HTA glossary, 2017; <http://htaglossary.net>). It has been typically linked to the next hurdle to be surpassed once a technology has reached the market, and linked to the analysis of the economic aspects related to the technology and its implementation in healthcare systems. However, health technologies are broader in their characteristics and scope than medical devices and drugs. Technology is knowledge integrated and devoted to solve problems, and health technology specifically refers to *'an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program or system'* (HTA glossary, 2017; <http://htaglossary.net>). According to this definition any intervention used by a health system is a matter of analysis and under the scope of HTA. Furthermore, HTA, broadly used to inform reimbursement decisions, is evolving in order to capture the complexity of the health technologies that have been analysed and is exploring the value of these technologies along the different domains that define value, including those with intended and unintended consequences. This means that not only clinical and economic aspects are evaluated, but also health technology and systems-related organisational, ethical, legal and social aspects are increasingly included in HTA evaluations.

HTA is used to define which health technologies should be included, while carrying out evidence-based assessments. New technologies are usually more costly than existing ones and contribute to rising health costs. HTA ensures that a new health technology is not added until it is proven to have value. Meanwhile, an existing technology is not removed from the health package until it is shown to have no value or less value than others. HTA is also concerned with ensuring quality, improving adequacy in practice and reducing irrational variability in practice.

HTA has also captured the interest of many countries all over the world, not only as a way of ensuring sustainability in budget constraints or finite budget situations, but also in those cases that aimed to ensure universal health coverage (UHC). In fact, the 67th General Assembly of the WHO approved a resolution encouraging member countries to implement HTA activities to ensure UHC (WHA67.23 – Health Intervention and Technology Assessment in Support of Universal Health Coverage. <http://apps.who.int/medicinedocs/en/d/Js21463en/>). This resolution concludes, among others, that it is crucial: *'to integrate health intervention and technology assessment concepts and principles into the relevant*

strategies and areas of work of WHO, including, but not limited to, those on universal health coverage, including health financing, access to and rational use of quality-assured medicines, vaccines and other health technologies, the prevention and management of noncommunicable and communicable diseases, mother and child care, and the formulation of evidence-based health policy. This policy was ratified in the 69th Assembly in which a proposal formulated by different non-governmental organisations (NGOs), in official relations with WHO, approved the implementation of HTA units or agencies in member countries. The same resolution stated around the priority setting processes in member states that they need *‘to consider establishing national systems of health intervention and technology assessment, encouraging the systematic utilization of independent health intervention and technology assessment in support of universal health coverage to inform policy decisions, including priority-setting, selection, procurement supply system management and use of health interventions and/or technologies, as well as the formulation of sustainable financing benefit packages, medicines, benefits management including pharmaceutical formularies, clinical practice guidelines and protocols for public health programmes*’. Moreover, the Panamerican Health Organisation (PAHO) was a pioneer and went further in its recommendations around the use and utility of HTA in the 28th Sanitary Conference in Washington DC, 2012 (http://www.paho.org/hq/index.php?option=com_docman&task=doc_view&Itemid=270&gid=26539&lang=en). PAHO urged Member States in its resolution CSP28.R9 to: *‘establish decision-making processes for the incorporation of health technologies based on HTA, which may include safety, effectiveness, cost, and other relevant criteria and the use of HTA to inform public health policies, including public health system coverage decisions and the development of clinical guidelines and protocols for new technologies*’.

Regarding priority setting, the same resolution concludes that Member States should: *‘encourage the **prioritisation of assessments** based on national and regional needs, strengthening systems for the collection of quality data, and adapting existing HTA studies to avoid duplication*’.

Here, we can differentiate between priority setting for the inclusion or exclusion in a benefit package or under the coverage and payment of a health system, and priority setting to decide which technologies should be evaluated and why. The first question has a broader perspective and relates to systems’ decisions; the second relates to HTA scoping and the capacity to evaluate. In fact, there are millions of existing health technologies applicable in healthcare as well as a constant flow of new technologies claiming for market access. For emerging, existing and/or obsolete technologies, the benefits for the population vary greatly, as do the impacts and healthcare costs. In all countries (not just high income countries), healthcare budgets are finite and cannot (and should not) afford to fund everything. In addition, some technologies provide minimal benefit and can even be harmful. There is a need to say (i) to manufacturers (industry) that not all the technologies will be implemented or at least not in all countries and at their desired prices; (ii) to healthcare systems that not all the technologies provide value, and thus, it is not worth paying for them; and (iii) to patients that not all the technologies will be available, and thus, they will need to decide, in accordance with the society, where the money will be invested and why.

The aforementioned resolutions by WHO and PAHO have shown that HTA can be a useful and practical way to assess the intended and unintended effects of health technologies; however, no HTA organisation has the resources to assess every possible topic. Therefore, topics waiting to be undertaken as HTA reports must be prioritised according to realities, such as (i) the value framework by which technologies are judged in the

country, region or hospital in which the HTA organisation is established; (ii) the capacity and expertise of the HTA organisation's staff members; (iii) the volume and urgency of requests flowing in from the clients (healthcare decision-makers); (iv) the current workload of the organisation; and (v) the types of HTA reports to be generated (brief vs lengthy, rapid response vs longer, etc.).

Priorities in Health and Priorities for Evaluation

Before going ahead on this chapter, the difference between the establishment of general priorities in health systems and the prioritisation of evaluation needs should be borne in mind. The first must be based on the epidemiological and health status of the country, the best available information, the general principles and preferences of the country, the system and its citizenship and the basis of its capacity to face the economic and social benefits of the endowment. The second has to meet the priority needs for information and, therefore, evaluation. Hence, although they may be overlapping, the overall priorities for establishing the services and the criteria used do not always coincide with the needs and criteria for evaluation. We would talk about priorities to determine services on the one hand and priorities for evaluation on the other. In fact, a service may not need to be evaluated if there is sufficient evidence and no controversy, and the country wants to endow it and can afford it. On the other hand, non-priority but controversial services of high social or economic impact may require a prioritised assessment to provide sufficient information to support a robust and transparent inclusion or exclusion decision [1].

In order to analyse the role of HTA in the decision-making process, it is necessary to understand the methods to elaborate an HTA project. It comprises several steps that include: Scoping, identification, filtration, prioritisation, evaluation, review, dissemination and information renewal or reassessment (see Figure 1).

Topic management is a three-step process that embraces identification, filtration and prioritisation. This depends on some other variables, such as: (i) what is the purpose of the HTA system?; (ii) who do you want to report?; (iii) what does the customer expect from the system (and what not)?; (iv) what kind of products and information are required?; and (v) what is the scope of the HTA system?

What is the purpose of the HTA system?

HTA organisations could have just one or more purposes including (i) the identification of new and emerging health technologies for their subsequent evaluation and their incorporation into the corresponding health systems; (ii) reports on evidence gaps that require primary research to inform decisions; (iii) the planning of HTA programs, research programs, government priorities, resource needs; (iv) the analysis of the variability in clinical practice to identify areas of inefficiency and adequacy in order to determine the standards that provide value and good allocation of resources and; (v) the disinvestment of unsafe, ineffective or low added-value practices from the health systems. These tasks will define the target or targets of the HTA unit and will determine its priorities.

Who do you want to report?

In any system the client is critical. Typically, HTA units were devoted to informing governments at a regional or national basis, even though the first unit to be established in Europe was implemented at a hospital consortium in France (*Assistance Public Hospitalaux*

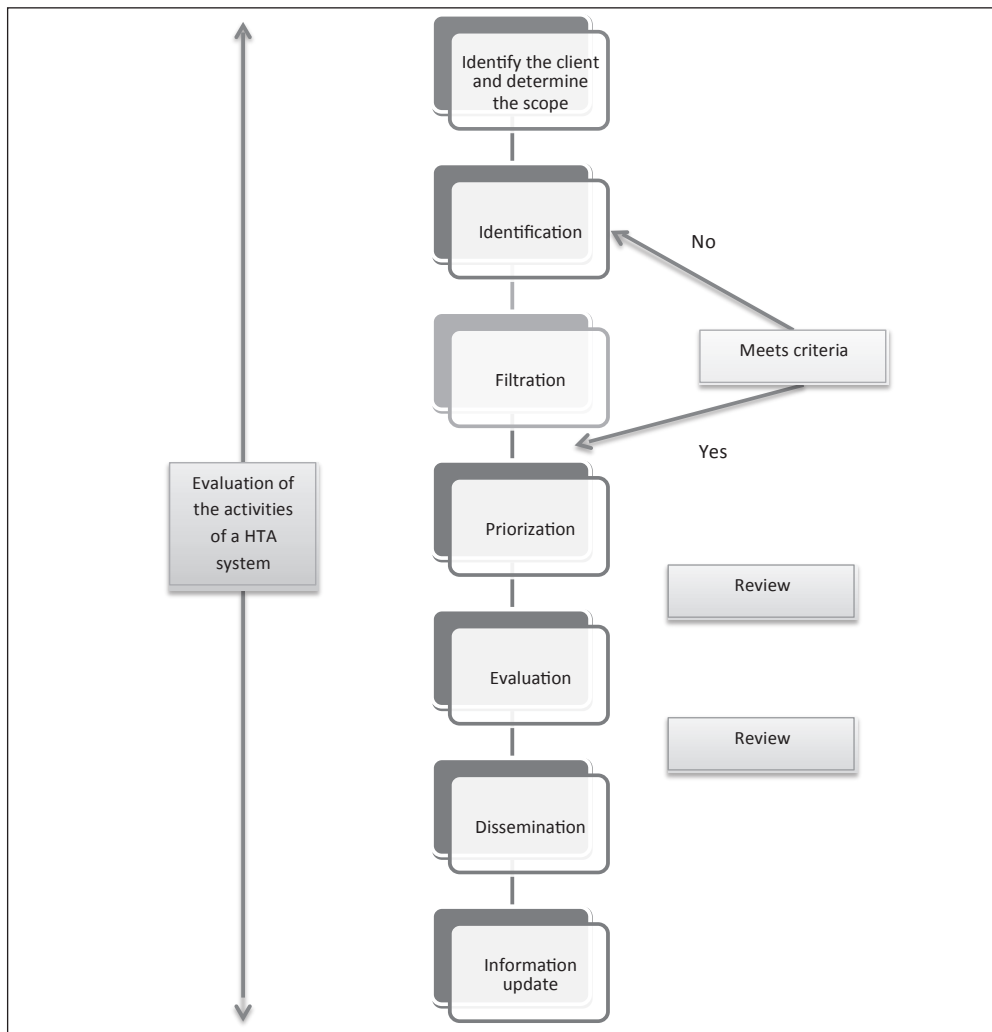


Figure 1. Main stages involved in HTA process.

du Paris – CEDIT) by the administration with the aim of supporting hospital managers in the management of health technologies. This trend of establishing units at the hospital level and establishing priorities within those premises have become more popular in the last decade and generate interest to decision makers at different levels, including funders of the European Union that promoted the project AdHopHTA (<http://www.adhophta.eu/>) in order to analyse the characteristics of those systems and to propose methodologies to implement hospital-based HTA units. Subsequently, there is a clear drift to establish HTA units closer to decision makers at any level of decision. This has proposed two main challenges to classical HTA: On the one hand, to move from a narrow perspective around value measurement as the next step after market-authorization; and on the other hand, the need to refine and/or adapt the language to the requirements of the new clients.

Current potential stakeholders of an HTA unit include health policy makers, commissioners, purchasers, healthcare providers/social care providers, reimbursement agencies, other HTA agencies, commissioners of research, patients and patient organisations, citizens and society. These new clients have required a refinement in the methods to deal with the complexity of the analysis, especially in the case of other technologies different to drugs and the adaptation of the language, the length of the reports and the dissemination media to address the characteristics and needs of these stakeholders.

What does the customer expect (and not expect) from the system?

Another crucial point to determine the requirements and priorities of an HTA system is what is expected by the customer and what the compromise of the system is. At the very beginning, HTA systems should state the profoundness of the analysis, the number of reports, the frequency and the time when they will be delivered, and the confidentiality or accessibility of these reports. They should also reflect the skills and knowledge of the potential clients, and the different aspects should be arranged with them.

What kind of products and information are required?

HTA provides information to different health technologies during their life cycle, and thus, the available information about them can be diverse. As a matter of fact, drugs are well regulated in most countries and information on safety, efficacy and costs is easily retrieved from trials because they are required by regulatory bodies. However, direct comparisons of new drugs against standards of practice in most of the countries, regions or even hospitals is lacking as it is not mandatory for market access. Similarly, information around medical devices is scarce, and in many cases it is unavailable through common circles [2] and is lacking in the case of procedures, programs or public health interventions requiring evidence from sources other than published journal articles. In many cases, evidence regarding different domains from clinical or economic ones is difficult to obtain from the scientific literature commonly used in evidence-based medicine and classical HTA. So, the systematic reviews approach should be combined with other sources of evidence when elaborating context-tailored HTA reports. The external validity of that information is low as they are part of the context characteristics; however, they give tremendous insights into the problems that may need to be resolved (including professional capacity, acceptability, affordability, ethical issues and legal problems) in the case of other systems. So evidence won't be directly transferred (poor external validity) but the structure of the analysis or the methodological approaches done to evaluate the technology could be useful when considering other contexts. They will need to feed their analysis with their context evidences and systems' characteristics.

Usually, HTA units present different kinds of products ranging from full HTA reports to new and emerging technologies' information sheets. Likewise, some HTA units present Clinical Practice Guidelines. This wide range of products depend on three factors: (i) the expertise of the unit professionals; (ii) the amount of retrievable evidence; and (iii) the timeframe negotiated or agreed with the client. It is necessary to remember that

perfectly presented reports can have no impact on decisions if they are not delivered on time and to the correct stakeholder, or provide adapted information to the stakeholder.

Buxton's Law

In 1987, the health economist, Martin J. Buxton, stated his well-known law that applied to surgical procedures: *'It is always too early for rigorous evaluation (of a new technique) until, unfortunately, it is suddenly too late'* [3]. This insightful statement has been broadly used to describe the phenomenon that occurs in the introduction of new health technologies or procedures in medicine. There is a natural reluctance to subject new health technologies – currently called innovations – to methodologically standardized assessment too early in the introductory phase in an attempt to avoid negatively biased results while professionals' learning or capacity building is still occurring [4]. Characteristically, this phenomenon has been described as the **learning curve** and has most often been applied to surgery and medical imaging that require an operator's expertise, but it also applies in all types of health innovations with the argument that analysis is creating paralysis in the access to better and innovative ways of management. Buxton's worry was somehow justified, because by the time the health technology has a well-established standard of practice and it is widely used on patients, many patients would not receive the latest and perhaps the greatest benefit assigned to the health innovation. Whereas each argument, early assessment, or delaying access is separately valid, the combination is a perilous system to follow because it obviates rigorous evaluation and denies best practice.

Despite the challenges addressed by Buxton's law, the present 'status quo' isn't reasonable. Most systems mainly rely on a case series to assess and reimburse new surgical techniques and only on U.S. Food and Drug Administration or CE kite marking for new devices (rather than evidence based appraisal and formal regulation). This is, surely, absolutely inadequate. As many experts defended in a paper, CE marking does little more than guarantee that a device won't break or oxidize [2]. Two approaches have been proposed to overcome this. On the one hand is the IDEAL framework that takes an evidence-based approach. IDEAL is based on the UK Medical Research Council's recommendations on complex interventions, which provides a framework to develop and evaluate innovations through several iterative phases; to use experimental rather than observational research designs when feasible (while recognizing that they won't always be feasible or appropriate); to measure outcomes as well as processes; and to report detailed descriptions of interventions to improve reproducibility, evidence synthesis, and wider implementation [5]. On the other hand is the post-introduction observation model proposed by the Spanish HTA network REDETS [6], which is implemented in the Spanish National Health Care System for medical devices and surgical procedures. This also has been called the 'monitoring systems', which allow monitoring of the results of the technologies introduced in the Spanish National Health System to obtain practical and real information on the safety, effectiveness and efficiency of their use in real-world conditions.

What is the scope of the HTA system?

The HTA units around the world differ in their scope and the intensity of the analysis; this is partly due to the client or clients of the unit and to the scope of the HTA system. Not all the HTA units evaluate all the types of technologies. There are systems that are focused on drugs, while others evaluate any type of health technologies, including vaccines, medical devices and diagnostics, procedures, public health interventions and health programs. The type of technology evaluated and the decision level required to inform also determine the characteristics of the evidence to be retrieved.

Value Measurement and HTA Evidence Requirements

In order to determine the evidence requirements from HTA to establish priorities in healthcare systems, first of all we need to define what the value framework is that has been proposed, if any, in different countries or systems. In most cases, health systems propose an undefined framework for the decision-making processes, which means that although criteria are used, how those criteria are selected and combined, and how final decisions are reached remains unclear. Criteria, such as costs, budget impact, efficacy, safety, affordability, cost effectiveness – or some less-defined ones, such as innovative technology, added-value or contribution to supersede inequities or inequalities in health – are commonly found in the theoretical frameworks for decision making in most countries and systems. However, decisions are taken under the pressure of stakeholders and media, and the timeframe in which politicians and managers operate is short in many cases. Having said this, value frameworks that attempt to provide transparent, robust and structured processes for decision making have been proposed and they are increasingly considered by decision makers in order to make their decisions accountable and methodologically sound.

The economic approach to value framework and the role of HTA and decision makers

The implementation of economic models and economic analysis was a step ahead in most of the health systems in high income countries around the 1970s. At that time, and during the first oil crisis, sustainability was a must and was the focus to ensure the survival of most of the systems. The UK, US, Australia, Canada, Sweden, the Netherlands ... Many countries have tried to incorporate the cost-effectiveness approach into health investment decision making, but only England and Wales in the UK (not even the whole UK) and Ireland explicitly indicated a range to define a threshold. Actually, in Scotland cost-effectiveness or, better said, cost-utility analysis was only part of the varied sort of criteria used by the Scottish Medicine Consortium (<https://www.scottishmedicines.org.uk/>) to make its final decisions for the Scottish NHS.

Cost utility is very attractive as a way to measure and compare different health technologies. First, it incorporates a quantitative scale; second, it introduces in the same equation costs and benefits; and last, it allows comparing different alternatives for different pathologies, under the same parameter. Utility is a measure of the subjective preferences that individuals have for a given health state, or a specific effect on health, measured under conditions of uncertainty. Other sources of utility other than that derived from changes in health status (e.g. process utility) can also be taken into account. Commonly, utility is measured as quality adjusted life years (QALY) or disability adjusted life years (DALY) in those cases in which the pathology will be chronic and the results will be obtained in the long term.

Three general approaches have been used to define the threshold in different countries: (i) thresholds based on per capita national incomes; (ii) benchmark interventions; and (iii) league tables. Currently, the most common approach has involved the use of thresholds based on per capita gross domestic product (GDP). Under this approach – which

has been promoted by the World Health Organisation's Choosing Interventions that are Cost Effective (WHO-CHOICE) project [7]. An intervention that, per DALY avoided, costs less than three times the national annual GDP per capita is considered cost effective, whereas one that costs less than once the national annual GDP per capita is considered highly cost effective.

However, this approach has been criticized by other authors saying that thresholds based on per capita GDP have major shortcomings as guides for policy makers, since each of the available approaches has substantial weaknesses [8]. The author proposed new frameworks that take into account other domains, such as equity, ethics and political feasibility.

In Spain, the importance of this criterion is clear at the theoretical level, but the lack of a threshold limited the role of economic evaluations in decision making. The reference used in the literature was 30,000 Euros per QALY, a figure that is above the estimate of a threshold, based on an opportunity cost that compares the health gains and losses associated with the introduction of a new health technology. A report commissioned by the Ministry for Health to the Spanish Agencies Network (REDETS. <http://www.redets.msssi.gob.es/>) has made it possible to specify the magic number applicable in contexts that require disinvestment to free resources that finance new interventions in the Spanish NHS: between 20,000 and 25,000 Euros per AVAC [9,10].

The question of what information should be used in a country to determine the cost-utility threshold also calls for a consensus around the formula proposed in different studies. In Spain, this formula considers that both the budgetary constraints of the health system (how much the system can allow paying for the assigned budget) and the general population's analysis of how much to invest in health (how much it is willing to pay for health improvements vs other possible expenditure options) should be taken into account.

Nevertheless, the cost-utility framework and thresholds also have been criticized due to the lack of profoundness in aspects other than preferences, quality and quantity of life. In this sense, technologies different to drugs incorporate other parameters to be measured in order to capture the real value for a concrete system, and those parameters determine (in most cases) the decision on investment or disinvestment. From a methodological point of view, the way of reaching preferences also has been criticized as it can offer different results [11], so the perspective used when measuring the costs in general relate to health-care system costs and not societal costs.

Cost-utility thresholds also have been critiqued from their imperfection in solving the issues of very expensive technologies (lastly implemented genetic therapies) or those that will be applicable to rare diseases. This is why thresholds have been modified for cancer or orphan drugs in those countries with defined thresholds.

Finally, the existence of thresholds have been criticized by those that claim that industry establishes the prices of some drugs by calculating the cost-effectiveness ratio below the existing threshold, without including reasonable costs related to production, fair trade and revenues [12].

The question and its importance

Evidence-based medicine established a method to transform the health-related questions into research questions for evidence search. The PICO or PECO questions were then defined as those that describe the characteristics of the Patients (P), the characteristics of

the Intervention (I) or the Exposure (E), the Comparator to that intervention or exposure (C) and the Outcomes of interests to be reached (O). Why the question is so important is related to the capacity of the PICO to define the profile of the patient of our interest and what the outcomes to be measured are. Both patient and outcomes are crucial to judge the value of an intervention, to which this question (intervention or technology) will be applicable.

There are four parameters to take into account when defining value: Patient, intervention, outcomes of interest and place in which it will be implemented. Those parameters are crucial in the sense that value will be altered according to the patient we want to manage, the intervention that is going to be promoted and against the intervention already in place (standard of practice), and the system and the conditions in which the intervention will be implemented or divested (professionals, organisation, structure, financial and social capacity, affordability and acceptability).

Without discussing the cost effectiveness of a certain technology, anyone can find examples of why a technology that has a better safety profile and provides theoretical added efficacy is not implemented in different health systems. In some cases, economic affordability or opportunity costs could be the answer to these contradictory decisions around the same health technology. Nevertheless, in many cases organisational aspects (lack of skilled professionals or prepared settings), ethical, legal or social issues are behind the decision. In other cases, it is just the outcome of interest that is behind the resolution. If we wanted to consider, for example, robotic surgery compared to laparoscopy to manage some pathologies, there are some journal articles that justify improvements in safety and even efficacy in terms of days of hospitals stay and other morbidities. However, when the problem of a system is reducing waiting lists, it seems to be that robotic surgery, at this stage of development, is not the best solution as it increases the time required to prepare the surgical theatre and then diminishes the number of surgical procedures that could be done in the same timeframe. So, value depends on the conditions of the context in which the technology will operate and the outcomes of interest or the question to be addressed in that context.

Ritual circumcision and South Africa. A perfect technology for an imperfect history

Worldwide, 30% of men are circumcised, mostly for religious and traditional reasons. In many African societies, male circumcision is carried out for cultural reasons, particularly as an initiation ritual and a rite of passage into manhood. The procedure herein referred to as traditional male circumcision is usually performed in a non-clinical setting by a traditional provider with no formal medical training. The prevalence (self-reported) of traditional male circumcision varies greatly between eastern and southern Africa, from 20% in Uganda and southern African countries to more than 80% in Kenya. In South Africa, a study analysed circumcision-related complications from register data for 10,609 young men circumcised in the Eastern Cape province, South Africa, in June 2005 [13]. Of these, 3% were admitted for circumcision-related complications. Amputations or mutilations occurred in 0.1% of the cases and 0.2% of the 10,609 young men died. Septicaemia, pneumonia and dehydration were the most frequent causes of death. Considering those figures, the government of South Africa in a joint action with WHO and a manufacturer developed a program to design a medical device that could be cheap, reusable, allowed sterilisation and was easy to use. The design finished with a medical device at an affordable price (less than US\$5). Despite the campaign being promoted and subsidized by the government and the WHO, the figures in the following years remained the same. The main reason was that the new device was totally unaccepted by the chieftains of the tribes that performed the ritual circumcisions. Therefore, the value of the technology was zero, although theoretically the technology was cost effective according to WHO parameters.

Topics To Be Evaluated: The Prioritisation Process

Various systems for prioritising HTA topics have been developed by HTA organisations all over the world, and experts appear to agree that there is no single gold standard [14]. Although those authors claim to harmonize the criteria to be adopted, they failed to discuss the reasons behind this situation. In fact, this reflects the need to develop a process of prioritisation locally, as different healthcare systems have adopted different methods to define value and preferences, and weights vary in different parts of the world. As the field of HTA has expanded and matured around the world, a number of HTA organisations have created HTA topic prioritisation processes – in many cases looking to others for their experience, then modelling prioritisation systems on those already developed and according to local needs and preferences. This method of development and adoption can provide a shortcut in time and resources, and can capture the modifications others have made as they have learned from the implementation of their prioritising systems in their contexts of implementation, and they have observed the pitfalls and problems others have tackled.

The methods for HTA topic prioritisation vary among organisations, reflecting differences in **values**, reporting structures, **healthcare priorities** and **local contexts**. This text is not aiming to perform an exhaustive analysis of the different methods employed by HTA organisations all over the world, as others have already performed systematic reviews and methodological exercises, which could serve as examples to build upon. The documents retrieved by other HTA organisations, and that have served to make an overall description, can be seen in Table 1.

Table 1. Documents included on HTA priority-setting criteria.

Jurisdiction	Year	Agency	Document name
Canada	2015	CADTH	Topic identification and prioritisation process: HTA and optimal use: medical devices; diagnostic tests; medical, surgical, and dental procedures. https://www.cadth.ca/sites/default/files/pdf/HTA_OU_Topic_ID_and_Prioritization_Process.pdf
	2013	PATH Research Institute at McMaster University (Tsoi et al.)	Priority setting for health technology assessment of non-pharmaceutical technologies: Practical Canadian and international approaches https://www.cadth.ca/media/symp-2013/2013-presentations/D2%20-%20Priority%20Setting%20-%20TSOI,%20Masucci%20-%20salon%20E.pdf .
	2010	CADTH (Husereau et al.)	Priority setting for health technology assessment at CADTH https://www.cambridge.org/core/services/aop-cambridge-core/content/view/35F7D842FA68046CAB571118B44D5EDA/S0266462310000383a.pdf/priority_setting_for_health_technology_assessment_at_cadth.pdf
	2007	CADTH (Noorani et al.)	Priority setting for health technology assessments: A systematic review of current practical approaches https://www.cambridge.org/core/services/aop-cambridge-core/content/view/AE08F9C5A740EF273D8EBD25DC0A5672/S026646230707050Xa.pdf/priority-setting-for-health-technology-assessments-a-systematic-review-of-current-practical-approaches.pdf

Europe	2014	EuroScan	A toolkit for the identification and assessment of new and emerging technologies https://www.euroscan.org/assets/Uploads/EuroScan-Methods-Toolkit-October-2014-FINAL-CC-added.pdf
	2015	Italy (Specchia et al., 2015)	How to choose health technologies to be assessed by HTA? A review of criteria for priority setting. http://www.epiprev.it/materiali/suppl/2015/EP2015_V4S1_039.pdf
	2010	NICE Centre for Health Technology Evaluation	Updated prioritisation criteria for referral of technology appraisal topics to NICE https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/Appendix%20B%20-%20TA%20prioritisation%20criteria.pdf
	1999	Netherlands Health Insurance council (Oortwijn et al, 1999)	Oortwijn W, Banta D, Vondeling H, Bouter L. Identification and priority setting for health technology assessment in The Netherlands: actors and activities. <i>Health Policy</i> . 1999 Jun;47(3):241-53. PubMed PMID: 10538921. http://www.htai.org/policy-forum/global-policy-forum.html
New Zealand	2014	NZ Burden of Disease Epidemiology, Equity and Cost-Effectiveness Programme (Holmes et al.)	Approaches to prioritisation and health technology assessment in New Zealand. http://www.otago.ac.nz/wellington/otago070001.pdf
Spain	2016	Spanish Network of Agencies for Assessing Health Technologies and Performance	Selection of health priorities: Criteria, process and strategic framework. Systematic review, http://avalia-t.sergas.es/DXerais/614/priorities%20selection.pdf
	2007	Avalia-T Galician HTA Agency (Ruano et al.)	Identification, prioritisation, and assessment of obsolete health technologies. A methodological guideline. https://www.sergas.es/docs/Avalia-t/ObsoleteTechMemFinal.pdf
	1998	Osteba	Prioritisation of topics to be evaluated http://www.osakidetza.euskadi.eus/contenidos/informacion/1996_osteba_publicacion/es_def/adjuntos/1996/d_96_01_e_prioritisation_evaluation.pdf
United States	2013	AHRQ	Prioritisation criteria methodology for future research needs proposals within the Effective Health Care Program https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0077220/pdf/PubMedHealth_PMH0077220.pdf

AHRQ = Agency for Healthcare Research & Quality; Avalia-T: Galician HTA agency; CADTH = Canadian Agency for Drugs & Technologies in Health; HTA – health technology assessment; NICE = National Institute for Health and Clinical Excellence; NZ = New Zealand; Osteba; Basque Office for HTA; PATHS = Preliminary Assessment of Technology for Health Services

Filtration and prioritisation: The case of CADTH

As shown in Figure 1, the process of starting an HTA project requires three steps: Identification, filtration and prioritisation. The Canadian Agency for Drugs and Technologies in Health (CADTH) is the National HTA coordinating office for HTA activities in

Canada. CADTH published a short report that resumes the process they follow in an easy and understandable way (https://www.cadth.ca/sites/default/files/pdf/HTA_OU_Topic_ID_and_Prioritization_Process.pdf). Three main criteria are used for filtration: First, duplication of effort; second, need and stage of diffusion; third, is a classically used criterion in most of the Early Awareness and Alert System as described by EuroScan, the International network of Agencies for the Identification and Assessment of New and Emerging Health Technologies (<http://www.euroscan.org>). This means that the stage of diffusion is essential when anticipating the decision in the case of new and emerging health technologies, as it was described in Buxton's law. The first criterion demystifies one of the most extended thoughts and matter of discussion around HTA organisations and their activities. In fact, in most cases, HTA activities are reasonably coordinated in regional and national networks, such as REDETSA (America; <http://redetsa.org/wp/home/>), HTAsialink (Asia and Oceania; <http://www.htasialink.org/>), EUnetHTA (Europe; <http://www.eunethta.eu>) and INAHTA (International; <http://www.inahta.org>) or EuroScan (as mentioned), and the duplication of efforts is scarce giving the also limited resources devoted to assessment in most countries. However, it is true that the same topics are reported by different agencies in different countries or regions, but they reflect different outcomes or health system characteristics, and the reports used previously assessed data from other HTA units or agencies.

Regarding prioritisation, CADTH uses five criteria: Clinical impact, budget impact, population impact, jurisdictional interest and equity. These criteria are weighted, with the clinical and budget having the highest impact (25% each). In the case of population impact, they don't have a correction statement for rare diseases; however, this is supposed to be under the equity criterion.

In the filtration process, there is a threshold of 200 points to reach in order to be considered for prioritisation. In the case of prioritisation, there is no threshold; the final decision regarding the topics to be undertaken by CADTH is done quarterly and is based on the ranked list, the resource needs for the topics and CADTH's capacity.

Common criteria for prioritisation

Although it has been mentioned before that there are no standardized methods or criteria to be included in a prioritisation process for HTA topics, there are certain criteria that are common in all the processes analysed. In this sense, there are a number of systematic reviews that have analysed the most shared criteria.

Four systematic reviews assessed HTA prioritisation criteria: (i) CADTH (2007 – updated in 2010 via consensus among members of their advisory committees); (ii) the PATH Research Institute at McMaster University in Canada (2013); (iii) the European analysis [14]; and (iv) the Spanish Network (2016). Table 2 contains the details of their analysis. Overall, the reviews noted the variability among priority-setting methods used by different organisations, and the mixture of quantitative (assigning scores to each category) and qualitative paradigms. The analysis of Specchia et al., 2015 [14] went further by using those retrieved criteria to make a survey that was submitted to 14 HTA organisations in Europe. Overall, the reviews agreed on five HTA priority-setting criteria: Disease burden, potential clinical impact of the technology, potential economic impact and budget impact, and existence and quality of evidence.

Table 2. HTA Priority-Setting Criteria Captured by Systematic Reviews.

Systematic review		CADTH (2007) (Noorani et al.)	CADTH update (2010) (Husereau et al.)	PATH Research Institute (2013)	Europe (2015) Specchia et al,	Spain (2016) Avalia-T for REDETS
Priority-setting criteria categories	Disease burden in the population / need for the technology / context / population impact	x	x	x	x	x
	Potential clinical impact of the technology	x	x	x	x	x
	Potential economic impact (e.g., cost effectiveness)	x	x	x	x	x
	Existence and quality of evidence	x	x	x	x	x
	Potential budget impact	x	x	x	x	x
	Presence of alternatives to the technology	x	x			
	Controversial nature of the technology	x			x	
	Feasibility and complexity of implementation				x	x
	Ethical, legal or psychosocial implications	x			x	x
	Level of interest in the technology (media etc.)	x			x	
	Timeliness of the review	x				
	Variations in rates of use of the technology	x			x	
	Current access and utilization		x			
Details about the review	End of literature search	June 2006	Not applicable	NR	November 2014	April 2015
	# documents included in review	17		16	7	17
	# priority-setting categories (# individual criteria)	11 (59)		9 (NR)	(18)	8 (56)

The aforementioned common criteria do not mean that any HTA organisation needs to use them, but at least they are a good starting point to begin discussions with different stakeholders in order to establish context-specific and agreed criteria.

Another element, which has not been discussed so far regarding this, is the need to determine not only the criteria, but also the weight of each of the domains or criteria finally used. Actually, all the analysed proposals define different weights for the diverse domains considered. Concerning the scoring there are few data regarding when to

establish different thresholds; however, in the literature, there are some examples that determine the threshold to define the highest scoring. Once again, CADTH defines the highest scoring for population impact to be when the technologies considered affect at least 5% of the population. Similarly, the criterion used by the members of EuroScan on population impact tends to define two focuses, on the one hand, those pathologies that have high prevalence, and thus, they receive the highest scoring, when for example, there are more than 500,000 patients affected in a medium-sized country or they are less than 1 in every 100 patients. This means there is a special focus on rare diseases or conditions, as in the case of Spanish healthcare system.

Whānau ora. The importance of context

The prioritisation system in New Zealand appears to be in change, although basic principles have been suggested, and among them there is a criterion linked to cultural issues: Whānau ora. How does the health technology contribute to the achievement of whānau ora? Driven by Māori cultural values, the goal of whānau ora is to empower to support families within the community context rather than individuals within an institutional context.

<http://www.otago.ac.nz/wellington/otago070001.pdf>

An additional area or criterion in which some agencies have established a threshold for the highest scoring, is budget impact. In most cases this criterion is used qualitatively and no further details are given on what can be considered of high impact or low impact to one considered health system; however, there are some HTA organisations that have defined a threshold. Once again, CADTH considers health technologies of high impact on the budget when they have the potential to be costly or cost saving (CAN\$50 million, or about US\$38 million).

This fact brings us to another interesting point around prioritisation. As it has been shown from CADTH, should HTA systems consider differently technologies that are to be evaluated for investment, for disinvestment, for further analysis or for unreasonable variability in practice? There are examples in different organisations that meet all those criteria in just one instrument, or that divided the criteria and domains to be considered for prioritisation when different decisions are going to be made.

Different criteria for different decisions: The consideration of the life cycle of health technologies

When considering topics to be prioritised, some HTA systems include the decisions that are going to be made. That means that they react and score differently when they are considering technologies to invest in and technologies to be divested of. Most systems consider technologies to invest in at the time they have obtained market access authorization. However, there are systems that, under their scope, include the whole life cycle of health technologies [19]. The concept of life cycle includes the different phases that a technology goes through from its inception to its disuse (see Figure 2).

Those agencies that consider one of the phases of the life cycle define some specific criteria that relate to that phase. For example, those HTA organisations that try to anticipate the possible impact of innovations include criteria such as the potential for inappropriate

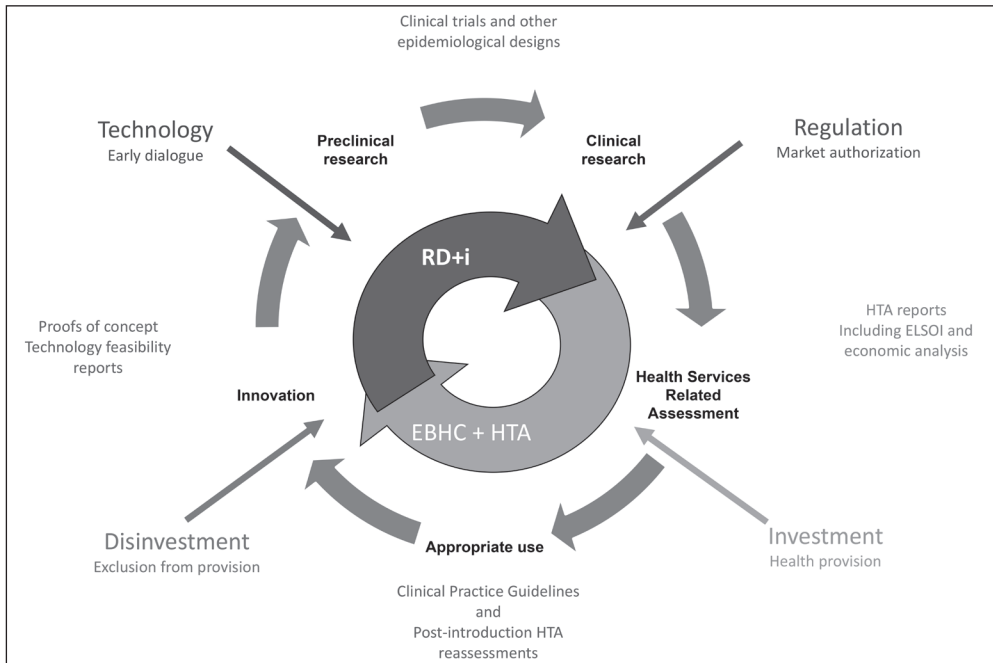


Figure 2. The concept of life cycle of health technologies. (Gutiérrez-Ibarluzea et al, 2017) [19].

diffusion given (i) the available evidence (too fast, too slow or misuse); (ii) the impact on improving the current approach; (iii) the development of alternative approaches for a given health problem; and (iv) the possible launch date (see EuroScan Toolkit).

Those organisations that consider disinvestment activities include criteria such as: Adequacy, variability in practice or opportunity cost for improvement. There is an interesting joint action coordinated by the Spanish Atlas of Variability Group and the Spanish Network of Agencies, which analyses the surgical procedures that are identified on different lists of disinvestment and how and where to use the HTA activities and variability in practice in a combined way in order to prioritise the procedures for disinvestment. The whole study is retrievable in Spanish at <http://www.atlasvpm.org/desinversion>.

One more example on the use of different criteria for prioritisation, in accordance to the decision to be taken, is the work performed by the Spanish Network of Agencies for HTA (REDETS) under the coordination of the Galician Agency Avalia-T. The theoretical work finished with a practical and freely available tool called PriTec (see below).

Existing Tools for Prioritisation in HTA

Each HTA system uses its tools but there are no available elements that can be used and adapted to the needs of the different contexts and be freely available. There have been different initiatives to implement tools that can be used under different

circumstances. Probably the most advanced initiative and is available on the internet is the PriTec tool designed and developed by the Galician Agency Avalia-T (<http://www.pritectools.es/>).

PriTec

The PriTec tool is web-based software, which, according to the webpage aims to 'compare up to 50 technologies simultaneously and generate a report that includes the main results in the format of tables or charts. The methodology applied has been developed in two projects that have been carried out within the collaboration framework established by the National Health System Quality Plan according to the collaboration agreement signed between the Institute of Health Carlos III, an autonomous organism part of the Spanish Ministry of Health and Consumer Affairs' [6,17].

PriTec also offers the possibility of prioritising technologies depending on the decision to be made; that is, technology observation (post-introduction observation of new technologies when there is lack of evidence), obsolete technologies (disinvestment decision) and a services portfolio (decisions around investment or reimbursement).

The main pitfall of this initiative is that it is not flexible and the adaptation of the current tool is not possible under the current software conditions.

Future Trends in Value Measurement and Their Impact on HTA Evidence Requirements

A recently published paper on developments in value frameworks to inform decision-making processes around the allocation of health resources, by the Policy Forum of the Health Technology Assessment international Society (HTAi; <http://www.htai.org>), stated that: 'value frameworks continue to evolve with significant implications for global incentives for innovation and access to health technologies. There is a role for the HTA community such as defining the core components for assessing the value of a health technology' [20].

The paper established four elements that have defined value in two Scandinavian countries (Sweden and Norway) in order to prioritise technologies: Severity of the condition, rarity of the condition, and the size of benefit and confidence in the data. However, the results were different depending on how the elements were considered and who used them. This reflects what has been discussed in this chapter; stakeholders' involvement and clear playing rules from the very beginning are crucial to determine an accountable process. The role of the HTA community in trying to find new approaches to value measurement is under no doubt.

There have been several initiatives, and one of the most successful is the EUnetHTA's Core Model[®], which tries to define what can be shared by different HTA organisations in Europe, and to approach other context-dependent domains by proposing a checklist of questions to facilitate analysis. The last version of the Core Model[®] can be found at <http://www.eunethta.eu/hta-core-model>.

Further initiatives have been developed to address specific needs or complex analysis. This chapter will address three of them: The IDEAL framework, MCDA and INTEGRATE-HTA.

IDEAL framework

The IDEAL framework was designed and developed in order to address the problems that were encountered when evaluating surgical or interventional procedures. One of the main issues was related to the non-existent regulation, the lack of mandatory frameworks for the study designs and the gaps of high quality evidence in most cases, including the standards of practice. The framework defines the stages through which interventional therapies go through, the characteristics of each stage and the methodological study design types, which the collaboration recommended for each intervention. These recommendations on designs are related to the different phases of technology development: Innovation, development, assessment and long-term study. Difficulties in undertaking randomised, clinical trials should be addressed by measures to evaluate learning curves and alleviate equipoise problems. The collaboration proposes that alternative prospective designs, such as interrupted time series studies, should be used when randomised trials are not feasible. They also recommended that established procedures should be monitored with prospective databases to analyse outcome variations and to identify late and rare events. <http://www.ideal-collaboration.net/framework/>

Multiple criteria decision analysis

MCDA, which is also called multiple criteria decision making (MCDM), is a framework that has been used in different areas of decision making (not only medicine or health) and that evaluates multiple conflicting criteria to reach a final result. The basis of this method is that there are different criteria that can be used for decision making, and depending on the person, the group or the organisation, they are considered differently. MCDA methods provide a structured and transparent approach to identify a preferred alternative by clear consideration of the relative importance of the different conflicting criteria and the performance of the alternatives on the criteria. The central features of any MCDA method are: (i) the alternatives to be appraised; (ii) the criteria (or aspects) against which the alternatives are appraised; (iii) scores that reflect the value of an alternative's expected performance on the criteria; and (iv) criteria weights that measure the relative importance of each criterion compared with others. MCDA approaches can be classified broadly into three categories: value measurement models, outranking models, and goal, aspiration, or reference-level models. The main strength of this method is the transparency from the very beginning and the participation of the stakeholders in the decisions of preferences and weights, and the application of the final developed tool. The criteria, the weights and the decisions are publicly available as playing rules. The main criticism of this method relates to its use and simplicity when complicated deliberations and debates need to be in place. To learn more about MCDA and its applicability in decision-making processes around new health technologies, there is an article by Angelis and Kanavos, 2016 [21] that explains the whole process.

INTEGRATE-HTA

INTEGRATE-HTA is a European Union 3-year funded FP7 project that ended in December 2015. The project aimed to develop concepts and methods that enable a patient-centred, comprehensive assessment of complex health technologies. The INTEGRATE-HTA model helps to assess complex technologies that take context, implementation issues and patient characteristics into account. The basis of the model is the construction of a Logic Model that embraces all the steps of technology implementation or deletion in a concrete context. The INTEGRATE-HTA Model has four dimensions with corresponding criteria: (i) HTA aspects that include effectiveness, socio-cultural, economic, ethical and legal issues; (ii) modifying factors that comprise patient characteristics, implementation issues and context; (iii) uncertainty of the assessment results that cover assessment results and the degree of uncertainty and; (iv) stakeholders with their values and preferences.

The model is run in five steps:

- **Step 1:** Definition of the technology under assessment and the objective of the HTA with the involvement of stakeholders.
- **Step 2:** Development of an initial logic model that structures participants, interventions, comparators, context, implementation issues and outcomes.
- **Step 3:** Based on the logic model, the evidence of the different aspects is assessed, taking the variability of participants, context, implementation issues and interactions between these into account.
- **Step 4:** The assessment results of Step 3 are structured and visualized by an extended logic model.
- **Step 5:** A structured decision-making process (not an integral part of the HTA in a narrow sense).

The model and its guidance were tested in a case study on palliative care (Case Study: Integrated assessment of home-based palliative care with and without reinforced caregiver support: 'A demonstration of INTEGRATE-HTA methodological guidance' – Executive Summary). The demonstration can be found in: <http://www.integrate-hta.eu/wp-content/uploads/2016/02/Integrated-assessment-of-home-based-palliative-care-with-and-without-reinforced-caregiver-support-Executive-summary.pdf>.

The basics of the model can be read in: <http://www.integrate-hta.eu/wp-content/uploads/2016/02/INTEGRATE-HTA-An-introduction-to-the-guidances.pdf> [22].

Main Facts to Bring Back Home Around HTA and Prioritisation

A prioritisation system for HTA should evolve with: The scope of the HTA organisation, its clients and the value framework that the health system in which the HTA organisation operates, defines. That means that there are no magic formulas or a framework that fits all. There are general criteria that should guide any prioritisation process: Transparency, robustness, inclusiveness and accountability. However, these are commonalities that any health system's action should follow.

The main principles to develop a topic's prioritisation tool should (i) be easy to apply; (ii) require comparatively few resources; (iii) be compatible with processes required by the client; and (iv) involve the main stakeholders in the process of defining weights and applying the final tool.

Any HTA system should be aware of the developments in value frameworks and assessment methodologies, in order to offer the best service possible to the clients it serves, which means the required evidence for each value framework. HTA systems should be the avant-garde of decision-making processes by revealing the many sides that involve decisions on health technologies in their broad definition, and by providing the best available evidence (whichever source it comes from) to reflect those sides. This will allow the decision makers to deliberate with all the evidence available and according to the value frameworks they have decided to use. It is desirable that this process be known to all the parties involved, including the public and publications, and it will require their involvement in as many phases as possible.

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CHAPTER 5

Priorities of Modern Clinical Management

Jordi Varela

Summary

Modern clinical management is subject to many tensions that lead to generating a lot of inadequate activity, so in this writing, I propose four ways to increase the value of health activities. The first of these is patient-centred attention to the development of shared decisions, but there is also talk of the need for clinicians to spend more time with clinical discussion, an authentic source of value. The second is the need to increase the understanding of risk on the part of the two main clinical actors: doctors and patients. This section discusses the predictive value of tests and overdiagnosis, with all its nuances (reservoir theory, incidentalomas and disease mongering). The third proposal deals with how clinical practice should move in the territory of grey areas with inconsistent evidence, or desert areas with few rigorous cost-effectiveness studies. It is estimated that the waste for practice of dubious value can be from 25% to 33% of the resources and, for this reason, the clinicians are encouraged to learn to better analyse the correct care sources and the triple aim methodology. To end the chapter, in the fourth proposal I discuss the evils of fragmented medicine, especially in treating chronic and fragile patients, and ways of combating fragmentation, by fostering the experience of patients as a motor for integrating changes in services and to promote continuity of care plans.

Introduction

The mission of modern clinical management is to provide elements that prioritise health activities according to the value they bring. For this reason, this chapter has been structured into four sections. The first is the promotion of patient-centred care, emphasising how shared decision making can be practiced in an environment overwhelmed by protocols and codes. The second section is to increase the training of professionals in the understanding of risk, since more and more of them are dealing with probabilistic risk in the clinics. The idea is that prescribing physicians must increase their skills in handling the predictive value of the tests they ask for, so that they can be shared with people who ask

for advice; this is the only way to combat the excesses of overdiagnosis. The third section is to promote clinical value practices, with an emphasis not only on those that should be discontinued (antibiotics in viral diseases) but also on those that should be promoted (e.g. training programs for the appropriate use of antibiotics). The fourth section talks about the evils of fragmented medicine and the need to move towards multidisciplinary teamwork in order to adjust the therapeutic plans to people's real needs.

Patient-Centred Care

In 1988, the Picker Institute in the United States coined the term Patient-Centred Care, and began its work with an investigation that determined the eight indicators that better define the quality of care from the perspective of patients: (i) respect for their values, preferences and needs; (ii) receive services in a coordinated and integrated manner; (iii) have relevant information in a clear and understandable way; (iv) achieve the highest possible quality of life, with special attention to pain relief; (v) have emotional support to confront fear and anxiety; (vi) involve relatives and friends in their process as they see fit; (vii) receive continued care regardless of the point of care; and (viii) obtain the maximum possible accessibility to the prescribed services [1]. Years later, in 2001, the Institute of Medicine published 'Crossing the quality chasm' [2], where it included the following definition of Patient-Centred Care: it is the provision of health services that is respectful of the preferences, needs and values of the people, and also guarantees that this policy will be maintained throughout the clinical process.

Despite unanimity in favour of Patient-Centred Care, doctors today are immersed in another diametrically opposed story: lack of time, consumer pressure, excessive requests for diagnostic tests, polymedication, the filling of forms to comply with codes and guides, and the efficiency indicators, to give some examples. The pressure and chaos leave no room for innovation, but the reality persists, and what we notice is that when the healthcare activity does not have a goal proportional to the real needs of each person, the results are bad. As an example, I'll only mention the figures of adherence to treatments by chronic patients, which, according to the latest surveys, barely reach 50%. A Cochrane review of 2011 [3], conducted from 86 clinical trials, found that patients who had made the informed decision ended up opting for more conservative clinical practices. A more recent review of the same team (2017) [4], this time with 18 studies, concluded that people who have had the opportunity to make clinical decisions with the support of specific materials, admit to feeling more prepared and more informed; they have clearer ideas about the value of their clinical processes and are probably more aware of the risks of each step they take. In this vein, a King's Fund publication lists the clinical decisions that are made with the uninformed patient as 'the silent misdiagnosis' [5].

Shared decisions

According to Glyn Elwyn, a researcher at The Dartmouth Institute: 'Shared decisions are a way of acting in which doctors and patients make decisions together, making use of the best available evidence on the probabilities of benefits and harms of each option, counting with which patients receive the necessary support to obtain verified information about their preferences' (notes taken from their conference in Barcelona on April 21,

2017). Victor Montori, an endocrinologist and researcher at the Mayo Clinic, goes further in the emotional component of patient-centred care and, also in Barcelona, on May 19, 2017, said: ‘Shared decision is an emotional matter. It’s a human expression of the care and looking after the patient, in which both protagonists should come together to a resolution that should have intellectual, emotional and practical sense. The shared decision is not a prescription; it’s a way of adjusting clinical practice to the way of being of each person.’

There are an increasing number of people who are not willing to delegate; they want to take control of their illness. Some do it by character, others by training or others because of their distrust in the health system. Be that as it may, beyond the shared decisions, we can see new requirements in the clinical activity – unthinkable a few years ago – such as the recording of the consultations, the control of ownership of the clinical data or the shared clinical notes that cause discomfort for some medical staff.

The time of the doctors

Often, rightly, doctors complain about not having enough time. They say, almost universally, that it’s more efficient for them to prescribe than to explain and listen; that if they had to spend too much time talking, they would not be able to meet the efficiency goals imposed on them from above. However, Kaplan et al. [6] dismantle these arguments by identifying several studies that prove that doctors’ time, despite being expensive, is cheaper than the treatments, tests and hospitalisations that occur to excess because of not having talked enough with the patients. Even more so, if we stick to chronic patients, it has been shown that the mere fact of being heard increases their adherence to treatments and, therefore, improves clinical effectiveness.

According to the experience of Victor Montori’s team, which has more than 10 years of development of materials to support the shared clinical decision, these instruments are demonstrating that involving the patient may imply a 2- or 3-minute addition to the standard paternalistic consultation. Some people will think that this can be like a new bureaucracy for the overworked world of the medical offices, but we must trust that the shared clinical decision is the future of medicine.

Doctors, restrained by the hourly compliances, have developed the practice of disruption. In a study carried out by Internal Medicine residents, it was found that only 26% of the patients had been able to express their problems completely without interruptions; whereas 37% had been interrupted; and with the rest of the patients (another 37%) the doctors had not asked them any questions about their concerns.

Understanding Risk

Margaret McCartney, a Scottish family doctor, in ‘The Patient Paradox’ [7] explains that more people are visiting the doctor’s office, not because they are sick, but because they are afraid of being sick. Early detection of cancer and risk factors for cardiovascular disease would illustrate the paradox McCartney refers to. The ‘sooner rather than later’ attitude has also made a fortune, and the vast majority of the population does not distinguish between the need to lead a healthy life to avoid disease, with secondary prevention programmes, many of which are failing to demonstrate that their benefits overcome their adverse effects.

Gerd Gigerenzer, director of the Harding Center for Risk Literacy in Berlin, in ‘Risk Savvy’ [8], argues that when a doctor explains a probabilities issue to a patient, two types of problems are observed. The first is that, sometimes, the explainers have not themselves understood the meaning of what counts. According to Gigerenzer, there are indications that many doctors do not understand the real meaning of the research. When it comes to reasoning about the value of a risk it’s not the same to have read a number in the conclusion of an article, or to have heard an academic authority defending their results during a congress, than to have understood the real scope of those figures, their confidence intervals or their robustness. The second problem lies with the patient, given that many people find it difficult to understand simple mathematical operations, and now they watch, surprised, how their doctor, at their desk or on a screen, handle numbers and graphs of risks and percentages. This is the world that communication experts call ‘health numeracy’ and ‘health literacy’ – a universe of misunderstandings and half-truths.

Nassim Taleb, Professor of Risk Engineering at New York University, in ‘The Black Swan’ [9] explains the inability of mathematical models to understand the future, and, to demonstrate his thesis, asks us to put ourselves in the mind-set of a turkey fresh from the egg. The first day a man approaches and the poor chick is afraid that the man will kill him, but the farmer is kind and gives him food. On the second day, the man returns, and the animal would like to know, according to his experience, what is the probability of getting fed instead of getting killed. If the turkey knew the Laplace formula, it would conclude that the probability is two-thirds, the next day three-quarters and so on, upwards, because his experience every passing day tells him that it has to trust that man more and more every day. And then the thousandth day arrives since it was born; the turkey is almost certain that his protector will bring him food, just like every day of the 1000 days before. It is such a shame that the turkey has not been attentive enough to know that day 1001 of his life is Thanksgiving Day and the man, against all odds, will cut his neck.

Sometimes, being attentive to a small detail that emerges in the clinical interview, or an unexpected sign in the scan, may be the touch of attention to properly reinterpret a diagnostic process. Recall that the turkey’s illusion is based on blind trust in data that are favourable to him, which has made him disparage other less objective details, which, when applicable, have been lethal.

Predictive value of the tests

When doctors ask for evidence, they should know their sensitivity; that is, the ability of such a test to give as positive cases that they really are, and their specificity, the ability to give as negative cases that are not really positive. But what is relevant to clinical practice is its predictive value, which is the probability of having a disease if the test result is positive.

If, for a moment, we stop to think about the formula, we will see that when we relate the true positives (TP) to the global population of positives, the variable of false positives (FP) appears in the denominator; if it’s very high it will reduce the predictive value.

$$\text{Predictive Value} = \text{TP} / (\text{TP} + \text{FP})$$

Siddhartha Mukherjee, an oncologist and Columbia University researcher, in ‘The Laws of Medicine’ [10], says strong intuition is more powerful than weak evidence. Let’s see how this statement is illustrated by the predictive value of the HIV test, which, with a sensitivity of almost 100% and a specificity of 99%, leads doctors to end up requesting the test for low-risk people, only for the fact of being sure that they are clean. The issue is that the missing variable – the prevalence of infection – is (fortunately) very low at 0.05%. Let us see with these data what would be the predictive value of the test performed on the general population?

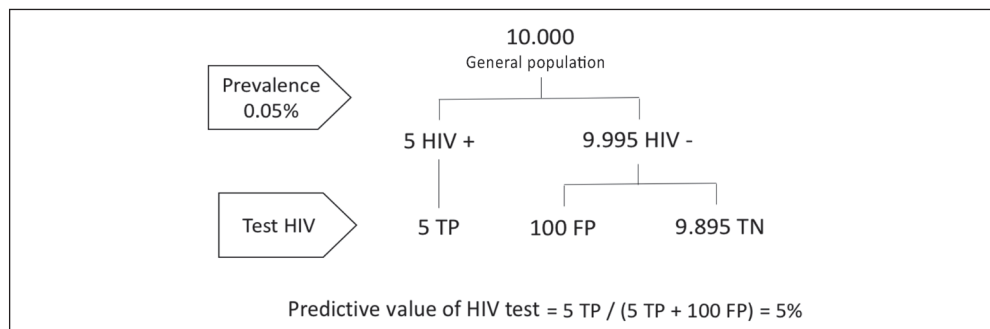


Figure 1. Predictive value of the HIV test performed on the general population.

In a population of 10,000 people, the prevalence tells us that there would be 5 HIV positive people, and if we pass the test to find out which specific people it is, we would get these 5 true positive cases mixed in a group of 100 false positives, because although the specificity is 99%, the population to apply the test to is very large. This means that the predictive value of the test is only 5%. On the other hand, if the physician, through a careful interview based on the selection of risks, was limited to requesting the test from people with a 19% chance of being infected, then the predictive power of the test would be up to 95%.

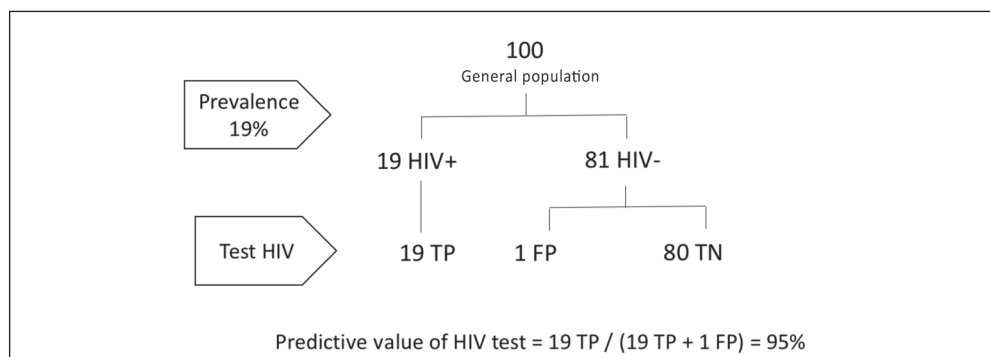


Figure 2. Predictive value of the HIV test performed on a selected population with a 19% risk.

As seen in the example of HIV detection, risk-based selection of medical history, especially in low-prevalence diseases, strongly increases the predictive power of testing, as Mukherjee stated.

Measuring ceruloplasmin in blood serves to rule out Wilson's disease, and the indication for the test application is very accurate. An article on the overuse of the serum ceruloplasmin measurement test to detect Wilson's disease [11] early was selected in 2015 by JAMA Internal Medicine among the 10 best papers that analysed medical overuse. In this study, 5,325 ceruloplasmin tests were retrospectively analysed, in which 8 Wilson patients were detected, in addition to 416 false positives. Therefore, the probability of having the disease in that series, if the test was positive, turned out to be 2%. The researchers concluded that one of the most important problems that led to the decline in the predictive value of the test was that many of the patients screened did not meet the prescribed requirements. The obsession with the early diagnosis of Wilson's disease, without sufficient prior clinical selection, was thus alarming hundreds of people, as well as having the consequences of subsequent unnecessary consumption of additional health resources.

Overdiagnosis

Overdiagnosis is the phenomenon that occurs when people are diagnosed for diseases that would never cause symptoms or shorten their life; instead, the alarm generated by the finding can cause undesirable consequences, both psychologically and socially, as well as sequelae due to disproportionate and inappropriate treatments [12]. It's a phenomenon that is counterproductive because some of the data that the evidence throws us go against the popular belief of 'the sooner the better' or the 'the more the better'; therefore, talking about overdiagnosis requires a certain amount of self-criticism in addition to the need to develop new clinical thinking to overcome the situation. Although the bulk of the overdiagnostics research is based on secondary cancer prevention, we should not be distracted because the phenomenon extends over the whole spectrum of the casuistry. To demonstrate this I have selected some examples.

A retrospective study (1993–2006) [13] in the United States found an 80% increase in the incidence of pulmonary embolism (PE) attributed to the new availability of computed tomography pulmonary angiography (APTC). However, there are two items of data from the study that point to overdiagnosis, because, despite a dramatic increase in the incidence of PE, the population the mortality was not reduced, while complications due to anticoagulant treatment increased by 70%. The experts point out that the APTC has brought to light a multitude of low-risk sub-segmental pulmonary emboli that previously passed unnoticed. The problem arises from the fact that these findings are forcing anticoagulation on a much larger number of people now exposed to possible bleeding.

What has the APTC – a test 'too good' according to the study authors – provided to the public health? This question must be moved from the tables of researchers to that of clinicians. The authors of the study have understood this; therefore, they propose to estimate the PE risk of each patient by means of 'Wells score' combined with blood levels of D-Dimer and, after that, reserve the APTC request only for patients with an intermediate or high risk. They also believe that ventilation-perfusion lung scan or echo-Doppler should be indicated for patients with low risk, in addition to considering the possibility of non-anticoagulating some patients with sub-segmental PE. The clinical objective of this proposal is to reduce as much as possible the number of anticoagulated patients without giving up to pursue the most risky PE.

Theory of reservoirs

In studies performed from autopsies of men who had died from any cause, it was observed that prostate cancer was present in a very significant number of them, with an upward prevalence reaching 59% in those over 79 [14], while this condition generates only 2.3% of overall male mortality in OECD countries (see *Health at a Glance 2015*). These data reflect that the biological reservoir of non-progressive prostate cancer is very important, so it's a subscriber site for the diagnoses of indolent lesions, which will justify aggressive therapeutic interventions with sequelae that will affect the quality of life of people, having provided them with no benefit, since their particular cancer had not progressed.

Among women, the prevalence of breast cancer is 1%, but this cancer has a biological reservoir of ductal carcinoma in situ of 9%, to which should be added another 10% corresponding to atypical hyperplasia (information obtained from the lecture by Elisabeth Thomas in *Preventing Overdiagnosis, 2016*). From all of this, it follows that, if tenaciously sought, in 20 women out of every 100, breast cancerous lesions would be found, while the female mortality from cancer was only 3.8% in the OECD. In a population-based study of 16 million women over 40 years of age in 547 U.S. counties, and after a 10-year follow-up, it was observed that the most active territories with preventive programmes succeeded in increasing the incidence of tumours less than 2 cm (the reservoir), but did not reduce mortality [15].

The incidence of thyroid cancer has doubled or tripled in the last 20 years in developed countries, which is mainly due to the introduction of new diagnostic techniques, such as ultrasound. It's a cancer that usually affects young people who, as with the previous examples, have an important biological reservoir in its papillary variant, a relatively non-aggressive modality. To realise the devastating effects of exaggerated prevention, it's worth taking a look at what is happening in South Korea [16], a country that has generated a natural experiment. Because of the active policies of government and insurers in the prevention of thyroid cancer, its incidence has multiplied by 15, without achieving any reduction in specific mortality. What are the consequences of such policies? In 2011 alone, 30,000 thyroidectomies were performed in young people who will have to undergo hormone replacement therapy throughout their lives, of which about 3,000 will suffer from hyperparathyroidism, and about 600 will suffer from dysphonia due to the involvement of recurrent nerves in surgical manoeuvres. These annual figures reflect the negative sequelae of early diagnosis programmes that don't achieve their goals, which, in this case, would be saving the lives of young people.

Incidentalomas

A group of radiologists from several American university hospitals (Massachusetts General, Cleveland, Brigham and Women's, etc.) have started a debate in the *Journal of the American College of Radiology* [17] on the possibility that radiologists stop reporting the occasional findings without clinical significance. The traditional role of the radiologist, they say, is to warn of everything you see, leaving the interpretation of the importance of the findings to the referring doctor. But now we open the opportunity to go further, not only to intervene by saying an observed abnormality is benign, but also to make the decision not to report the slightest, since it is possible that our opinion creates confusion and ends up provoking disproportionate actions.

The radiologists who signed the article decided not to report the level I renal cysts of the Bosniak classification, using these four criteria: (i) the cyst is not the reason for the examination; (ii) it does not generate local problems; (iii) it has no malignant potential; and (iv) it is not likely to generate polycystic kidney disease.

The authors acknowledge that the proposal of not reporting opens new legal risks for radiologists, and for this reason they believe that professional debate should be reinforced with the deployment of analysis that contrasts the benefits and risks both of reporting and of not doing so. It is necessary to generate, say, a body of doctrine in this regard, because today's scanners, with enhanced functional and perfumctory techniques, have an impressive ability to visualise all kinds of findings unthinkable until recently. By way of example, the American College of Medical Genetics and Genomics has developed a consensus that geneticists should only report genetic variants that have been shown to be pathologically related and, therefore, they are discouraged to inform to the patient genetic anomalies that are not known to have pathogenic associations.

Disease mongering

A collaborative study, led by Ray Moynihan [18], analysed 16 studies in which there had been changes in criteria in the diagnostic definitions of common diseases such as hypertension, asthma, attention deficit hyperactivity disorder, chronic obstructive pulmonary disorder and dementia, among others. One of the findings was that these changes of criteria fundamentally followed three directions: (i) the creation of pre-diseases; (ii) the lowering of analytic values; and (iii) the introduction of methods of early diagnosis. Another finding was that these changes in criteria, which only increase the legion of people affected by supposedly pathological circumstances, are not accompanied by assessments of the negative or even pernicious impacts on the health of 'new patients'.

In this line, pre-diabetes is a term that, lately, is used when a person is detected with higher than normal levels of blood glucose without becoming pathological. Pre-diabetes could be understood as a premonition to be able to develop diabetes in the future. According to that chain of risks, and with a healthy intention to reduce morbidity and mortality, an escalation, led by the American Diabetes Association (ADA), is being observed to consider that glycosylated haemoglobin (HbA1c) – a test that can be done without any preparation or need for fasting – becomes a new criterion to detect pre-diabetics. The concern arises when, according to this diagnostic extension, it is estimated that in China there would be 493 million pre-diabetics, in the United States 86 million and in Spain 6 million, to cite three countries from which we have data.

At the dawn of a new epidemic, many experts question whether pre-diabetes should be subject to a healthcare action of the characteristics of the one being prepared in the United States. John Yudkin and Victor Montori say they are worried because the scale of this epidemic will collapse health systems and lead millions of people into unnecessary treatment. According to them, pre-diabetes is an artificial category with no clinical relevance when, they say, there is nothing to prove that if these new pre-patients are treated they can be prevented from developing the disease. In this sense, the Spanish Society of Diabetes (SED) follows the same path, although in a more moderate way. In a consensus report, despite advising the detection of pre-diabetics, the SED admits that once the cases

are discovered, medical actions should be limited to modifying lifestyles, since the drugs, such as metformin, are not an effective option.

Victor Montori goes further when he argues that if we really want to do something to prevent obesity and diabetes, instead of pursuing suspicious cases, it would be much smarter to propose policies that would reduce the causal factors of the epidemic from a cultural perspective; such as food, education, and social and economic factors. Montori makes clear his position in an interview where he explains that when he stated that pre-diabetics should not be medicated, he did not mean that they should not be given medication, which is obvious to him, but, in his opinion, groups with risk factors for developing diabetes should be sent to the gym and the greengrocer store, instead of defining them as pre-patients and throwing them into saturated medical consultations.

The Value of Clinical Practices

Donald Berwick, President of the Institute for Healthcare Improvement, in the monograph 'right care' of *The Lancet* [19], argues that the quality of care, as we understand it, is too focused on guaranteeing the procedures. Despite that, the question now is: What do inappropriate clinical processes contribute to people's health? Berwick states that quality must be understood as the provision of services that respond to people's real needs. The effectiveness has thus been filtered out in the world of quality.

Grey areas in the field of efficiency

In the same monograph, Sabinet Kleinet and Richard Horton, editors of the journal, have developed the following definition of 'right care': healthcare that brings more benefits than unwanted effects, taking into account the circumstances of each patient, their values and way of looking at things, which is also based on the best available evidence and cost-effectiveness studies. Having a definition of 'right care' is a first step forward, but that does not mean that the difficulties that follow are not huge. To begin with, the quantification of undesirable benefits and effects is often very difficult, because the evidence is usually incomplete and the iatrogenic results are poorly documented, and the threshold between appropriate and inappropriate is usually a gradient, and may vary between people, cultures and countries. The truth is that the bulk of the clinical activity moves in the territory of grey areas.

Many clinical practices used in the past (bloodletting, lobotomies, hysterectomies, tonsillectomies, radical mastectomies, hormonal treatments for menopause, etc.) had to be abandoned when the benefits they brought were contrasted with the problems they caused. Ian Harris, in 'Surgery: the ultimate placebo' [20], explains that half of the surgical interventions of the orthopaedics departments of three Sydney university hospitals were not supported by consistent assessments, a further proof that clinical practices move in a territory where grey zones predominate. It is striking that, after more than two decades of the emergence of evidence-based medicine, more than half of the existing clinical practices have not yet been sufficiently rigorously assessed; in contrast, the vast majority of research resources are obsessively aimed at assessing the effectiveness of the novelty clinical practices.

Desert areas in the field of effectiveness

Two systematic reviews, conducted by researchers at the Centre for Research in Evidence-Based Practice at the University of Bond, Queensland, Australia [21,22], found that (i) 88% of individuals overestimated the actual benefits of clinical interventions; (ii) 67% underestimated the adverse effects; (iii) only 11% of physicians know how to value the benefits of the clinical activities questioned; and (iv) only a small 13% were well informed of the corresponding adverse effects. Almost 80% of physicians opt, as do patients, for optimism, in terms of both positive and negative effects. It seems that humans have a predisposition to overestimate the effects of our actions, with a tendency to infer causality where there is none, which generates an unjustified enthusiasm in doctors and patients about the expected clinical results, a phenomenon known as ‘illusion therapy’.

If grey areas predominate in the field of efficiency, desert areas prevail in the field of effectiveness, given that on the one hand, most of the people who occupy medical offices and wards (chronic patients with multi-morbidities and the elderly) are systematically excluded from clinical trials; and, on the other hand, it appears as if there is no professional interest or sufficient funds to investigate the effectiveness of clinical activities. So the question is: What is the point of investing so many resources in research that answers questions that have little or no clinical interest? The bias of research funds towards news and technology is very evident, so it's urgent to change mentalities by promoting many more evaluations on the value that the provision of health services contributes to the health of the people.

Estimation of waste for practices of dubious value

Waste due to low-value clinical practices can be measured in two different ways. The first way is the direct method in which a committee of experts reaches prior agreements about what is appropriate and what is not, and then undertakes a clinical audit in selected centres. This methodology was used by a group of researchers at Stanford University and, after reviewing thousands of clinical records, concluded that the waste of valuable practices, in the California hospitals analysed, consumed a volume of resources ranging from 25% to 33% of its expenses [23], which have subsequently been corroborated worldwide in the monograph ‘right care’ published in *The Lancet* (see previous quote by Donald Berwick). The second way of measuring waste is the indirect method of analysing the variability in the use of health resources. Measuring the variability is not the same as evaluating what should be appropriate and what is not, since only statistical criteria are used in these studies, but it is assumed that if a variable observes a large dispersion, it is probable that the centres or units that are at the extremes of normality may be generating situations of overuse or underuse for the people to whom they offer their services.

Right care sources and methodologies

The initiatives that warn clinicians about non-valuable clinical practices are an advanced product of evidence-based medicine, motivated primarily by the difficulties clinical practice guidelines are having in adapting to patients' needs and the requirements

of complex processes. In recent times, these initiatives have multiplied, including: ‘Do not do’ recommendations from the National Institute for Health and Clinical Excellence (NICE), ‘Choosing wisely’ promoted by the ABIM Foundation, ‘Too much medicine’ of the British Medical Journal and ‘Less is more’ of JAMA Network.

The United States Institute for Healthcare Improvement (IHI) has proposed that we recognise as a ‘triple aim’ those clinical projects that achieve the triple objective of (i) improving patient experience; (ii) improving clinical effectiveness; and (iii) reducing costs. This relatively simple methodology starts from the idea that for an innovative project to be successful, it must be able to seek the desired clinical effectiveness, with patient complicity, and without forgetting that the costs should be affordable.

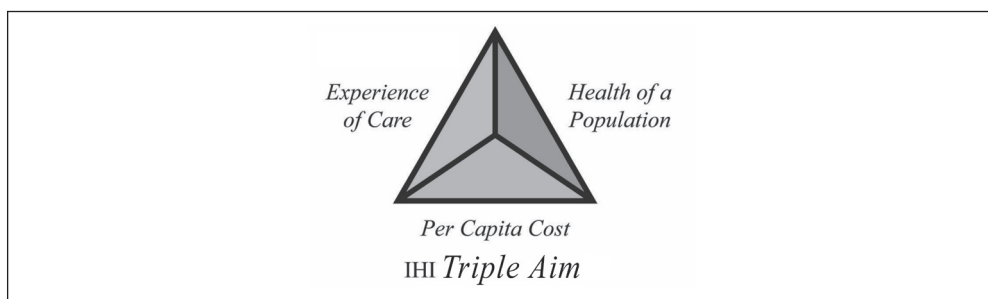


Figure 3. Triple Aim from the Institute for Healthcare improvement.

To apply the ‘triple aim’ methodology, clinical leadership is required. These projects move outside the official regulations, convincing the team that promotes them; therefore, they have a real capacity to bring about changes and to achieve improvements that are unthinkable from bureaucratic directions. Let’s take the example of the project ‘bacteraemia zero’. Peter Pronovost – a Johns Hopkins critical care doctor – and his team, promoted a study in 108 intensive care units, which showed that catheter-based bacteraemia could be reduced by more than 60% to rates lower than one infection every 1,000 days of the catheter, if compliance with a very basic guideline was guaranteed (hand washing, surgical precautions, skin cleansing with chlorhexidine, avoiding the femoral vein and withdrawing the catheter as soon as possible) [24]. Since its publication in 2006, clearly encouraged by the ‘triple aim’ of the Pronovost initiative, most governments have rushed to deploy ‘bacteraemia zero’ programmes.

An IHI team has evaluated the impact of the ‘triple aim’ initiative by analysing 141 projects from 10 different countries [25], and, according to those clinical projects, if they are unable to produce institutional integration – which is always difficult – they must know how to replace this limitation by a strong integrative will. The heart attack code or tumour committees are two good examples of integrative systems. In both cases, the willingness of professionals to achieve favourable clinical outcomes goes beyond their corporate affiliations. The integrative will of the professionals is a very powerful force.

Lessons learned from the early years of ‘triple aim’ could be summed up in only three principles: (i) identification of the target population; (ii) integrated (or integrative) management of essential resources; and (iii) generation of multidisciplinary teams capable of learning from experience and, therefore, entering into continuous improvement processes.

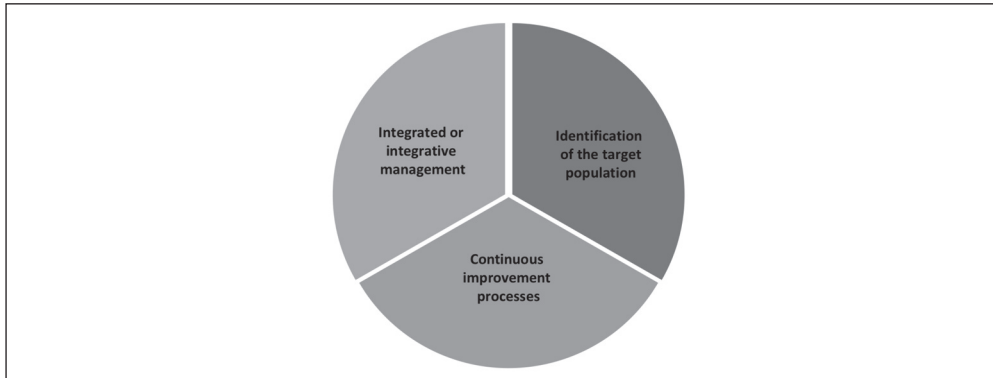


Figure 4. Three lessons learned from the early years of ‘triple aim’ (see citation [25]).

Alignment of Clinical Outcomes

The organisational model of hospitals is doubly pyramidal: the doctors on the one hand, and the nurses on the other.

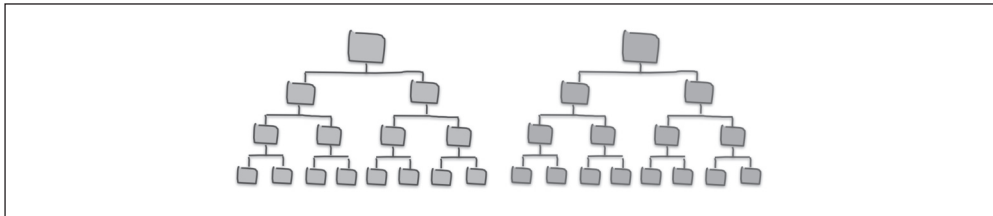


Figure 5. The two pyramids (doctors and nurses) that make up the organization chart of hospitals.

If we adhere to the medical pyramid, we observe that each of the so-called medical departments is a silo in itself, since, in addition to possessing the knowledge base in the matter (usually an organ or system), each department manages the resources that have been estimated to be needed for the practice of the specialty: clinics, beds, operating rooms, day hospitals or exploration cabinets. These services operate with a rigid internal hierarchical order.

Problems of fragmentation

If we observe the vast majority of patients admitted to a hospital (up to two-thirds), due to their own fragility, their comorbidities or the complications that arise, nobody ends up having a global vision of their problems; therefore, the bad results of the fragmented organisation for this large group of patients are evident, especially in six outbreaks:

1. The cul-de-sac of the patients in the observation units of the A&E.
2. Patients in the hospital wards blocking beds because the referring doctors have not been able to manage discharge satisfactorily.

3. Patients admitted during the weekends seem to have a higher mortality than those admitted on weekdays. There are controversial studies on what the cause is, but not on the fact itself.
4. Maximum disruptive medical practice with the excessive request for diagnostic tests and the accumulation of medication often not reconciled.
5. The lack of adherence to treatments at less than 50% in chronic patients.
6. End-of-life processes that are not adjusted to patient values, such as patients referred from home, or from nursing homes, to death at the hospital.

With very high levels of inadequacy, hospitals must be restructured if they want to preserve the quality of their services. This is a great challenge, because the resistance is enormous. For this restructure, hospitals will need four allies: patients, generalists doctors, referring nurses and primary care professionals; we will call these last three elements 'continuity of care'.

Patient experience

Patients have asked to speak, but now the issue goes beyond shared clinical decisions, because in some hospitals the necessary organisational reforms are already being carried out by the patients themselves. This is evident in the experiences of 'design thinking', a participatory dynamic involving patients and professionals alike, and whose objective is to redesign clinical units. This movement began many years ago in haemodialysis units in which all logic indicated that, if structural or circuit reforms were to be successfully implemented, it would be best to select volunteers among users to be involved in the process of planning a service, which they probably know better than anyone else.

Focus groups of patients as a change factor for hospitals have been proposed to make structural changes based on the experience of the patients. Johns Hopkins Hospital chose a group of patients to express what they thought about the organisation. The patient profile was like Podge Reed Jr., a well-known person with a double lung transplant who had accumulated six hospitalisations, two surgical and four medical ones, eight ambulatory procedures with anaesthesia, more than 100 visits to outpatient clinics and 700 laboratory tests. With this curriculum, the hospital felt that Reed should be a person with an opinion. Jane Hill, the Director of Patient Relations, says that most people entering hospital, despite assessing the technical quality of services, also ask to be treated with kindness and care. Feeling bedridden in a hospital is not an easy experience for anyone.

With the same idea as Johns Hopkins and the Beryl Institute principle, 'all workers are important to the patient's experience', Cleveland Clinic organised half-day workshops with 10 professionals each, mixing all professional categories at random so that a clerk could share a meeting with a kitchen clerk, a neurosurgeon, a nurse, etc. It was about exchanging stories and finding solutions to problems together. Basic training in personal treatment was also included.

Continuity of care

In order to improve the continuity of care and the quality of care provided to hospitalised patients, general practitioners should have full dedication to the clinical work of the hospitalisation room with a desirable coverage of 12 hours a day, in morning and

afternoon shifts. Each patient admitted would have a referring doctor and a nurse who would be responsible for elaborating the general and integral evaluation and the individualised plan jointly with the primary care professionals. The challenge of the heavy hospital structures is to evolve towards a new redistribution of beds that are more adapted to the needs of the current casuistry.

Concluding Remarks

Modern clinical practice is strongly pressured by the consumerist desire of society and the industry related to the provision of services. In addition, this phenomenon subsists with a profound and persistent change of casuistry towards complex chronicity and geriatric frailty, which requires an offer of personalised care instead of fragmented actions. With all this, healthcare systems survive in a wicked environment, thus they need a global transformative vision as well as much tenacity.

This chapter has focused on the need for current clinical practice to add more value to people's health, and for this reason, four strategic lines have been proposed which, if the 'wicked problem' is to be addressed, should occupy the decision-makers' agendas:

1. More strategies to promote patient-centred care, based on greater training of clinicians in motivational interviewing and shared decisions.
2. More professional debate in academic environments to reduce overdiagnosis and overtreatment.
3. More resources to evaluate clinical practices that still do not have enough evidence to support them.
4. Less fragmentation and greater alignment of care objectives among professionals who care for patients with social and health complexities.

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CHAPTER 6

Should the Spanish NHS be more explicit in the prioritisation of health services?

Salvador Peiró, Juan del Llano

Summary

Priority setting (a synonym for resource allocation and rationing) occurs at every level and every corner of every healthcare system, in two basic (and not exclusive) forms: implicit and explicit rationing. Explicit priority setting refers to situations where the choices adopted about resource allocation are made clear. Also, but not always, the basis upon which those decisions have been made are revealed. In contrast, implicit priority setting refers to the discretionary decisions made by managers, doctors and other health professionals under a budgetary restriction. Implicit prioritisation may be exercised fundamentally at the *micro* level of clinical decision making (bedside rationing), while explicit prioritisation should be, above all, a responsibility of the *meso* and *macro* decision makers. In order to really ‘make sense’ and to constitute appropriate care, implicit prioritisation in daily clinical practice needs a competent, well-defined framework of explicit priorities fixed at the *meso* and *macro* healthcare decision-making levels.

Priority Setting, Resource Allocation and Rationing

Priority setting occurs at every level and every corner of every health system, and is one of the most relevant healthcare policy issues of the 21st century [1]. It was, in fact, a cornerstone of healthcare management also in the 20th century, but we did not come to realise its importance until the end of the century. In this section (which, hopefully, no one is reading, because talking about prioritising always seems politically incorrect, even a little impolite), we will seize the opportunity to point out that priority setting is a synonym for resource allocation. Priority setting, despite the fears associated with certain words, is also a synonym for rationing or even for the belligerent term of ‘cuts’, although there may be some nuances between them, depending, on occasion, on the context in which they are used.

In free markets (but are there really any free markets?), consumers use their income and make preference-based decisions about how much they are willing to pay for particular goods or services, and suppliers consider the profit for which they would be willing to produce and sell these goods. Then price links consumers and suppliers preferences allowing for the adjustment of what is produced and who consumes it. But, as everyone knows, consumers' willingness to pay depends not only on preferences, but also on income and wealth.

Most societies nowadays – even with many differences between them – believe that for some goods and services, such as healthcare, free market distribution is unfair (because individuals with low income and poor wealth are unable to purchase some medically necessary services, even urgent or lifesaving care) or inefficient (due to the asymmetry of information and other market failures) [2]. In these societies, population-wide healthcare coverage systems (either more or less universal, more or less obligatory, funded through taxes or premiums, with public or private provision of healthcare services) have been put in place to ensure that (almost) everyone receives (and to a defined extent) these 'merit goods'.

To make a distinction between allocation through freely competitive markets and other forms of resource allocation, economists distinguish between 'price rationing' and 'non-price rationing' [3] (or, plainly, rationing). Rationing, in our context, basically refers to the fact that the (limited, scarce) healthcare services and health benefits are allocated to users (citizens not always sick, consumers and patients) in a way that is disconnected from their price, and on the basis of criteria (if any) other than their actual preferences, their willingness to pay, their income or wealth [4].

As sustainability of mandatory assurance (whether provided publicly or by private firms) depends on the achievement of a certain balance between income (taxes, premiums or cost-sharing schemes that set the 'budget'), and the expenses supported by the insurer, rationing healthcare seems unavoidable. In the words of Victor Fuchs: *'No nation is wealthy enough to supply all the care that is technically feasible and desirable; no nation can provide "presidential medicine" for all its citizens'* [5]. However, still some authors postulate that *'the demand for healthcare must be finite: the population is finite and only a proportion of the population can benefit from and want treatment'*, and that the assumption of scarcity (and, its consequence, rationing) is not supported by scientific evidence [6]. The plain fact is that, to date, innovation in healthcare has not achieved productivity increments to reduce demand and health spending (but rather it seems that the opposite is happening), so in this work we accept the scarcity assumption (and its logical consequences).

In this framework of *inescapable fate*, there are many practical forms of allocation subject to constraints (and even more ways to call them) that can be perceived differently by different agents. *Priority setting* is the friendly face of rationing and may be interpreted positively as a way to optimise budget constraints and maximise health outcomes. Obviously, this idyllic vision forgets that in a context of limited resources there is always prioritisation (explicit or implicit, by action or omission) and this does not imply that priorities have been properly settled down. *Cuts*, in turn, are perceived negatively, as a rough way to maintain the budget limitation independently of health outcomes and social welfare. This perspective, in turn, forgets that cuts in unnecessary services, with a negative risk–benefit balance or even those with a higher price but neutral in health outcomes, could allow

resources to be devoted to more useful activities (i.e. cuts can mean appropriate prioritisation). Finally, the word *rationing* is sometimes depicted as Trojan horse stuffed with cut-outs and may generate social mistrust.

The nuanced meanings that can be attributed to all these terms, which incorporate ideological components about social inequalities, have been shaped by social experience; however, they also inform about the interests of the agents that choose one term over another in seeking to benefit from the processes of resource allocation, including health-care professionals. Anyway, the truth is that after the severe processes of prioritisation, rationing and cuts occurred in almost all public healthcare systems associated with the recent economic crisis; professionals and citizens may not be sensible to semantic subtleties and whoever utters any of these words will be scarcely popular in his/her neighbourhood.

Interestingly, Klein differentiates *rationing* (allocating resources to individual patients by medical judgements) from *priority setting* (allocating services to the specific services of client groups by societal and value judgements) [7]. Even admitting, like Klein himself, that this distinction '*does not always hold and becomes blurred in practice*', it is an attractive nuance that can be very useful to navigating the raging sea of rationing in healthcare. Under these definitions, priority setting will involve rationing, but not all rationing will derive from setting priorities.

Rationing in healthcare is conventionally defined as the **denial of potentially beneficial services, benefits, interventions or treatments** [8]. Therefore, rationing does not apply to situations where ineffective treatments or services are not provided. There will be 'rationing' whenever underuse occurs (understanding underuse as not prescribing a treatment or intervention that would benefit one patient in a specific situation; e.g. not prescribing oral anticoagulation to a patient with non-valvular atrial fibrillation with a certain level of thrombotic risk).

Because 'beneficial' may have different interpretations (even among different doctors, or by a single doctor when treating different patients), this definition is only useful when the concept of 'beneficial' (or necessary, appropriate or effective in a concrete condition) is, in turn, well defined. Some public and private insurers tend to use softer concepts to address 'value' (or lack of it), such as 'interventions or treatments that offer only marginal benefit' or 'low value care'. Once again, the concepts of 'marginal benefit' or 'low value' also remain elusive and need to be defined from a risk-benefit perspective (efficacy), added value with respect to the pre-existing treatments perspective (incremental effectiveness), a cost-benefit perspective with respect to the alternatives at stake in each patient condition or other, not always homogeneous, criteria [9].

The use of euphemisms is common in politics and in health policy. Supporters of a particular policy that implies rationing will try to avoid the so-called 'R word', at least in public debates and documents, and they will prefer to talk about *priority setting* [10]. Nobody likes to hear that giving priority to something implies giving inferiority to something else [11]. Even if the term *priority setting* may sound better to the ear, in essence it implies rationing, but it adds a touch of meaning of rationality in the proposed rationing. However, real-life experiences of priority setting in healthcare have not always been a prodigy of rationality.

In short, rationing, in its wide sense, is a synonym for resource allocation and refers to any method to determine who receives, and to what extent, a scarce good or service. Rationing in healthcare can incorporate the price mechanism; however, in our specific

healthcare field, it mainly refers to the non-price mechanism for allocating limited, free (or almost) goods or services at the point of delivery. Under rationing, by definition, some patients will be allocated 'beneficial' goods or services, to a prioritised extent, and some will not.

Levels and Types of Priority Setting

In addition to rationing associated with price mechanisms in free markets, some forms of resource allocation decisions are also outside the aim of this work; such as the so-called 'tragic choice' situations. Tragic choices involve circumstances in which demand for a scarce and non-expandable lifesaving service exceeds supply, and urgent decisions must be made about who receives the service. Who should receive the only available heart when there are several candidates for transplantation? Which patients should be treated first in an emergency? Who should receive the last available critical care bed? These questions usually respond to life threatening situations and, in general, are resolved by clinical criteria related to the vital urgency and the expected benefit. These criteria do not derive from economic reasoning and, despite the gravity of this kind of situation, there is a broad consensus among lay people and professionals, that they 'have more symbolic than practical significance' from the rationing perspective [12].

Total exclusion of goods and services from private markets is also outside the scope of this work. For example, virtually in all countries, law forbids organ markets, and patients – whether served by the public or the private sectors – are queued on receptor waiting lists. This market exclusion (which does not happen in other life-threatening conditions not subject to the availability of organs; e.g. oncological diseases) is a form of egalitarian priority setting where disposable income is prevented from being a determining factor in the prioritisation of transplantation.

This work focuses on the allocation of (scarce) healthcare resources, limited by an (always scarce) budget, in universal (or almost universal) insurance systems whose services are provided free at the point of delivery (or well below the market price), both by public and private healthcare providers. Typically, those are the characteristics of countries with national health services (typically financed by taxes) or with social security systems (typically financed by social security contributions and taxes) that include healthcare among their benefits.

Priority setting in this context can adopt two basic (complementary rather than mutually exclusive) forms: implicit and explicit rationing (Figure 1). Historically, there is a strong controversy about the merits and demerits of each one of these approaches [7,12-15], partly because pro and con arguments often refer to rationing at different hierarchical levels within the healthcare organisation.

Explicit priority setting exists when **choices that have been made about resource allocation are made clear and publicly available** and, but not always, **when the grounds on which those decisions have been made are revealed**. Administrative authorities usually implement explicit priority setting, and stipulate the amount and type of resources to be made available to eligible populations and the specific rules for allocation. Both under public and private insurance, a significant volume of explicit rationing is made with regard to the incorporation into the offered portfolio of services,

technologies, medicines, facilities and programmes, the allocation of funds to alternative programmes or activities, and the delimitation of eligible candidates to benefit from these interventions.

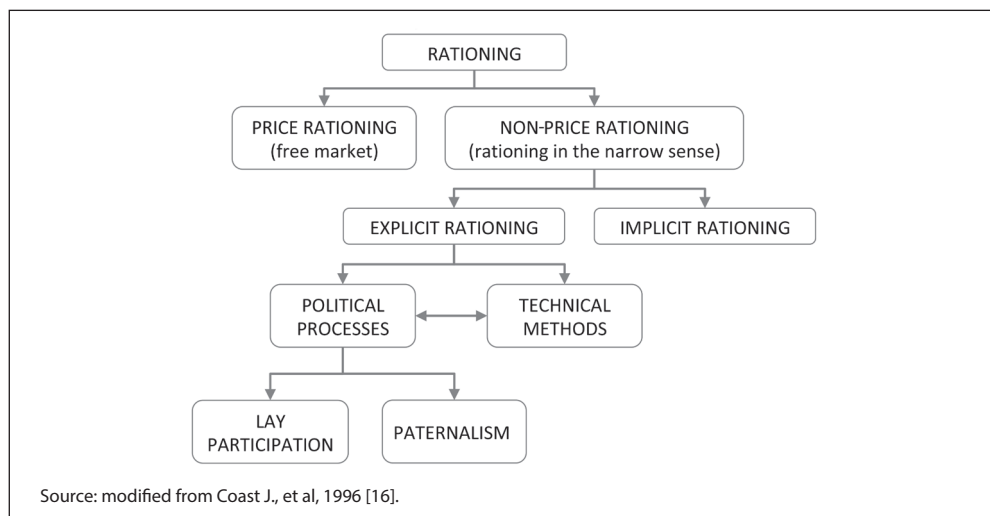


Figure 1. Rationing (or prioritisation) in healthcare.

Implicit priority setting refers to the **discretionary decisions made by authorities, managers, doctors and other health professionals under a budgetary restriction**. Here, care is restricted, but **neither choices, nor the basis for those choices are clearly expressed**. Whether it is in a conscientious manner or not, doctors and managers can use a variety of rationing strategies to reduce utilisation and costs, such as queuing, substituting costly services or drugs for other less expensive ones, reducing the intensity or the quality of services or, above all, deciding whether services are necessary or not (including preventive services, diagnostic tests, treatments, surgery, hospitalisations, rehabilitation and others).

At the micro level, implicit priority setting is inherent to the provision of health services [17]. When a patient asks for an appointment with her/his family doctor, someone – usually a receptionist – makes a decision about when she/he will be attended (rationing by deterrence, as defined in the seminal paper by Roy Parker) [18]. When the patient is seen by the doctor, the latter will decide whether to spend 3 minutes or 15 minutes for the medical visit, whether to order a test, to prescribe a treatment or to refer the patient to another doctor. If her/his doctor has requested a test or a referral, the patient may be placed on a waiting list (rationing by delay, in Parker's terminology). Still, this family doctor may not be authorised to request a particular test and shall refer the patient to a medical specialist. If a treatment has been prescribed, it may be subject to authorisation before dispensing. Eventually, a patient can go to the hospital and, after a process of triage and waiting according to severity, can be attended to in an Accident and Emergency Department (A&ED) where, again, doctors will decide if she/he needs to be admitted or not. Common to all these processes is the fact that multiple professionals make decisions

about the resources they are willing to devote to a particular patient. These also include decisions about when to discharge or when to stop a treatment (rationing by termination of treatment).

All these micro-choices are adopted according to the needs of the patient as perceived by different healthcare professionals, usually under conditions of uncertainty. In fact, decision making at this level is at the core of the 'medical practice variation' phenomenon (see Box 1).

The context where implicit rationing processes take place is important. Micro-prioritisation is framed by meso- and macro-rationing decisions made for a whole health primary care centre, a whole hospital or a whole healthcare system. For instance, if hospital-at-home services are lacking or very difficult to access, they will be rarely prescribed.

Finally, it is considered that resource allocation has a history. Patterns of distribution between different types of resources (human, medicines, equipment), between clinical areas (emergencies, cardiology, surgery, intensive, other), between categories of personnel (doctors, nurses, pharmacists or others), between levels of care (hospital vs primary care, internment vs home care), etc., are often dragged on for decades – in many cases from the opening of a hospital or the beginning of an organisation.

In this sense, priority setting is, whether we like it or not, an incremental exercise: it typically involves allocation decisions over increases in an annual budget (even if in the last few years, priority setting has been mostly confronted with negative budget variations, and the exercise then turns into selecting what goods and services must be reduced according to budget cuts). Although it is possible to reallocate some pre-existing resources (disinvestment), the adoption of 'zero-based budget' strategies in healthcare systems is out of the question. Rather, the need for pre-existing services (which unfailingly have large queues of patients waiting to be served) will significantly determine its annual increase. And even in the case when demand for pre-existing services may not be evident (an unlikely situation in an environment where the supply generates its own demand), organisational resistance would make it difficult to make substantial changes in the new budget.

In summary, effective priority setting is the result of a very complex interaction of multiple decisions and choices made at different organisational levels, in an explicit or implicit way, and by decision makers that may not be fully aware of the rationing implications of their decisions (or their lack of decisions).

Priority Setting in Practice: Implicit Rationing in the Spanish National Health System

New and the Rationing Agenda Group [20] (and based on the aforementioned early work of Roy Parker [18]) describe a useful framework for understanding the different ways in which access to care can be rationed by priority setting, mostly by implicit rationing but sometimes constrained (or contextualised) by explicit priority setting (see Box 2).

Rationing by denial refers to the exclusion of specific services or treatments from the National Health System portfolio (often explicitly – an aspect that will be addressed in the next section) or from the portfolio of one healthcare provider (usually one hospital) that believes that such treatment or service is unnecessary or of low-value. Many times these

Box 1. Medical Practice Variation

- How many, when, where, why, how and for how long people are hospitalised or treated, what kind of treatment do they receive, what is the cost of care episodes, and what outcomes in terms of improved length and quality of life for patients do they achieve? These are critical questions for all healthcare systems. Sadly the answer to these questions may depend more on which municipality people are living, than on how sick they are. At the population level, geography, not morbidity, is the main determinant of healthcare utilisation and health expenditure. Furthermore, higher spending regions are failing to achieve better outcomes.
- Researchers have consistently demonstrated remarkable unwarranted variations in clinical practice. Such waste deprives potential patients of care from which they could benefit. The three core findings of clinical practice variation research are: (i) geographical variations in healthcare utilisation and spending are systematic (not just random noise), substantial, pervasive and persistent over time; (ii) risk adjustment for individuals' characteristics and health status attenuates but does not remove variation; and (iii) there is no correlation between healthcare utilisation/spending and healthcare quality or superior outcomes.
- Medical practice variations are not explained by differences in population morbidity or by the patients' clinical status. Beyond concerns about social or access inequalities, the most disconcerting message from these unwarranted variations is the one that strongly suggests that physicians provide very different care for patients with similar clinical conditions, undermining the traditional belief that health professionals uniformly apply an unequivocally appropriate treatment for each health problem.
- Unwarranted variations for effective treatments (e.g. antiplatelet drugs in secondary prevention of ischemic heart disease) suggest underuse in low utilisation regions. In the so-called 'supply-sensitive' treatments, variation suggests overuse in high-utilisation regions. In the so-called 'patient-sensitive' treatments, variation suggest differences between the preferences of patients and those of their doctors.
- An important part of health spending is associated with practice patterns that do not translate into improved outcomes for patients and populations. Thus, mitigation of variations in medical practice is a way to reduce health spending without harming the health of patients. Resources saved can be redirected to provide beneficial care to other patients. So, addressing medical practice variation is important for public health systems. Additionally, studies on medical practice variations suggest that dysfunctional geographical areas are characterised by hospitals providing fragmented, expensive and not always appropriate care. Therefore, it is likely that a reduction of variations may result in better outcomes for people living in these areas.

Source: Peiró S, Maynard A, 2015 [19].

decisions are based on evidence about lack of clinical effectiveness, and denial sometimes is not negative for patients, especially if this gets rid of ineffective treatments with the risk of adverse effects. Sometimes, however, effective treatments may be denied.

Rationing by denial is closely linked to rationing by selection, but the latter is based on the characteristics of the person being treated, while denial is based on the characteristics of the service itself. In any case, services or treatments that are denied to all patients in any circumstance are very rare, and it is usual for both forms of rationing to be combined.

The Spanish National Health System (sNHS) has a limited budget (which has been further reduced during the deployment of the fiscal stability plan adopted by the government to deal with the economic crisis) and cannot pay for every potential treatment or offer every potentially effective service. Since 2006, the sNHS has formally defined a broad

Box 2. National Health System Rationing Strategies

- **Rationing by denial.** Exclusion of specific services or treatments from the National Health System portfolio (often explicitly) or from one healthcare provider (near always implicitly) that believes that such treatment or service is inappropriate.
- **Rationing by selection.** Exclusion of some patients of some treatments because they do not meet certain eligibility criteria fixed by the regulator (often explicitly) or the provider (near always implicitly).
- **Rationing by delay.** The demand that cannot be met by a rigid offer remains on hold (waiting list) and the wait acts as a barrier to access and, in many cases, as a *de facto* denial of care.
- **Rationing by deterrence.** Barriers placed, either consciously or unconsciously, by the healthcare providers that make it difficult for patients to find out about, and book appointments with, some healthcare services.
- **Rationing by deflection.** Patients being shunted off to another institution, agency or programme.
- **Rationing by dilution.** Services continue being offered to patients, but with fewer resources, and the quality of care gets worse.

Source: based on New B, Rationing Agenda Group, 1996 [20].

and explicit (but at the same time implicit) portfolio of services [21], which basically consolidates what the healthcare services of the sNHS have been doing, and periodically incorporates new procedures that are introduced in the healthcare system. Exclusions are very limited and entitled people have guaranteed access (or, better expressed, a general legal right to access) to the services portfolio '*whenever there is a clinical and sanitary indication for it*' [21]. That is, one sNHS doctor has to ultimately evaluate the appropriateness of every care intervention for every single patient. Under this formula, the definition of the sNHS services portfolio almost completely puts the responsibility for setting priorities on the health professionals and (except for the few services expressly excluded and some in which eligibility is restricted) devolves to the world of the implicit what apparently was a process of explicit priority setting.

Undoubtedly, Clinical Practice Guidelines (CPG) have some influence on the decisions made in health centres and by health professionals, but the sNHS is not obliged to follow any CPG (not even those that the same sNHS develops through Guiasalud) [22] and CPG do not generate a right to receive the recommended treatment/intervention. Therefore, many of the choices about which treatments are really available are made by hospital committees or by clinicians 'at the bedside'. Unlike other countries, Spanish hospitals do not usually publish lists of non-available treatments in their centre. The so-called 'Therapeutic Positioning Reports', published by the Spanish Agency for Medicines and Health Products (AEMPS), are a peculiar form of explicit priority setting that will be addressed in the next section.

In Spain, treatments excluded at local level broadly fall into three categories: (i) low value treatments; (ii) high-priced drugs – as some oncologic, biologic or treatments for ultra-rare diseases – with little evidence of incremental efficacy, a usual situation with recently approved drugs; and (iii) treatments reserved for only certain individuals based on factors that can affect the probability of success or adverse effects (rationing by selection). Note that, to a large extent, these restrictions may be beneficial for patients. However, with a lack of explicit prioritisation criteria at a national level, decisions will

be made locally, and exclusions can be very different depending on the centres, generating a potential source of unwarranted variation that can ultimately be associated with a hindrance in the quality of care.

Despite some efforts, the use of low-value treatments does not seem to be dropping in the sNHS. The *sNHS Atlas on Medical Practice Variation Group* recently published an interactive Atlas of procedures of 'doubtful-value' in the sNHS. The selection of procedures of 'doubtful-value' is derived from lists drawn up in other countries or from assessment reports published by the health technology assessment agencies existing in Spain, which includes obsolete procedures, outdated by more effective or cost-effective alternatives; procedures of low-value when used outside of their main indication; and procedures for which the evidence of effectiveness is still insufficient.

While the rates of use in the population of some of these doubtful-value procedures have shown some reduction, the utilisation rates of many others (see Box 3 for some examples) have not changed nor increased in recent years. Astonishingly (maybe someday we will no longer be surprised by the things that happen in the sNHS, but we are not really sure), the significant reduction in health spending during the period of implementation of the stability plan does not seem to have affected the rates of use of low-value procedures. Targeting those low-value procedures for disinvestment (priority setting) appears now to be a lost opportunity to rationally release the system from its ineffective activity burden.

Rationing by selection refers to the exclusion of some patients from some treatments or interventions because they do not meet certain eligibility criteria. As previously stated, selection (by personal characteristics) and denial (by treatment characteristics) are closely related, and in many cases these selection/denial decisions are based on evidence about the risks and benefits of a given treatment in a certain subgroup of patients with certain characteristics. For example, an orthopaedic surgeon may not indicate a knee arthroplasty in an obese person or an elderly person with dementia if the doctor considers that the intervention will fail or will not improve the patient's functional independence and quality of life.

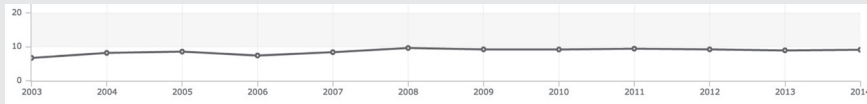
Although selection can be explicit, it is usually made by individual clinicians during consultation (so it is sometimes called 'bedside rationing'). As in rationing by denial, CPG service protocols (criteria agreed by one or several clinical services), pathways, referral criteria and similar approaches constitute guidance for decision making, but there can be huge differences among centres (and among doctors in the same centre). Even when we look at the most common and clinically effective procedures that are undertaken, we observe utilisation rates that vary significantly across territories in the country. The information available in the Atlases does not allow the presence of overuse, underuse or any combination to be established in the same area; however, it does show that populations with similar clinical conditions are allocated to very different interventions depending on their place of residence, even when it comes to neighbouring areas served by two different hospitals.

As previously commented, sNHS do not usually publish lists of non-available interventions for specific groups of patients, although there are a few exceptions, such as in-vitro fertilisation procedures and some others with public criteria defined in the Spanish regulations [21].

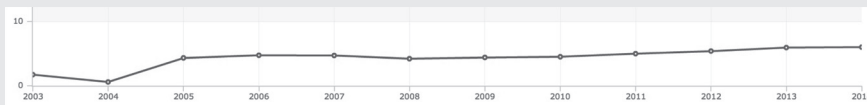
Rationing by delay is the most renowned form of rationing in the sNHS. The demand that cannot be met by a rigid offer (rigidly regulated, with health professionals having a quasi-civil servant status) remains on hold; the wait acts as a barrier to access and, in many cases, as a *de facto* denial of care.

Box 3. Utilisation of Some 'Doubtful-Value' Procedures in the Spanish National Health System: Temporal Trends 2003–2014

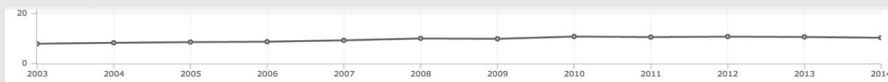
Standardised rates by age and sex of tonsillectomy (with or without adenoidectomy) per 10,000 inhabitants under 20 years of age.



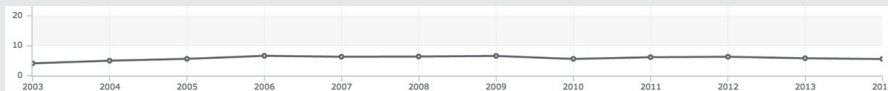
Standardised rates by age and sex of carpal tunnel release surgery per 10,000 inhabitants over 15 years of age.



C-section percentage in low obstetric risk deliveries over the total of low-risk births, in women between 15 and 55 years.



Standardised rates by age and sex of tympanic drainage (grommets) per 10,000 inhabitants under 20 years of age.



Source: García-Armesto S et al. [23]. With permission.

The sNHS has waiting lists everywhere, and waiting times without formal waiting lists. The most popular waiting lists are those related to elective surgery, basically because they have been published every 6 months for more than a decade (not without some accounting creativity and some media frenzy). However, the sNHS keeps waiting times for many diagnostic tests, for referrals to different medical specialties, for rehabilitation and physiotherapy, and for many specific treatments (e.g. in-vitro fertilisation, morbid obesity surgery or some oncological procedures).

Other important waiting times in the sNHS are hospital A&ED waiting times, which seem to be growing (probably due to the growth of non-urgent healthcare demand attempting to access the system via A&ED), and the increasingly frequent waiting to get an appointment with family doctors. There is a lack of published data available on this latter subject, in the same way that it is lacking in many other areas, such as nursing care, mental healthcare, hospital-at-home or primary home care.

Rationing by deterrence refers to barriers placed, either consciously or unconsciously, by healthcare services to make it difficult for patients to find out about and book appointments with local services. Phones to ask for appointments that nobody answers, unhelpful receptionists or unkind professionals are part of these barriers. Probably the most important deterrent barrier rises from the lack of information about the availability of services and ways to access them. If individuals are not given information about a service, they will not demand it, and they may not realise that their access to care has been restricted.

Deterrence may lead patients to seek care in other centres (rationing by deflection), which can lead to a worsening of their condition before they decide to seek care again (a hidden waiting list), or it may become an informal denial if they give up seeking care. As mentioned before, the absence of information is a critical aspect of deterrence rationing. It may specially affect specific programmes for some patient subgroups (health education and self-control for elderly diabetics, prevention of unwanted pregnancy in young people, respiratory rehabilitation for patients with COPD, cardiac rehabilitation post-infarction, etc.), and specific services, such as home visits of paediatricians and family doctors. In fact, those are two of the services that in Spain – unlike other countries – have experienced a huge reduction in recent years by means of deterrence mechanisms.

The concept of **rationing by deflection** is used when a healthcare provider refuses to provide assistance, and the patients are shunted off to another institution. The provider can ‘deflect’ the patient elsewhere in the system, but in the sNHS typical ways of deflection are derivation to another payer (e.g. to social services department); to another sNHS organisation (from family doctors to hospitals, from hospitals to family doctors, from one specialty to another); or to the healthcare private sector (typically for elective surgery and after exceedingly long waiting times without receiving care in sNHS hospitals).

The most common forms of deflection include referral of some patients with a significant burden of disease to social services (and vice versa – referral of patients with social charges to health services); referral to primary care (from the hospital or from emergency services) of unstable or not sufficiently stabilised chronic patients; referral from primary care to hospital A&ED (in many cases patients can seek assistance directly if their experience with primary care has been unsatisfactory: rationing by deterrence) or to specialised care; and crossed referral among multiple and diverse specialists treating patients with multimorbidity, where no one assumes the integral care of the patient, resulting in care silos and fragmentation. Samuel Shem superbly narrated some of these deflection mechanisms by using the terms to ‘turf’ (finding any excuse to refer a patient to a different department) and to ‘bounce’ (a turf that has returned to its first department) [24].

An increasingly widespread form of deflection is referring patients to other hospitals or not accepting those coming from geographical areas other than the one assigned to the hospital. For example, when a patient has been prescribed a very high-priced medication dispensed at the hospital’s external pharmacy and thus is charged to the hospital’s budget, or when a hospital has a long waiting list and does not want to deal with more patients.

Deflection can create patient uncertainty and anxiety as organisations pass the buck. Also, delaying access and having to repeat the same information multiple times creates frustration. Ultimately, patients may be deterred from seeking care, transforming deflection in denial.

Lastly, when **rationing by dilution**, services continue being offered to patients, but with fewer resources and reduced quality. Patients access the same facilities and receive similar treatments, but there are fewer nurses, or fewer doctors or other resources have been reduced. Appointments are shorter or more spaced in time and some care protocols are modified to reduce workload.

Not all staff shortages are caused by budget cuts; not all result in patients receiving lower-quality-of-care; and not all are harmful to patients. Some can even be very positive by reducing exposure to unnecessary care. But in many cases, reductions of human resources translate into reduced quality of care and worse results for patients. For instance, mental health services in the sNHS have historically suffered this process of dilution. Ultimately, mental health provision in Spain has ended up configuring a rickety structure compared to other clinical areas and, more importantly, when compared to the need of mental care in our society.

When explicit priority setting (such as denial) is substituted by implicit forms (such as dilution), rationing becomes largely invisible. The small number of referrals of patients to clinical psychology or psychiatry services may be a form of unconscious rationing due to decades neglecting these services (dilution) rather than reflecting a genuine scepticism of sNHS physicians toward the clinical value of these disciplines. In this last case, there would be no rationing because the clinical need for the service would not be established. Patients who have not been referred will not claim for delayed care. There is no denial and no waiting lists. Dilution, the sunken part of the rationing iceberg, is the foreseeable result of the implicit priority setting carried out for many years at the macro-level of decision making, and is the demonstration that a lack of explicit rationing at the macro level leads to important opportunity costs for patients and populations. Dilution due to lack of explicit rationing also reflects the lack of accountability of macro-level decision makers in the sNHS.

Explicit Priority Setting: The Case Against the Spanish National Health System

One unappealing characteristic of the sNHS (and probably of each and every regional health service that constitute the sNHS) is its tendency to centralise budgets and recognition, and to decentralise, dilute and blur responsibility. It is likely that this phenomenon characterises not only the sNHS but also any heavily politicised health systems and, as a matter of fact, the vast majority of political activity. National and regional health ministers are always happy to proclaim increased benefits for some patient group, to inaugurate new facilities (hospitals are the golden boys) or to announce new equipment or new services (especially if it is a first-in-Spain technology that the rest of the regional health services do not provide). But very rarely do they explain which services will no longer be provided or what alternative new services are discarded when funds are allocated to the new interventions.

The most visible form of priority setting would be to explicitly include (or exclude) certain benefits or services in the sNHS portfolio, but this has always been unmercifully rejected by the national and regional health authorities in Spain. As previously stated, the 2006 formal regulation of the sNHS portfolio of services detailed that services under

sNHS coverage were the same services and activities that traditionally had been carried out in the system. For instance, the primary care portfolio included '[...] care, diagnostic, therapeutic and rehabilitation activities, as well as those of health promotion, health education and disease prevention, which are carried out at the primary care level [...]'. Specialised care suffered the same fate and included '[...] healthcare, diagnostic activities, therapeutic and rehabilitation and care, as well as those of health promotion, health education and prevention of the disease, whose nature indicates to be performed at this level' [21]. Beyond the circularity of definitions (the sNHS includes what the sNHS do), the legal text is a clear example of the weight of history and status quo maintenance in the setting of priorities in the sNHS.

Exclusions in the 2006 regulation were limited to almost all dental care, cosmetic procedures and surgery, correction of refractive problems (glasses, refractive surgery), snoring surgery, double reversal of tubal ligation or vasectomy, psychoanalysis and hypnosis, some para-pharmaceutical products (cosmetics, dietetics, mineral waters, elixirs, dentifrices, homeopathic treatments, medications, accessories and sanitary consumables that are advertised to the public), and some drugs (principally drugs for smoking cessation, obesity, hair treatment, erectile dysfunction, and others that were withdrawn from public funding due to poor effectiveness or to address 'minor symptoms'). Additionally, as said before, selection criteria were incorporated in some procedures, such as in vitro fertilisation [21].

In almost every case, these exclusions have been present in the sNHS since its inception; therefore, their impact on public budgets have only been marginal, but they surely reveal the limits that our health authorities do not want to transgress so as not to raise social controversies. Even so, some of these exclusions are harshly attacked every now and then; for instance, when a new drug on an excluded condition becomes available or when there is a doctor willing to promote the development of an excluded service.

Besides, most exclusions can be overcome for clinical individual reasons, for instance, when a cosmetic problem produces a psychological disorder. Also, the Spanish regulation contains several *escape clauses* that allow banned procedures to be reintroduced at the individual level if a clinician considers it necessary.

This analysis of the rationing dynamics of the sNHS portfolio shows that instead of an explicit prioritisation approach, the Spanish health authorities have adopted a tricky strategy, by transferring decisions on rationing that should be adopted at the macro and meso levels to the micro level (the clinician level). In this way, they aim to avoid giving the impression that there is rationing, but in practice, and under the assumption of scarce resources, this neglect of explicit priority-setting duties translates into a colossal process of implicit priority setting in the sNHS.

This elusive strategy comes with a great emphasis on implementing and monitoring adherence to CPG and protocol recommendations at the micro level. In the same way, computerised clinical decision-making algorithms are in place and make it difficult (or at least uncomfortable) for doctors to prescribe medication (especially those that are costlier than available alternatives) or tests not recommended by selected CPG. Performance indicator frameworks have been developed to monitor (and sometimes economically encourage) compliance with specific CPG recommendations. These ways of constraining doctors' implicit rationing can be positive or neutral for most patients (if the instruments are well designed) and can obtain some savings for the sNHS. But when suboptimally

designed, or when interpreted too rigidly by doctors, it can be difficult to individualise treatments. In a highly bureaucratised healthcare system, with semi-civil-servant salaried professionals, which are accustomed to the imposition of this type of measures, this risk should not be underestimated.

The 'case against' the absence of real explicit priority setting in the sNHS does not apply only to the incorporation of procedures and benefits to the sNHS portfolio. Decisions about the building or opening of new hospitals (and their hospital services), long-stay centres, hospital-at-home services, primary care centres, mental health units, etc., commit resources for decades and have escaped from an explicit prioritisation process. Workforce long-term planning in the sNHS also seems to run through the avenues of discretion and historical status quo. (Note that the number of residents admitted to the sNHS each year is a function of the training capacity of the different medical specialties!) On a wider societal perspective, it would also be advisable to make explicit decisions about how many resources we want to allocate to healthcare as a society and what should be the share of publicly funded care.

In the absence of explicit decision making, the sNHS is not an aimless system. We are just following the course marked in the 1970s and 1980s. Whether it is appropriate to follow this course is a question that has been stolen for decades from public debate, which is more prone to simplistic binary discussions (public/private, free/cost-sharing, centralised/decentralised, and similar).

In Conclusion: Appropriate Implicit Priority Setting Requires More and Better Explicit Priority Setting

In view of the foregoing, it is only fair to highlight the importance of the implicit rationing carried out by health professionals. It is likely that it is only at the micro level where there is sufficient knowledge of the patient and her/his clinical needs to make appropriate rationing decisions. In fact, if these decisions were perfect, we would not be talking of rationing (underuse), nor of overuse: all patients would receive the necessary care for their clinical condition.

However, the recognition of the essential role played by the implicit rationing carried out by health professionals does not exclude the urgent need for more and better explicit rationing from our health authorities. Explicitness tends to enhance accountability by making the allocation of decisions transparent (and the role of pressure groups in lobbying for additional resources for their priorities); however, above all, explicit macro and meso decisions are necessary for an adequate sNHS performance. Although this work focuses on the underuse of health services (rationing), a large amount of evidence shows that the sNHS has a significant problem with overuse (precisely arising from implicit decision making at the clinical level in a deficient explicit decision-making framework at the macro and meso levels).

Spanish medical practice variation studies plus studies on the inappropriate use of drugs (e.g. antibiotics, but also many others), diagnostic tests, hospitalisations, surgical interventions and referrals to specialised care, not to mention the use of hospital A&ED, suggest that one in four to five services provided by the sNHS could be unnecessary. These figures are probably no different from those of other countries in our environment,

but they should cause enough concern to try to better define, through explicit priority setting, the admissible variation in clinical judgments. Explicit priority setting requires, in turn, technical expertise, social participation and political responsibility – all three elements being very scarce in our context. Guidance addressing the implementation of an explicit priority setting process in the sNHS is described elsewhere [25].

In conclusion, adequate priority setting is not about choosing either to muddle through implicit rationing or to be corseted by an exhaustive, rigid and explicit interventionist structure at the macro, meso and micro decision-making levels. This dichotomy fails to capture the complexity of priority setting in practice [26]. We need more and better explicit priority setting, not to substitute but to improve implicit priority setting.

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CHAPTER 7

Bioethics and Health Technology Assessment: The Not-So-Odd Couple

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Summary

The role of health technology assessment agencies has evolved since their boom in the 1980s. With the creation of the Office of Technological Assessment (OTA) in 1972, a critical and independent current of analysis and synthesis of new scientific and technical complexities was born, aimed at helping politicians, managers and public administration make informed decisions. In reaction to the epidemiological, social, technological and economic changes of recent years, the agencies have taken on new functions, as exemplified by Agency for Health Quality and Assessment of Catalonia (AQuAS, as per the acronym in Catalan). This chapter provides a brief review of the principles of bioethics, and considers them in the context of real-world projects currently being carried out at AQuAS.

Health Technology Assessment and the Role of Assessment Agencies

Health technology assessment is the systematic process of evaluating the properties, effects and/or impacts of health technology; it should take into account medical, social, ethical and economic factors and its main aim is to provide decision makers in the field of health with information [1]. It includes aspects, such as the degree of benefits and efficacy, clinical and technical safety, and cost effectiveness.

In this context, the role of assessment agencies is to provide quality evidence to support decision making and, therefore, to promote the incorporation of new technologies that are also cost effective, thus avoiding those of questionable value for the health system.

The role of the agencies has evolved since their boom in the 1980s. With the creation of the Office of Technological Assessment (OTA) in 1972, a critical and independent current of analysis and synthesis of new scientific and technical complexities was born, which was

aimed at helping politicians, managers and public administration make informed decisions. This assessment was based on a broad, multidisciplinary perspective, which shed light on the clinical, economical, ethical, legal and social issues arising from the application of new technologies [2].

In Europe, the Agency for Health Quality and Assessment of Catalonia (AQuAS, as per the acronym in Catalan) – initially part of the administration (1991) and later an independent agency of the Generalitat de Catalunya (1994) – and the Swedish Council of Technology Assessment in Health Care (1992) were the first agencies to be deployed.

The epidemiological, social, technological and economic changes of recent years have spurred agencies to take on new functions, activities and projects. This is exemplified by AQuAS, founded in 1994 – more than 20 years ago – which has been able to adapt to a changing and uncertain environment. During its existence, the agency has risen to the challenge of providing improved services (information and knowledge) to the different stakeholders in the health system (patients, professionals, insurers and planners), ultimately to enhance the quality and maintain the sustainability of healthcare [3,4].

Obviously, assessment remains the focal point of the organisation, but its implementation goes far beyond systematic reviews of scientific evidence for a particular new technology. Currently, targeting public projects, assessing mobile health (m-health) or innovative public spending are of equal or more importance [5].

This chapter briefly reviews the principles of bioethics, and considers them in the context of real-world projects currently being carried out at AQuAS.

The Principles of Bioethics

Among the various definitions of bioethics, the one that best integrates issues related to health technology assessment is by Abel, who defines it as ‘the interdisciplinary (transdisciplinary) study of ethical decision making for the solution of problems arising in different ethical systems due to medical and biological advances occurring in the microsocial and macrosocial, micro and macroeconomic environment, and their impact in society and its value system, both in the present and in the future’[6].

In 1979, bioethicists Tom L. Beauchamp and James F. Childress defined the four principles of bioethics as autonomy, non-maleficence, beneficence and justice. These four principles have been adopted by assessment agencies because they provide a simple, accessible and culturally neutral approach, covering most of the moral issues that arise in healthcare.

There may be tensions between these principles. One principle does not have absolute priority over another unless there is direct conflict. In this instance, priority must be given to one or the other, depending on the case.

The Principle of Autonomy

Definition

Respect for autonomy recognizes the rights of individuals to make informed decisions about healthcare, health promotion and health protection. From this arises the concept of patient choice/decision making.

Patient autonomy is understood as the integration of the patient's value system in decision making after they have received sufficient understandable information; this is essential in today's society as the public is increasingly educated and informed. This is the deliberative model of the patient–healthcare relationship. Knowledge is essential for decision making: knowledge of indications, contraindications, side effects or anything else that can influence a decision. Competence is also vital; it is understood as the ability to perform a particular task or activity well, which, in the case of the patient, is the ability to express their beliefs and opinions regarding the recommended treatments and their alternatives.

Thus, autonomy presupposes having the necessary competence to make decisions in a rational and responsible way after a process of critical reflection. Therefore, for each decision it is necessary to take into account that everyone has a different level of capacity and degree of autonomy. In this sense, the principle of autonomy should be respected as the norm, but it cannot be applied universally or independently of other principles or social values. For example, in certain situations people may not be self-reliant, may suffer mental or physical disabilities and may be unable to make informed decisions. Another example could be a public health measure imposed on an entire population, such as banning smoking in enclosed spaces.

In the medical field, informed consent is the maximum expression of the principle of autonomy, representing the patient's right and the doctor's duty. From an ethical point of view, the patient's preferences and values come first, and it is assumed that the doctor will respect the patient's autonomy because it is their health that is at stake.

AQuAS project examples

Shared decision making

The models of the relationship between healthcare professionals and patients (or healthy individuals) have changed over time [7]. The users of health services are acquiring a more decisive voice, partly because they have more information available to them and they are becoming more organised in peer groups that share problems and solutions. Other reasons are the transformation of the doctor–patient relationship model (from paternalism to deliberative), the rise of the principle of autonomy of the individual who wants the right to choose (despite having imperfect or asymmetrical information), as with any other goods or services, and reconfigured health systems truly centred on the patient [7].

In shared decision making, professionals and patients work together to decide which tests or treatments are best aligned with the patient's preferences and values based on scientific evidence [8]. These decisions are especially recommended when there is more than one alternative to a diagnosis or screening, a medical or surgical procedure, pharmacological treatment or lifestyle change. Shared decision making is particularly useful when it is sensitive to a patient's preferences or when there is uncertainty about the effectiveness of the treatment [9].

The participation of people (healthy or sick) in healthcare is recommended by the Catalan Health Department as a way of safeguarding the public's right to easy access to complete, suitable and understandable information about their health. This information

should allow people to make decisions about their own health in a context of freedom of choice. The shared decision model reflects a major shift in ideas about how people should participate in healthcare.

There are several models for the relationship between the healthcare professional and the individual (healthy or sick). The AQUAS ‘Shared Decision Making’ project (<http://decisionscompartides.gencat.cat/ca/inici/>) seeks to avoid paternalistic or purely informative models and is working towards an approach in which the individual actively participates in the process of choosing their treatment or healthcare intervention [10].

In the deliberative model the health professional recommends the best option, based on personal knowledge of the patient and with their best interests at heart, but doing so through dialogue and joint deliberation. In the interpretative model, the doctor helps the patient to identify their values and preferences, and suggests the most suitable interventions. In the informative model, the patient is given all the relevant information and has complete control of the final decision. Finally, in the paternalistic model, only the health professional decides which therapeutic option is best, without the participation of the patient.

There are several reasons why people may want to share decision making about their treatment and lifestyle with healthcare professionals. First is the peace of mind that comes with feeling well informed. Doctors are often seen as a reliable source of advice, so sharing decisions with them helps people feel reassured and confident that together they have chosen the best option.

Second is that each patient has unique experiences, beliefs and priorities, which can influence their choices. Sharing decisions allows health professionals to take these into account and tailor treatment options to each individual.

Third is the question of participation and control. Being involved in decision making can make the patient feel more empowered and secure that their situation is under control. Finally, there is the question of therapeutic compliance. If the individual participates in decisions about their treatment, they are more likely to follow the agreed plan of action; for example, taking the prescribed medication as stipulated. Some research studies also show that patients who take part in decision making have better health outcomes than those who do not.

Shared decision making implies a collaborative relationship and information exchange between the health professional and the individual (healthy or sick). In order to choose the best option for each person and each specific situation, the decision-making process follows certain steps [11]: becoming informed about the diagnosis, sharing preferences and choosing co-responsibility.

Decisions cannot be made without information. Health professionals should explain the different available treatments in a clear and understandable way, pointing out the advantages, disadvantages, benefits, risks and uncertainties of each option. In decision making with co-responsibility, the patient should be given the following information:

- Clinical evidence for the outcomes of different treatments (including survival, quality of life, symptom control);
- The consequences of not following any treatment;
- The frequency of side effects of different treatments;
- The option their own doctor would have chosen in similar circumstances;
- The experience of other patients after following the various treatments.

Patients then express their preferences, goals and expectations. They also may have researched and read about treatment options and can bring this knowledge to the conversation. The Internet is a recurrent resource in the search for information on health and illness, but the participation of the health professional is important to help people verify whether it is accurate. The patient and their family can also discuss their previous experiences in healthcare and treatments.

Finally, the health professional and patient jointly assess the different treatment options available and decide which one best matches the patient's preferences. Even when there is only one available treatment, the decision not to follow any treatment at all is always a viable option for the patient. The health professional may disagree with a person's decision if they believe the choice is unsafe or unreasonable. This situation can arise if the individual has obtained information on their own account and does not want additional advice. In practice, such extreme situations are unlikely and most decisions are shared at least to some degree.

There is no doubt that shared decision-making processes will become more frequent and widespread, but the necessary cultural adaptation will not be immediate. In Spain, there exist another interesting experience in the Canary Islands [12]. Required changes include professionals improving their communication skills and patients assuming responsibility for their own body and health. Tools to facilitate this process also should be developed jointly (by patients, professionals, scientific societies, and patient and family associations).

Results Centre

The function of the Results Centre of the Catalan health system is to measure, assess and disseminate the results achieved in the field of healthcare by the different health centres, with the ultimate goal of facilitating decision making in the provision of quality healthcare in Catalonia. The reports of the Results Centre are commissioned by the Catalan Health Service, who, in their role as public guarantor, are interested in gauging the performance of the different health centres.

The Results Centre seeks to be a useful reference tool for the public, health centres and administration. In an integrated and comprehensive way, it offers a transparent system to measure and assess the results achieved by the different agents that make up the health system to foster accountability, benchmarking and best practice sharing [13].

The centre aims to provide the general public with broader and better health-related information. It encourages people to interact with the health system and to participate in decisions that affect health – thus promoting the principle of autonomy. It enables health centres to compare outcomes, and to identify and share the best practices, providing opportunities for improvement and cooperation between institutions. For the health administration, the Results Centre responds to the demand for transparency in health policy decisions, as well as accountability to the public in the use of resources [14,15] (again promoting the principle of autonomy).

The aim of the initiative is not so much to help the public choose the best health centre, but rather to encourage service providers – both organisations and professionals – to examine in depth the system structures and processes so they may learn from the best-performing providers.

The Catalan Results Centre has been publishing annual reports since 2008. These were general at first, but now are focused on specific areas (hospital care, primary care, social health care, mental health, public health, territorial analysis, medical emergencies and specialized health training). Each report includes indicators of patient-centred care, effectiveness, adequacy, safety, efficiency, sustainability, and research and teaching. More recently (since 2012), together with the outcomes of each indicator, the service provider unit has been identified (i.e. each health centre is named). The experiences of some of the best performing centres and expert opinions are also included, and a version of the report for the general public is provided. All the results can be consulted in detail in table form, with explanatory technical data sheets (<http://observatorisalut.gencat.cat>) [16].

In addition, in response to the Generalitat de Catalunya's objectives of transparency and proximity to the public, the information is presented with the most suitable and simple tools. Therefore, the results are also available as open data, using infographics and interactive outcome maps to facilitate understanding.

The Results Centre reports are produced by the Observatory of the Health System of Catalonia together with a large number of collaborators. So, for example, along with staff of the Catalan Health Department and the Catalan Health Service, 40 editors and analysts participated in the latest issue, which features the opinions of 23 experts and the innovative experiences of 25 professionals. In the same line, within the framework of the AQuAS Advisory Council, since 2014 the Results Centre has deployed a committee of experts formed by professionals with considerable experience in the fields of clinical knowledge, clinical management, economics of health, public health, research, systems and information and communication technologies (ICT). Professionals also participate through expert groups and discussion workshops.

The Results Centre constitutes a pioneering initiative in Spain. Although the Spanish Ministry of Health, Social Services and Equality provides the public with information on the health system (national and for each autonomous community) and some autonomous communities (Madrid, Andalusia) publish specific data, in no other cases are healthcare, teaching and research outcomes of health centres nominally presented. Other countries, such as the UK, the Netherlands, Germany, Australia, the USA and Canada, have long been publishing this type of report. Therefore, this initiative places Catalonia among the most advanced countries in terms of transparency and accountability in health policy.

Principle of Non-Maleficence

Definition

Non-maleficence is the obligation not to inflict harm (physical or psychological) and is associated with the maxim of 'first, do no harm'. Any treatment or intervention potentially has adverse consequences; it is therefore necessary to weigh up the benefits and drawbacks when deciding whether an intervention is appropriate.

The application of this principle requires:

- Knowledge: being informed about the treated condition, techniques, beneficial effects and side effects;
- Expertise, skilful performance: the virtue of practice makes perfect;
- Prudence: deliberation on the facts and, above all, their consequences.

The principle of non-maleficence has to be adjusted to the reality of healthcare, where most activities may cause damage, pain or injury [17]. The principle of non-maleficence can be applied in specific clinical situations, such as when deciding whether to initiate or withdraw treatment, apply proportionate or disproportionate means in a treatment, or use life support therapies.

AQuAS project examples

Essential: adding value to clinical practice

While some clinical practices are of proven effectiveness, others are less so, and there is evidence that some are of no value whatsoever. Avoiding clinical practices that do not add value can help to improve the quality of healthcare, innovation and sustainability of the health system, as it frees up resources for allocation to procedures that do add value to clinical practice [18].

Over-diagnosis and over-treatment [19] by prescribing professionals, although induced by multiple causes (including viewing healthcare as merely another consumer product and an end in itself, rather than as a means to achieve another purpose), should receive particular attention: the so-called quaternary prevention. As well as iatrogenic effects (and the resulting costs), such practices also waste limited resources, since they do not add value and are even harmful [18].

The overall aim of the Essential project (<http://essencialsalut.gencat.cat/ca/inici/>) is to improve the healthcare system by promoting beneficial clinical practices and avoiding those without value for the public (promoting the principle of non-maleficence). Underlying this goal is the ethical imperative to act against low-value practices, to improve the quality of healthcare, and to obtain the maximum value from the available resources for health services [20]. The project is on the same line that other well-known initiatives like 'Do not do' [21] and 'Choosing Wisely' [22].

The specific aims are to: (i) inform the professional community and the general public about procedures that fail to provide health benefits for the patient, according to scientific evidence and expert opinion; (ii) encourage health professionals to help identify practices of low value; and (iii) assess the impact of the recommendations on the health system, both on the process and the end result.

The project consists of several stages: identifying practices of low value; prioritizing recommendations; active communication and impact assessment. In the initial phase, low-value clinical practices are identified from multiple sources of information. AQuAS coordinates this process in collaboration with scientific societies, the master plans of the Catalan Health Department and the professional community. The recommendations are then introduced into the database on the project website as part of an ongoing prioritization process according to the following criteria: disease prevalence and burden; frequency of use; adverse risk/benefit; impact on the organisation, and patient preferences – always bearing in mind that they should be in line with the health plan, master plans and scientific societies.

Subsequently, an active communication strategy is designed specifically for each prioritized recommendation, which is tailored to the key stakeholders using the most suitable communication channels in each case (social media communication tools, press releases,

scientific communications, etc.). Finally, whenever feasible, an impact assessment is carried out by measuring the degree of awareness of the priority recommendations and their adoption by health professionals, as well as any changes in healthcare provision attributable to the implementation of the recommendation.

Principle of Beneficence

Definition

Beneficence is closely related to non-maleficence and consists of a moral obligation to act for the benefit of the individual.

It must be assumed that no clinical or public health intervention can always be beneficial for everyone. Achieving a balance between benefit and harm is very important in the work of health assessment agencies.

In medicine, the principle of beneficence is understood as promoting the patient's best interests, but often without taking their opinion into account. The doctor is assumed to know (and can therefore decide) what is best for the patient, who lacks professional training and knowledge. In other words, everything is done for the patient, without his/her input.

A notable drawback of this principle is that it dismisses the opinion of the patient, the main protagonist of the situation, because of their lack of medical knowledge. Yet doctors and patients may not coincide in their personal preferences and may disagree on what is harmful or beneficial. Therefore, it is difficult to defend the primacy of this principle, because if it forms the basis of a medical decision, other valid principles such as autonomy or justice are ignored.

The examples of the principle of beneficence given below are not taken from specific medical situations, but from good practices.

AQuAS project examples

The Observatory of Innovation in Healthcare Management in Catalonia

The aims of the Observatory of Innovation in Healthcare Management (Catalan acronym OIGS) in Catalonia are to collect, validate, organise and assess the knowledge acquired by the Catalan health system from the numerous innovative projects currently underway [23]. The Observatory brings together the innovative efforts made by organisations in various spheres of management. It provides a forum for compiling innovative experiences and an innovation community web page (oigs.gencat.cat) that fosters interaction and exchange of experiences among 1,300 professionals.

The process to register an innovative experience in the Observatory begins by signing up with the innovation community. Innovative experiences should meet certain criteria: implementation within an organisation, bringing about a change, having an impact on resources, and scalability. Organisations may submit a self-assessment of their innovative experiences, which will be reviewed by the Observatory. Those deemed to have met the established inclusion criteria are then awarded a certificate of quality issued by AQuAS.

The Observatory has compiled a total of 450 innovative experiences, the majority of which are focused on improving strategic and care processes, managing patients with chronic illnesses, the use of healthcare information technology and the consumption of pharmaceuticals in the areas of primary and specialized care.

The compilation of innovative experiences allows the spotlighting of some of the best practices in the health system. Through the public and innovation community websites, the Observatory functions as a display cabinet to promote the transferability of good practices with the potential for widespread application in other areas to improve outcomes and patient satisfaction. It also forges ties among institutions, helping to create synergies and joint projects. One of the main challenges in the future will be identifying barriers and drivers for implementation, sharing problems, acknowledging failures and finding solutions in different contexts for the adoption and spread of good practices.

Impact of research

The ‘science of science’ is a new expanding discipline focused on science and innovation, research ecosystems and an effective management of research funds. Understanding ‘what works’ in research funding is critical to building strong knowledge-based economies and societies. The importance of assessing the social impact of research is evident in that organisations are accountable for public funds or philanthropic donations invested in research, research is promoted in specific areas, and resources are distributed to optimize returns and maximize the value of research investment [24,25].

Although the pioneering groups in this discipline are located in United Kingdom and Canada, lately the practice of assessing research has extended to the USA, the rest of the Anglo-Saxon countries and Scandinavia [26-29]. In Spain, the ISOR (Spanish acronym for Social Impact of Research) Group has taken the lead: in the last 10 years it has assessed calls for clinical research and in health services in Catalonia, as well as the impact of biomedical research funded through the telethon *La Marató de TV3*, and recently the impact of mental health research in Spain on clinical and health decision making.

The ISOR group started off by carrying out assessment studies of the research groups of one Catalan hospital. The group expanded its scope with the assessment of the publicly (non-commercial) funded research call for Clinical and Health Services Research between 1996 and 2004. It has also broadened the profiles of its expert members, who proceed from different disciplines and backgrounds, to include clinical and health service researchers, physician practitioners, economists, biologists and psychologists. The ISOR group’s capacity has greatly benefitted from the collaboration with the Epidemiology Unit of the Cardiology Service of Hospital Vall d’Hebron.

A fundamental ‘raison d’être’ of the ISOR group is to support the Ministry of Health of the Catalan Government and the Carlos III Health Institute of the Spanish Government with regard to research-based management, decisions, strategic design and implementation. In this context, the ISOR Group has promoted the creation of a registry of research inputs and throughputs (clinical trials) of the Catalan biomedical research centres and institutes, which can (and might) be implemented at the Spanish level. This information has been used for the implementation of the 2012–2015 Research and Innovation Strategy of the Catalan Ministry of Health. In particular, it is being applied to implement

pay-for-performance criteria in the allocation of public resources for research in the Catalan biomedical research institutes and centres. To our knowledge, the ISOR group has been a pioneer in the Spanish research ecosystem and we congratulate their effort in contributing to making local learning global and global learning local.

Principle of Justice

Definition

The principle of justice entails treating everyone as is their due, thereby minimizing situations of inequality (ideological, social, cultural, economic, etc.). In our society, achieving equality for everyone is only an aspiration. However, there is a desire to reduce inequality, and it is expected that equals are treated equally and unequals unequally. The principle of justice can be divided into a formal principle (treating equals equally and unequals unequally) and a material principle (determining the relevant factors for the distribution of health resources: personal needs, merits, economic capacity, personal effort, etc.).

In an optimal policy, the principle of justice supposes a generalization of social benefits in order to obtain the greatest good for the greatest number. Public policies are designed according to certain material principles of justice. In Spain, for example, healthcare is theoretically universal and free; therefore, it is based on the principle of necessity. In contrast, in the USA, most of the population's healthcare depends on individual insurance contracted with private healthcare companies. Justice in healthcare refers to a fair and appropriate provision of services, facing the inevitable problem of a mismatch between demands and resources.

In order to exclude any kind of arbitrariness, it is necessary to determine which equalities or inequalities are to be taken into account when determining each treatment. The patient expects the doctor to do everything possible for the benefit of their health, but they should also realize that medical actions are limited by situations imposed on the doctor, including legitimate interests of third parties.

It is also a matter of redistributive justice to ensure that resources invested in health are of value to patients and society. In the context of the current budget constraints, it is necessary to evaluate the cost effectiveness of the various treatment options, prioritizing those that add value to the healthcare relationship, and avoiding those that are of questionable value to health systems.

The doctor–patient relationship is fundamentally based on the principles of beneficence and autonomy, but when these principles clash, often due to the scarcity of resources, the principle of justice comes into play to mediate between them. On the other hand, health policy is based on the principle of justice, and is all the fairer when it achieves greater equality of opportunity to compensate for inequalities.

AQuAS project examples

Observatory of the effects of the economic crisis on public health

It is recognized that health service accessibility and quality are not the major determinants of health; rather it is genetic, environmental and especially behavioural and socioeconomic factors that make the difference. The recent economic crisis has had a

significant impact on the social determinants of health, limiting disposable income and affecting living, working and housing conditions. In this context, social inequalities in health remain a pending subject to be addressed in our health system.

Some European health systems have been more resilient than others in the face of an economic crisis, and among the factors responsible are public policies on health expenditure and other forms of social protection, adequate levels of public health expenditure, the absence of gaps in health coverage, and low levels of direct payment by the public.

A review of the literature on the impact of economic crises – prior to the one of 2008 – on public health, in some cases, reveals an increase in all-cause mortality associated with unemployment, a rise in suicides (although with certain nuances) and an increase in mental health problems. The people most affected by the effects of an economic crisis are those belonging to the most vulnerable groups (i.e. people in long-term unemployment) and children.

In Spain, the recent crisis seems to have had little impact on indicators such as life expectancy or general mortality, but there is evidence that it has affected health determinants, certain life styles and access to health services.

Monitoring the impact of the crisis on health and health systems is a priority of the World Health Organisation's Regional Office for Europe. Among the recommendations to Member States, the importance of social safety nets and employment policies to mitigate the negative impact of the crisis on health is highlighted, and there is a warning to avoid excessive and prolonged restrictions on health budgets.

In 2013, the Catalan government created the Observatory of the Effects of the Economic Crisis on Health (<http://observatorisalut.gencat.cat/ca/observatori-sobre-els-efectes-de-crisi-en-salut/>), within the framework of the Observatory of the Health System of Catalonia, to monitor the main indicators of health determinants (principle of justice). Since then, the Observatory has published three reports: the first analysing the evolution of the social and economic determinants of health [30], the second focusing on children [31] and the third based on territorial analysis [32].

The most recent report [33] analyses the socioeconomic inequalities in health status and the use of health services according to socioeconomic level, using individual information of all the inhabitants of Catalonia, and with special emphasis on the most disadvantaged groups (principle of justice). For this purpose, a classification has been constructed that takes into account each person's employment status and income level, based on economic contributions to the Social Security system and the level of patient pharmaceutical co-payment (based on income level). This information has been matched with other data, namely the health status, the use of services and the consumption of pharmaceuticals of each Catalan citizen.

In the future, it will be important to monitor the different waves of analysis produced by the Observatory in order to understand which factors are responsible for the variations in observed inequalities, and if they can be tackled by policy, or by understanding how their fundamental mechanisms operate. In any case, the need to respond to this situation by policy on health, as well as on education, social protection, the labour market and quality of employment, has been demonstrated.

Allocation of primary health care resources based on a socioeconomic indicator

In recent years, coinciding with the economic crisis, the concern about the effect of social inequalities on public health has resurfaced. The desire to mitigate the effect, in a context of limited resources, has revived interest in economic deprivation indices. The use of deprivation indices for the financing of primary health care services is especially important in order to prevent social deprivation being associated with worsening health services [34,35].

Socioeconomic deprivation indices allow the concept of insufficient economic and social resources to be objectified and transferred to small geographical areas, and territories to be classified according to their degree of deprivation. Deprivation rates began to be used during the 1980s in Britain – the best known being the index of Townsend [36], Carstairs and Morris [37,38], Jarman [39,40] and the Index of Multiple Deprivation [41,42]. All these indices are constructed by the addition of various weighted socioeconomic indicators or are the result of a multivariate statistical model.

In Spain, the 2007 project ‘Mortality in Spanish Small Areas and Socioeconomic and Environmental Inequalities’ (Spanish acronym MEDEA) involved the creation of a deprivation index based on census data for small areas (census tracts) in five Spanish cities: Barcelona, Bilbao, Madrid, Seville and Valencia [43,44]. The MEDEA index has been widely used to analyse health inequalities in small urban areas and by municipal public administrations and health service providers to identify and prioritize territories of special socio-economic vulnerability.

The revision of the resource allocation model for primary health care in Catalonia in 2016 identified the need to create a deprivation index that is valid for all basic health areas (both urban and rural) is easy to interpret, can be updated more frequently than indices constructed from census variables and is related to the need to use health services (principle of justice) [45].

The variables used to construct the index were: exemption from pharmaceutical co-payment, income below €18,000, income higher than €100,000, manual occupations, low level of education, mortality before the age of 75 and potentially avoidable hospitalizations. The use of a multivariate methodology – namely the analysis of principal components – has been considered the best option, since the correlation between these variables is high and theoretical estimates of their individual contributions to the concept of deprivation are not available.

In summary, a deprivation index was constructed to improve the allocation of primary health care resources, but its definition turned out to be sufficiently general for application in other areas, such as health policy planning or the study of inequality. The result of this calculation has been integrated into the model of primary healthcare resource allocation from 2017 onwards (principle of justice).

Conclusions

As shown, some of the projects currently ongoing at AQuAS are quite far away from classical health technology assessment (HTA), are much more wide and complex, and with an intensive participation of both clinicians and patients/citizens, but share in common a

strong evidence-based background. Moreover, all of them are related to the principles of bioethics, one of the key elements of HTA assessment.

Given the high development of ICT and the availability of big data analytic tools, it is most likely that an area of future development around HTA will be the intensive use of routine data (administrative databases), which will become greatly digitalised, with increasingly rich clinical information and be linkable between areas (i.e. drug consumption, hospitalizations, primary care use, specific registries [stroke, myocardial infraction, cancer, etc.]) to assess the effectiveness of drugs, devices and health policies. The use of these databases also has ethical implications, which will need to be analysed.

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CHAPTER 8

The Uncomfortable Truths of Healthcare Prioritisation

Angel Puyol

Summary

A correct approach to healthcare prioritisation requires accepting certain uncomfortable ethical and political truths. This article sets out and analyses some of these truths. Specifically, these are: that health prioritisation (i) is inevitable; (ii) means the denial of available resources to patients who need them for some kind of health benefit; (iii) is an issue of social justice and not of mere equitable access to the health system; (iv) is an ethical issue, which is not resolved through mere clinical and/or economic reasoning and will not be resolved through applying a morally painless ethical criterion; and (v) demands a commitment to solidarity above individual freedom. This article analyses each of these uncomfortable truths and how they relate to the correct management of health prioritisation.

Introduction

The greatest of the uncomfortable truths of prioritisation is that it is inevitable. It has several specific causes. The main one is, probably, the enormous technical progress made in healthcare brought about by advances in scientific knowledge; this has led to the appearance of ever more expensive new technologies. Nonetheless, there are other, no less relevant, factors. Among these are the progressive ageing of the population; the appearance of new diseases; the increase in the number of chronically ill patients; and a new concept of health as complete physical, mental and social well-being (as generously defined by the World Health Organisation [WHO]), and not merely as the absence of illness. The result is that we now have greater knowledge than resources to use this knowledge in the medical needs of all patients.

Therefore, the greatest challenge to equity is not knowing if all citizens have guaranteed access to healthcare, but choosing the criteria to provide such access when the demand for healthcare outstrips supply. For example, should those patients with a better

prognosis be given priority over those who are sicker? Should we take into account the individual's responsibility for their illness and discriminate access for this reason? How much of the budget should be assigned to the chronically ill, the terminally ill and in prevention? Should hospital costs be reduced in favour of socio-medical costs? What is the list of treatments, services and medicines that must be excluded from a free public health system? How can the conflicts between efficiency and equity be resolved? The answers to these questions force us to reinterpret the meaning of the right to healthcare, a right that has traditionally been linked to equal access for equal need. How can we make the right to healthcare compatible and, at the same time, ration limited medical resources?

At times prioritisation is, naturally, the consequence of morally debatable economic and health policies (e.g. ideologically motivated policies cutting health budgets); at other times, prioritisation is the result of the majority values of a society that prefers to use part of its wealth to cover other social assets, such as education, transport infrastructures, security or private consumption. As Ronald Dworkin reminds us, it would be a foolish society that mortgaged its entire wealth in health prevention (e.g. by contracting unlimited health insurance policies), thus ignoring the funding of other social assets that also contribute to the construction of a good life.

Nonetheless, while at times we may reduce the need to prioritise, it would be a delusion to believe that we can totally avoid health prioritisation and be utopian in current societies.

Another uncomfortable truth of prioritisation is that, in reality, it is not merely a prioritisation. Prioritisation is a euphemism referring to an uncomfortable truth in a wealthy, consumer society such as ours. When we prioritise, we ration limited resources, giving those resources to some patients but not to others while knowing that the resources denied would have been beneficial in some way to those who have not received them. This uncomfortable truth is the basis of four further truths that I will discuss below. The first is that healthcare prioritisation is an issue of social justice and not only of equitable access to the health system. The second is that healthcare prioritisation is an ethical issue that mere clinical and/or economic reasoning cannot resolve. The third is that prioritisation will not be resolved through applying a morally painless ethical criterion. The fourth is that prioritisation demands a commitment to solidarity above individual freedom. Each part of the text below is dedicated to one of these uncomfortable truths.

First Uncomfortable Truth: Health Prioritisation is an Issue of Social Justice and Not Only of Equitable Access to the Health System

One of the uncomfortable truths of healthcare prioritisation arises with the appearance of social determinants of health. Current epidemiology sustains that the greatest inequalities in health are not mainly explained by biological factors or voluntary lifestyles; neither are they explained by unequal access to the health system, but by inequality related to social determinants of health. While the health system is, itself, a further determinant of health, it is not even the most important, as shown in the Black Report and the Whitehall Report of the 1980s. Numerous studies have corroborated this since then, and in 2008 the WHO's Commission of Social Determinants on

Health published a conclusive report with data on health inequity from around the world (CSDH. *Closing the gap in a generation: health equity through action on the social determinants of health. Final Report of the Commission on Social Determinants of Health*. Geneva: World Health Organization; 2008 [1]). The report reached two basic conclusions that would defeat health inequalities: improve daily living conditions, and tackle the inequitable distribution of power, money, and resources. In other words, if we wish to eliminate or reduce health inequalities, we must eliminate or reduce social and economic injustice. A fairer access to a quality health system is another measure in social justice, but it is neither the sole nor the most important one in reducing health inequalities. Therefore, the most pressing and basic health prioritisation is that which prioritises improvements in the standard of living of the poorest while reducing social and economic inequality. The best health policy is that of greater social justice.

What is the above affirmation based on? Health inequalities are, above all, due to social factors related to differences in status, and material inequalities. This is the conclusion drawn when incorporating social determinants of health to the epidemiological analyses; the conclusion leads to at least two effects on equity, when this is taken to be the elimination of unjust differences in health [2]. Or, in more operational terms, as the absence of systemic disparities in health between groups with different levels of advantages/disadvantages linked to gender, wealth, power, ethnic origin, age, etc. The first effect is that the relation between the social determinants of health and equity become very close; the second is that their impact should redefine the aims of healthcare equity.

Regarding the first point, the concern of equity for inequalities of health between individuals and social groups is also at the heart of social epidemiology. Both areas of knowledge are committed to the explanation of the causes of illness and their social distribution. Hence, the moral concern for social inequalities in health and the hypothesis those social determinants of health responsible for these patterns of inequality create a close correspondence, a symmetry of interests, between equity in health and epidemiological research into such determinants.

Regarding the second effect, social determinants of health should contribute to the redefinition and widening of policies that are traditionally associated with equity in health. Traditional explanations of inequality tend to focus on biomedical factors, including healthcare attention, which are those that healthcare professionals best master, leaving aside social factors of health, which the professionals find far harder to detect, control and change. Perhaps this is one of the reasons why social determinants of health have not normally received the attention they deserve. Nonetheless, access to quality healthcare has a limited explanatory capacity to deal with inequality in health. The proof is that this still exists in countries that have high-quality free, universal healthcare. In Great Britain, for example, and despite the existence of the National Health Service, life expectancy in a wealthy neighbourhood of Glasgow can be almost 30 years greater than in a poor one [3]. In a Spanish city like Barcelona, the difference between the wealthy neighbourhood of Pedralbes and the poor one of Torre Baró is 11 years [4]. Indeed, over the past century, in countries with universal access to healthcare, this accounts for just 20% of the increase in life expectancy. The remainder has been mainly due to improvements in quality of life, above all in hygiene. Universal access to high-quality healthcare is a requirement that is necessary but insufficient to mitigate the great differences in health.

The argument that lies behind the idea of equity based on access to healthcare services is based on social justice: the equitable, universal access to the healthcare system is needed to ensure the health of the population, itself one of the requisites of equal opportunities. However, the evidence of social determinants of health undermines such an argument [5]. While it is still true that equity in access to the high-quality healthcare system is a requirement of social justice, real equity in health is not only, or even principally, achieved through universal access to high-quality healthcare services; above all, it is achieved through a fair redistribution of social determinants of health. As well as the material resources of subsistence, the determinants mentioned include psycho-social factors, such as control over and autonomy of one's work and life, social support (mainly through the social networks of family, friends and neighbours), and the absence of anxiety and stress leading from a lack or shortage of social recognition [6]. These factors explain how societies with greater social inequality are also those with greater inequality in health. This does not mean that social inequality directly causes inequality in health, since the causes may well be found in associated factors. Furthermore, it should be borne in mind that the causation does not automatically result from the correlation [7].

Consequently, the best strategy to reduce inequalities in health, by which we mean increase justice or equity in the health of the population, is achieved when exposure to an illness is the same regardless of class, and not only when equal access to high-quality medical treatment is achieved. This is due to the fact that, while access to the healthcare system is fair, social determinants of health show that individuals may access the system already being ill for *socially unjust* reasons that are not only related to exposure to toxic external agents (the explanation offered by classical epidemiology), but rather to the impact of the unequal social structure in the appearance and development of illnesses (the explanation given by modern social epidemiology). If social determinants of health are not fairly distributed among the population, the power of equity in access to the healthcare system is limited to not further increasing this existing unfairness, but it can neither eliminate nor even reduce such unfairness. The result is that, while access to the healthcare system is through health needs and not, for example, through an individual's ability to pay, those that suffer most from social inequalities are guaranteed neither equity in health nor equality of opportunities.

Another consequence of the impact of social determinants of health in equity affects the redefinition of bioethical priorities. The origin of bioethics is closely linked to the vindication of patient autonomy. The horror produced by the discovery of Nazi experimental medical atrocities and legal cases in the USA in the 1960s regarding demands for patient autonomy led to a rethinking of the fundamentals of medical ethics and the birth of modern bioethics as an academic subject. Bioethics is now taught in all advanced medical faculties and forms part of the essential, high-quality training of healthcare professionals.

Nonetheless, with the arrival of evidence provided by social determinants of health, bioethics should reorient its aims. The autonomist bias still dominant in bioethics should be compensated in favour of greater research into social justice and equality of opportunities in health. Justice should take over from autonomy in bioethical priorities. This is for two reasons. First, if we bear in mind the magnitude of the facts, the greatest current challenges of bioethics are not a greater vindication of respect for patient autonomy, but the urgency and need to address questions of fairness locally, nationally, internationally and globally.

Respect for patient autonomy, whether in clinical or experimental medicine, is increasingly well covered in the legislation of democratic countries and, while the old, excessively paternalist attitudes of some professionals do not match legislative advances, the path is well marked. This does not mean that the conflict between autonomy and welfare can always be easily resolved. There are particularly complex issues and cases such as euthanasia, the difficulty of knowing when a patient is truly able or competent to decide, or specific issues of confidentiality. There is no easy answer to these questions from the standpoint of public ethics, meaning that they require special, continuous attention. However, the most important step in the vindication of autonomy was taken some time ago: the recognition of its unquestionable value in all fields of medicine, from the legislative to medical merit.

Nonetheless, the principle of fairness is still far from being respected. Despite the declarations of the WHO in favour of the right to health, this is far from respected in almost the whole world. Inequalities in health are huge. For example, the life expectancy at birth of a Japanese or French person is above 80, which is double that of someone from Swaziland. It should be added that such inequalities are greatest in women and children. A sub-Saharan woman is 100 times more likely to die in childbirth than one from an industrialised nation, and an Angolan child is 73 times more likely to die before the age of five than a Norwegian child [8]. Over 11 million children die each year from treatable illnesses, such as diarrhoea or malaria. Tuberculosis alone kills almost 2 million people in poor countries [9]. It goes without saying that, with such data, questions of justice are, and should be, a bioethical priority henceforth.

The second reason that justifies the priority of justice in future bioethics is found in the evidence taken from the intervention of social determinants of health. These show that their distribution is enormously unfair, that the social factors that determine the appearance of illness are not equally spread, neither do they follow a fair distribution pattern. In a classical epidemiological or biological model, differences in health are explained by factors that are not susceptible to fairness or unfairness. Ultimately, the biological nature of each individual does not follow moral patterns. Nonetheless, on proving that health and illness are closely related to social determinants of health, the distribution among the population of which is clearly unequal, with those people and groups most affected not directly responsible for this, the problems of justice are evident.

This does not mean that it is easy to identify those responsible for the injustice in the unequal distribution of social determinants of health or the right policies to resolve or significantly reduce such injustice. However, this is a further reason to suggest that bioethics, along with epidemiology and other scientific disciplines greatly affected by the arrival of said determinants, such as the economy of health, should include the study of justice among its priorities for the 21st century. If, despite being a science, epidemiology has an ethical base and moral purpose, (e.g. reducing health inequality among the population), bioethics, with its concern for social justice in relation to health, needs the knowledge provided by epidemiology. In other words, if we demand sound epidemiology, whether social or of another kind, and if we want to understand what social justice consists of, we must place moral and scientific concerns for human health at the heart of the theory and practice of social justice. As Michael Marmot and Sridhar Venkatapuram say, 'epidemiology as a field is inescapably linked to the moral concern for the health of people, and no conception of social justice can be considered complete if it does not account for the

social bases of impairments and mortality' [10]. Without a rationale that combines ethics and science, and justice and inequality in health, it will be impossible to build a general theory of justice in health that takes into account all the causes, degrees and consequences of illness and the kind of social response that should be offered.

Second Uncomfortable Truth: Healthcare Prioritisation is an Ethical Issue That is Not Resolved Through Mere Clinical and/or Economic Reasoning

It is often argued that there are insufficient funds to pay for all the healthcare the population needs. And this is true. This justification has been used in many countries over recent years to make cutbacks in public healthcare budgets that lead to an increase in waiting lists and problems obtaining dependency benefits for the most vulnerable patients, as well as other socio-sanitary and preventative measures. The result is that the population's health suffers and worsens. Although we already have data regarding the effects on health of cutbacks [11], the worst effects will doubtlessly be produced in the medium- and long term. This is not only because health problems that are not now being corrected in time will become more acute in the future, but also because those people most affected by health cutbacks are also those worst affected by the economic crisis, the working- and middle classes. Quality of health depends on the quality of the healthcare system, but above all, on the quality of life in general and the level of social and economic inequalities, and the social determinants of health, as seen above. Therefore, should social and economic inequalities increase – as is happening in the current economic crisis (in Europe, at least) – and should the problems of access to the best possible quality public health system also increase, unfair inequalities in health will also increase. Inequalities in health are unfair when they are unnecessary and socially avoidable [12].

Although there are a number of causes of inequalities in health, ethics cannot be ignored in their analysis; in other words, without taking into account the moral value we place on health and equity. To justify this idea, three concepts that are frequently found in times of economic crisis in healthcare need to be analysed. Authorities often say that 'we should be more efficient' and 'the system should be more sustainable'; that is, the health system needs to be 'rationalised'. This normally means adding greater rationality and less passion, greater management and less policy, greater economy and less ideology. Such expressions (efficiency, rationalisation, sustainability) seem to contain an aura of moral and ideological neutrality, of a technical or pragmatic solution to the problem, as if maintaining equity is only guaranteed through general solvency.

There is no doubt that, in principle, it is better, morally better even, to be efficient than inefficient. Neither is there doubt that it is preferable to maintain, or sustain, something good – such as public healthcare – over time than enjoy it in the present and lose it in the future. What happens is that, in practice, efficiency and sustainability are not morally innocuous ideas from the viewpoint of justice, as they often benefit some while discriminating against others with no sound ethical justification.

The communicator usually expresses their intentions through the language they choose. For example, the limitation of a basic asset, such as healthcare attention, leads to the need for its rationing. We can substitute rationing for rationalization (which means

applying reason or reasoning to the understanding of a fact or the solution to a problem), or for prioritisation (for example A preceding B, without us knowing yet the moral value or importance that the order has for us). However, the word that best describes the limited access to a basic social resource is neither rationalisation nor prioritisation, but rationing. This word carries with it historical overtones of times of shortage and misery (wartime, for example) that are avoided when we turn it into a euphemism for rationalisation or prioritisation. However, reality is stubborn, and modifying or renaming it does not make it vanish.

Something similar happens with the words 'efficiency' and 'sustainability'. A priori, nobody sensible could be against increasing the efficiency and sustainability of the health system. The problem arises when they are applied, including painful ethical, and at times unjust, compromises. These are not always obvious and should be unmasked.

For example, efficiency indicates that we should not prioritise expensive medical treatment of low effectiveness. If we prioritise more effective treatments at a lower financial cost, we optimise the amount of healthcare we can offer, not only because it is cheaper, but also because we free resources to cover other needs. However, efficiency does not tell us how many resources to invest, the importance we place on the aim of the investment or what to do with 'inefficient' patients. This last point is especially compromising, since it leads to a moral problem that lies at the very heart of efficiency. Let us imagine that there is an expensive, not very effective (but not totally ineffective) treatment for a minority or rare disease. Few patients, very expensive treatment, low effectiveness; in other words, all the ingredients needed to place its funding by the public health system at the end of the list of priorities. The problem is that the treatment to be eliminated for its inefficiency is perhaps the only one that can improve the lives of specific patients. If we eliminate it, we cannot say that efficiency is forcing us to discriminate against these patients. Efficiency is the main reason we give to justify the cutback or priority, but the final decision, the end reason, is ethical, along the lines of 'the health of all is equally important, but the health of those who can gain most health with the same resources is morally more important'. Therefore, the health of some people is more important than that of others. The paradox is apparently avoided when we add the following argument, 'the health of all is equally important *in that we do not wish to discriminate against anyone for reasons unrelated to health*, but, precisely because we are only guided by health, we favour those who are able to generate greater health with the same resources, and we discriminate against those who cannot, even though these patients do not deserve to be discriminated against'. However, we must not forget that when we benefit and discriminate against some patients over others, these are moral and not merely technical choices. Efficiency may be a good reason to justify a specific prioritisation, but it does not release the person who uses it from moral responsibility as another decision could, strictly speaking, have been made. We are not morally obliged to be efficient in the same way a doctor is morally obliged not to harm a patient or a judge is to follow the law. Once could, for example, choose – and it would not be a morally reprehensible choice – to prioritise the patient with a rare, serious disease – the only treatment for which is expensive and not very effective – and not treat less sick patients who are better converters of health resources. That is, a more inefficient decision could be made that is fairer for morally more important reasons unrelated to efficiency.

A balance needs to be struck between efficiency and equity, and between these and people's rights. Not schooling a child who lives isolated in the mountains may be efficient, but it denies them their right to education. Making a healthy person give (and not donate) their kidney to a patient to save their life is also efficient from a health point of view, but it violates the right to personal integrity and individual freedom. On the other hand, it should be stated that rights are neither sacred nor limitless, and should be considered in arguments about efficiency. Does a dying 90-year-old have the right to demand all possible (and expensive) available resources to lengthen their life by a few weeks if the same resources can be used to improve the health of many? This is a debate that a mature society should urgently have; however, this debate should start by recognizing that its conclusions should be ethically (and, perhaps, politically) justifiable, but not from clinical and/or economic rationality that, in this context, are mere instrumental rationalities.

Let us now address the question of sustainability. Sustainability consists of creating the conditions under which the health system can continue to function with the same quality and equity in the future. To achieve this, austerity is generally recommended in the present use of available resources. Excessive current spending (even through great borrowing) may lead to the bankruptcy of the system, thus depriving us of its benefits in the future. Any family easily grasps the meaning of sustainability, and knows that it is connected to prudent savings and thinking about tomorrow.

What, though, do we want to be sustainable? The answer would seem to be clear: the high-quality and equitable healthcare system we have enjoyed until now. So, how can we achieve sustainability without harming current quality or equity? If, for example, we eliminate some healthcare services, we can maintain the quality of those that remain, but it is hard to maintain equity. If we maintain equity through cutting, if not eliminating, some services, maintaining the same quality as now, with less staff, fewer ambulances, more obsolete medical technology, fewer hospital beds, etc., is highly complex. If this is the case, then we should be honest and admit that the sustainability of the healthcare system discriminates against today's patients in favour of those of tomorrow. This painful exchange would not necessarily be unfair were those future patients, for example, responsible for the precarious situation of the healthcare system or, even should this not be so, they democratically accept the sacrifice of their personal interests in favour of those of future generations. Nonetheless, currently, neither of the two conditions is given. In any event, this is not the place to discuss this important political issue.

On the other hand, leaving aside intergenerational equity, the intragenerational equity of the healthcare system is maintained if the rationing of health resources affects all patients equally, or if, at least, any discrimination is proportional to their responsibility for worsening the system. This is not happening where there are cutbacks in healthcare. If we leave aside, for the time being, the responsibility for the economic crisis, those patients discriminated against by limiting public healthcare service resources are those with insufficient purchasing power to access private healthcare of the same quality. The consequence is that the sacrifice made in favour of sustainability is not equitable and is, therefore, unfair. We need to be aware of the contradiction involved in sacrificing current equity in health in favour of producing – if not merely sustaining – future equity. If the health of the current population is to be sacrificed for sustainability, equity calls for the sacrifice to be the same for all, independently of their economic state. And if we accept inequality in access to healthcare services, those who suffer from worse access should be

fairly compensated. Whatever the case, all roads of healthcare equity lead to a reduction of unfair inequalities in healthcare; that is, a reduction of social and economic inequalities in the population. If there is an economic crisis and sacrifices have to be made, if future generations have to be protected, all citizens should be committed to this – the greater sacrifice being demanded of those less affected by the crisis: the richest. The opposite is inequitable and, unless we can accept such a contradiction, it cannot be justified by the need to make the system sustainable.

Third Uncomfortable Truth: Healthcare Prioritisation Will Not Be Resolved Through Applying a Morally Painless Ethical Criterion

Equity is not an unequivocal concept. Formally, it means that we should treat equal as equal and unequal as unequal. But, who are the equal and, above all, the unequal in the healthcare system? Citizens are equal, and as such, they should have equal access to healthcare services. As is obvious, this is the limit to strict equality. Nobody imagines that each citizen has an equal share of medical resources regardless of their illness. Access to resources should be unequal depending on a morally relevant criterion of inequality. This criterion has traditionally been either medical need or the patient's ability to pay. The first means that illness is the only requisite necessary to receive treatment, with the other conditions such as sex, ethnic origin, religion, social class, geographical origin, personal financial situation, etc., being irrelevant. The second means that treatment is given to the person able to pay the medical institution or doctor's fee. The first criterion is the basis of the public healthcare system, while the second leads to the private system. In some countries both systems coexist, although not fully. For example, in countries with highly established public healthcare systems, such as Great Britain, France or Spain, patients such as undocumented immigrants or unemployed young people are sometimes denied access to numerous health resources. The private system is often closely linked to the public system through fiscal advantages or the private management of some public services.

We will look at the moral justification for the private health system and its relation to prioritisation later. Regarding the public system, ethical problems are not restricted to the above-mentioned discriminations. At the very heart of medical need are at least two morally exclusive alternatives; these become more evident as the need to ration or prioritise between patients becomes greater.

The priority between patients occurs when people have unequal access to limited resources. It would be ideal for access to be equal; that is, that everybody who needs healthcare attention obtains it independently of other considerations. The problem here is that this is simply not possible. A shortage of resources means that we cannot all have equal access to the resources we need; while scientific and technological progress makes this inevitable to a degree, it is also avoidable, as has been mentioned. While it may seem to be a contradiction, the question is the following: what kind of inequality best respects the principle of equality among people to healthcare access? What is the legitimate inequality to access scarce healthcare resources? The tradition in the field of public healthcare is that those with the same medical needs are equal, so providing equal treatment means prioritizing those with the greatest needs.

That said, invoking the concept of medical need as something that can be defined solely in medical terms does not resolve the problem of prioritisation among patients. This is partly so because the meaning of health and illness is often social, which leads to numerous discrepancies as to what medical need really is. Two cases in point are a change of sex and artificial insemination. It is also true that there are epistemological problems on determining who needs what. For example, medical specialists do not always agree as to the treatment a patient needs. However, above all, the conception of medical need is not a merely technical question as there are at least two diverging philosophical interpretations of what medical need is.

The classical view of medical need is linked to the severity of a patient's illness – the most ill patient being the one who deserves greater attention. Nonetheless, this interpretation does have its detractors. They argue that it makes no ethical sense to dedicate resources to gravely ill patients with no, or very remote, chances of recovery if those resources are denied to less ill patients but whose state of health may greatly improve due to them. Those who argue thus believe that the real need of healthcare attention increases with the benefit that this attention can provide. They say that if the aim of healthcare institutions is to offer health to citizens, the greater the health they can provide, the better they fulfil their task. Need does not then depend on how ill the patient is, but on the benefits expected from the treatment. Those who defend this argument generally measure healthcare benefits through a formula that combines years of life gained and the quality of life over these years, or QALY (quality adjusted life years).

Nevertheless, this second interpretation of medical need leaves some ethical questions unanswered. For example, while there is no clear justification, it is taken as given that, since a person generally prefers to live longer than not, it is preferable that a person lives more years than that 'another' person lives fewer. Among other things, this means that young people have total priority over old people. Therefore, resources dedicated to paediatric medicine are of much greater value than those dedicated to geriatrics. Taken to an extreme, this means that there would be justification in investing all resources in saving the life of a new-born baby (who, in our society can expect to live until 80) even if this meant letting 79 old people die who would only gain a year of extra life each through using the same resources. In philosophical terms, this utilitarian approach falls into the fallacy of the absence of moral separability or 'separateness' of persons; that is, it assumes that the moral value of people is interchangeable, the health that some gain compensates for that which others lose while the result is a positive total.

Moreover, the utilitarian criterion ends up prioritising, paradoxically, the healthiest patients who access the healthcare system as they generally have greater possibilities of recovery through the available resources. It seems that the system functions under the motto 'the sicker you are when you need medical care, the later we will treat you'. The criterion of maximization of health that hides behind this interpretation of medical need is clearly related to the utilitarian theory of justice, a theory that has received numerous philosophical criticisms.

But the ethical dilemmas of prioritisation are not limited to the definition of medical need. Alternative criteria exist to prioritise patients that are not ethically negligible. We could, for example, prioritise those citizens who have made, or are expected to make, a greater social contribution, or those who have greater social obligations (e.g. taking care of dependent relatives), or those who have known how to take greater responsibility for

their own health, or the poorest who have no access to private healthcare. Whatever the case, it is clear that equality and equity (in this case in healthcare) are not unequivocal concepts, but include distinct meanings, each of which has its own weight in an open ethical discussion that is committed to the principle of equality [13].

All these criteria are merely orientative regarding the rationing of healthcare services and treatments. In countries that have put into practice an explicit prioritisation (and we should not forget that one is always tacitly prioritising), even with wide social debate regarding the soundness of the criteria, it has been impossible to reach sufficient consensus regarding fair prioritisation. The more detailed the list of resulting criteria, the greater the disagreements that arise. We are yet to have a socially successful criterion and combination of criteria. This failure is explained, among other reasons, by the refusal of the population to generally accept that what is scientifically possible may not be economically *within the reach of all*, and much less so if it concerns an asset as basic as medical care.

Prioritisation exists, even though it is not openly talked about and is often invisibly and arbitrarily carried out by the decision maker (the politician, manager or doctor); this person may not even be aware that they are prioritising through ethical criteria or even differently to their colleagues. But when it is openly mentioned, or when rationing criteria are made public, almost nobody wants to accept it. A certain moral infantilism is imposed; life and health are held to be priceless, but few are willing to mention the economic cost of such a statement, and much less accept the social and political cost of rationing. We expect the State to cover all healthcare needs with money that, as taxpayers, we are not always willing to give (and that our governments cannot limitlessly borrow on the international financial market), since, at the moment of truth, we show we have other priorities, such as building more roads, bailing out banks or enjoying greater private consumption. Each and every one of us is responsible for healthcare prioritisation, even if we look the other way when it is mentioned.

Nonetheless, the difficulties in facing up to healthcare rationing do not depend solely on this moral naivety. There are other causes. One of them is the characteristic of tragic choice that healthcare prioritisation sometimes shows. In a tragic choice of this kind, any decision as to the distribution of limited resources substantially affects the life of people. An often quoted example of tragic choice happened in 1841 with the survivors of a ship that sank between Liverpool and Philadelphia. One of the lifeboats was occupied by more people than it could hold. The survivors knew that, unless the weight was soon reduced, all would drown in the icy waters of the north Atlantic. In an attempt to avoid the certain death of all, 14 people were thrown into the sea. The criteria used to choose were 'not to separate husband and wife and not throw any women overboard'. The lifeboat bore the weight of the lucky ones, who were finally rescued. The most surprising aspect of the story is that one of the survivors, a member of the sunken ship's crew, who was responsible for carrying out the chosen prioritisation criteria, was tried and found guilty of murder [14]. The surprising part is that he was the only person who was brave enough to take responsibility for his actions and carry out the moral decision that had been made.

The tragic choice above consists of the fact that all possible choices are morally detestable. There were basically three alternatives: (i) wait for the death of all those in the boat, which would happen, for example, on following the Kantian rule that nobody should be sacrificed to the benefit of another, or the Christian mandate that only God has power over life or death; (ii) save a specific number of people thanks to a random criterion of choice,

such as tossing a coin, and; (iii) save as many people as possible using a non-random criterion of choice, which requires stronger moral commitment as in, for example, the case itself, or that which would have probably saved most lives: prioritise the thinnest.

This example highlights the fact that bioethics and rationing often have to grapple with tragic choices. An example of this is the separation of Siamese twins that will lead to the certain death of one of them; in the choice of patients who are to receive an organ transplant; in the tolerable waiting list for highly dangerous diseases, etc. The particularity of a tragic choice lies in the fact that, in extreme situations, no individual deserves the grave but inevitable discrimination that the final choice leads to.

A possible alternative to avoid this type of decision consists of the abdication of moral responsibility, for example through the use of random choice systems, such as the lottery, or the 'first come, first served' criterion that is so common in healthcare. From a theological standpoint, one can defend that in random procedures only God makes the moral choice. However, from a secular standpoint, one can reply that abandoning the moral choice to the lottery or, simply, to fate, is a way of running away from the ultimate commitment to human responsibility. If we leave someone to die when we could do something to save their life, even if we leave them to die in order to save an equally valuable other life or lives, we must assume the moral responsibility of this choice.

When faced with the inevitable contexts of tragic choices, two further uncomfortable questions arise; (i) who should choose, and how, the ethical criteria of rationing? and; (ii) to what degree should citizens be informed that they are being denied resources that are to be used in treating other patients?

Let us address the first question. Who decides, and how, what is fair in healthcare prioritisation? Who decides that it is fairer to treat a seriously ill patient who has a good prognosis instead of treating one with a poor prognosis? Who decides that it is better to dedicate part of the healthcare budget to preventative campaigns that may save many lives than to use the same resources to treat a patient with a rare disease – the treatment for which is very expensive and who has little, but not non-existent, likelihood of recovery? The decision maker can legitimize difficult choices in a number of ways. One is that they have been democratically elected to make this kind of decision. The legitimacy here is not provided by the results, but rather the procedure used to designate them. Procedural legitimacy can be improved through a group of democratically selected experts that deliberatively takes morally complex decisions by examining the medical and economic evidence. Daniels and Sabin [15] sustain that this type of procedural legitimacy incorporate various conditions: (i) that citizens should know who the experts are, and their presence should be both technically and politically justified; (ii) the experts must publically answer for the decisions they take and the criteria they use, and citizens should deem such decisions reasonable; (iii) that these decisions are based on criteria that are under constant review as new facts, evidence or discoveries come to light; and (iv) that the experts must ensure that the above requisites are respected at all times.

As there may be a greater conflict of values or reasonable disagreements than in procedural justice, legitimacy is placed on the procedure and not the result. However, this system is not free from problems. One of these is that it is not immune to the tyranny of experts; that is, that the ethical values of the experts prevail over those of the general population. Another is that, in valuing what should be prioritised, experts impose their values indirectly when giving priority to some evidence over other. There is no question

that a fair decision-making process is better than one that is arbitrary and/or lacking in transparency, and that it is also better to leave the making of difficult decisions to the decision maker. Deliberation and accountability should be two essential conditions in taking any morally complex decision in healthcare prioritisation. However, we must accept that no method of choice avoids the most uncomfortable truth of all: that healthcare prioritisation demands that some patients will not receive an existing treatment that could help them.

Let us now look at the second, thorny point. Should ethical criteria of prioritisation be explained so that patients and the general population know why a certain patient will not receive the medical attention they require, or is it more convenient to keep the prioritisation criteria used hidden or implicit? There are reasons in favour of and against both attitudes. Let us first examine the latter.

First, we already know that there are different ethical prioritisation criteria and that we cannot always affirm that any one of them – or any specific combination – is clearly better than the others. There are no criteria universally valid for all cases. We have seen that, in some cases, even seriousness or order of arrival may not be morally recommendable criteria. Should there be no clearly superior criteria, and should the population know this, permanent controversy may further complicate the consensus necessary to apply ethical prioritisation criteria. This argument calls for the doctors and politicians responsible to be the ones to decide, without consulting or informing patients and population, in order to avoid the proliferation of arguments, controversies and confusion that would only complicate things even further.

Linked to this argument, another one arises which sustains that an explicit prioritisation or rationing would produce enormous 'disutility', caused by the fact that both patients and population would know that they do not receive certain treatments or they would receive them too late due to economic reasons tied to the limiting of resources or, whatever the case, for reasons unconnected with medicine itself ('too expensive', 'too old', 'too irresponsible with their health', 'less ineffective', 'too little social value', etc.). This knowledge of the truth would produce anxiety, indignation and frustration, both in healthcare professionals, who would become rationers instead of good Samaritans, and in patients, who would know that they were being denied resources they needed for reasons unconnected with medical need. It can also be argued that there is something inhumane in explicitly informing a patient that, while there is a cure for their illness, it is very expensive and the healthcare system is not going fund it or provide further doctors and services. It would, thus, be better for patients to believe that if they do not receive treatment, or are at the bottom of the waiting list, it is basically due to clinical reasons, even though this is not the whole truth.

Third, it can be argued that explicit prioritisation has numerous administrative and political costs. It complicates the professional lives of doctors and nurses who are forced to examine moral questions far removed from strictly clinical practice. It also complicates the lives of healthcare managers, who have to publically set ethical limits and receive constant criticism by society and those patients most discriminated against. It complicates the lives of politicians, who have to be *burnt* telling people that they will not be treated for economic or other, but not clinical, reasons. Furthermore, there are too many unique cases for the general population to understand that what is morally good for one person is not so for another. Mistrust of the system may become generalised, thus increasing not only

administrative costs but also the loss of the healthcare system's social legitimacy. Therefore, it would be preferable for patients to believe that the reasons they are not correctly or quickly treated are always clinical, even though this is untrue.

Nonetheless, there are also reasons that support explicit, open and transparent ethical prioritisation. First, and despite there being numerous criteria for access to a waiting list, those that are related to seriousness or defined by *need* have certain moral advantages. Need may be determined by the grave condition of the patient, their ability to benefit from available treatment or the social needs linked to the care of their dependent relatives; however, whatever the case, need is a morally superior criterion to social merit, age, personal responsibility for health, nepotism, sympathy or ability to pay. It is true that, among the criteria of need, unanimity does not always exist as to the best combination, and criteria not associated with need should not just be discounted, as some of them may and should play a specific role in prioritisation; nonetheless, there is doubt that need-related criteria provide extra moral legitimacy to healthcare prioritisation, bearing in mind that the kind of asset to be distributed fairly is health [16].

Answering the suspicion that social disutility would result from making the ethical criteria of healthcare prioritisation explicit, one could argue that a lie is not the best producer of social utility. The more mature a society is, the less it accepts lies, whether they be white or paternalist lies. Moreover, the right to be informed is morally superior to the disenchantment or frustration that comes with knowledge of an uncomfortable truth.

Making the ethical criteria of healthcare prioritisation explicit would doubtlessly lead to administrative, political and professional costs. Nonetheless, the rights of patients and the general population to know the truth are greater than the inconveniences caused to the system and its professionals. Secretiveness, arbitrariness, and the lack of transparency in such a delicate question may also lead to abuses. Overall, the arguments in favour of making the ethical criteria of healthcare prioritisation explicit, including waiting lists and the denial of treatment are superior to those against it. Whether society is mature enough to understand and support this is another question. However, banking on social immaturity is never a sound democratic policy.

Fourth Uncomfortable Truth: Prioritisation Demands a Commitment to Solidarity Above Individual Freedom

The main challenge the current healthcare system faces is not so much the production of morally explicit and committed criteria of healthcare equity, but the struggle against the risk of reducing public responsibility for health. Policies of cutbacks are usually accompanied by privatisation measures and, in a wide sense, an abandonment of public responsibility for patients' health and demands that they assume the costs of their healthcare. A range of political, economic and social interests lie behind such policies, but this text will emphasise the neoliberal argument that supports it.

According to this argument, which Robert Nozick [17], among others, has explained well, it is not fair (as it violates individual freedom) for some people to be forced to pay (under the coercion of law, police and justice) for the healthcare attention of others if they have not caused their loss of health. The State has to allow free generosity, for example, by promoting benevolence (or charity), but it can in no way oblige citizens to pay the

healthcare costs (or educational, professional training, pension or social security costs, to sum up – the welfare state) of others through coercive measures, such as taxes. For those who defend this general argument, nobody is responsible for the accidental loss of health of third parties. Let us imagine, for example, that a child develops a grave genetic disease that requires expensive treatment. The neoliberal thesis sustains that, although the child suffers from a disease, it has no special moral reason to request compensation in the form of healthcare. Nobody should help the patient beyond the dictates of their own conscience or wishes. Any aid the patient may receive is due to the feeling of charity or personal commitment to others, but there is no demand for justice. According to Nozick, justice is reduced to the process by which we legitimately appropriate things. Physical misfortune is a mere trick of fate and justice is no reason for it to be socially compensated. Therefore, a citizen has no right to healthcare unless they have purchased it through the market. Any attempt to redistribute resources to treat those whose health is worse is essentially unjust. Applying this criterion means that there is no justification for either the public health system or the guarantee of justice-based healthcare attention criteria. In the minimal State designed by neoliberals, which limits protection and guarantees to the right to private property, there is no place for the universal protection of health [18].

Many objections to this neoliberal position can be made from the standpoint of justice. The main one is that, in the name of the inviolable nature of individual freedom, the health of millions of people depends, in the best of cases, on the charity of the richest, both nationally and internationally. Furthermore, since it supports the arguments of those who defend social responsibility in healthcare matters, placing the emphasis of justice on individual responsibility may paradoxically go against the neoliberal aim to protect private property. Social epidemiology reminds us that unequal social structure (a product of society and not of chance or need) is the main cause of inequalities in the population's health [19]. Therefore, the responsibility for the damage caused would force society *to take charge* of the healthcare necessary to remedy it. Moreover, many medical discoveries and technological innovations have been made using public funding. Why, then, deny the population the beneficial consequences of research that their taxes have contributed to?

On approaching the concept of responsibility for health, three further arguments should be highlighted. The first argument affirms that health is a requisite of equality of opportunities and not merely the result of free use of equal opportunities. It is true that individuals may use their social and life opportunities to place their health at risk, and that they should take responsibility for doing so, but it is also true that health is a condition of almost all social opportunities. Without good health, the quality of life is very poor, severely limiting one's personal projects. Therefore, health cannot only be treated as a reward or punishment for the free actions of individuals, but, above all, as a condition of freedom.

The second argument sustains that healthcare attention cannot be treated as just another commodity, comparable to mere consumer goods, such as a telephone or a watch. Health is a necessity and not only a preference. While it is true that, at times, it is a socially and culturally shaped need, health is not a simple social preference subject to a liberal market's laws of supply and demand; for example, the need to cut one's hair is not morally comparable to the need to regain lost health. In the second case, the need is much closer to an urgency [20], and a society that does not attend to the necessary moral urgencies of its population treats them with neither respect nor dignity. Health itself has a moral value that other consumer goods lack [21]. Why then, should some people bear the costs of the

health protection of others they have not harmed in any way? Let us return to the example of the child with a serious genetic disease whose parents cannot afford the treatment the child needs. Why, despite everything, do we have the duty of justice, and not charity, to attend them? The answer is that the health of people is a good in itself.

According to this argument, health has a special moral importance since limiting it impedes the enjoyment of equality of opportunities, but this should not lead us to think that its value is merely instrumental. Health has a value in and of itself. This is a normative judgment, but it has an empirical base. The person who loses their health does not only think about the loss of a valuable resource with which to achieve important life goals. They also experience harm in itself, the deterioration of their body and the pain of the illness. These internal effects are health-based; they define the loss of health itself. It is the attribution we place on the moral importance of this loss that finally gives value to the need to recuperate health. Therefore, the value of health not only depends on the external effects that can be produced, such as greater personal freedom, gaining employment and wealth, greater social opportunities, etc. Such effects make health even more important, but its final value is intrinsic. To put it another way, someone's health could be undermined if this results in an increase in their wealth or freedom. For example, the State could coercively worsen the health of its citizens in exchange for a better-paid job that leads to greater social opportunities or economic advantages to the community. If we believe that health should not be the price of these positive consequences, it is because we believe that the value of health does not solely depend on them. The thesis that health is good in itself and not just in its use is not an example of metaphysical essentialism, neither does it require any justification apart from health itself (e.g. by sustaining that health is good in itself because God has so wished). Health is good in itself because its value does not depend on what we can achieve through it or its consequences. Health is a good in itself as is freedom. Freedom and health are necessary conditions for achieving other ends, but the enjoyment of freedom and health is independent of these other ends.

This does not mean that a person cannot freely compromise their health through deciding for themselves what best serves their own idea of health. Health is an objective good, but it is also subjective. Just as there is no single way in which to exercise personal freedom, there is no single definition of good and bad health. Someone may, for example, believe that their personal freedom means that moderate alcohol intake and smoking marijuana with friends from time to time, or taking part in a hazardous sport, is all part of what makes them happy, of what forms a healthy life overall. This person must be aware that there is a probability that certain lifestyles can negatively affect their quality of life in other important senses. Even so, the last word on the right way to maintain this global concept of good health must go to the person affected and with all available information.

However, the freedom to decide what one's own health consists of is not a reason for it not to be protected by everyone. Health protection is still a social responsibility under socially agreed terms as to the basic conditions of good health (and bearing in mind the possible limiting of resources) as part of what it means to protect the existence of people, always with the option that the exercise of individual freedom and autonomy may mean that such protection is totally or partly refused.

Conversely, the idea that health and freedom have an intrinsic value may clash with the duty to protect them. This happens, for example, when the principle of justice is at stake. Let us imagine that somebody refuses to have a medical procedure for religious

reasons (e.g. a blood transfusion). The doctor, following their duty of medical beneficence, offers them an alternative, or second best, treatment at a much higher cost. Should we all fund this second treatment? Probably yes. People should not be punished for exercising their freedom to the detriment of their own health. Let us now suppose that the refusal of the most effective medical treatment is due to personal choice that is unconnected with religion (e.g. a woman who refuses a mastectomy, a procedure considered effective against her breast cancer, for esthetical reasons or of personal identity). Let us imagine that the second treatment entails greater expense in medicine to prevent possible future relapses. Should we make this woman pay the difference between the two treatments? No. Personal freedom must count when accepting or rejecting a medical proposal, but it should not mean that the person exercising it is socially or medically punished. In both cases, individual responsibility for one's health does not free society from offering the best possible treatment that the individual will accept, and restrictions to second best treatments must follow reasons of ethical prioritisation unconnected to individual responsibility.

Therefore, if health is a good in itself, we should not care who is responsible for the illness when determining *what we owe* patients. And not just this. If health is a good in itself and we know that a fairer redistribution of wealth improves the health of the poorest without harming that of the richest, *ceteris paribus*, then we should make this redistribution. This is a classic argument in favour of progressive taxation.

We have the moral obligation to protect our own health and that of others. If greater health protection can be achieved through incentivising individual responsibility, it should be taken into account, but never at the cost of not attending to the sick or leaving people unprotected against illness. This does not mean that we should place the good of health before individual freedom to do with one's health what one believes convenient. Society owes people their health protection, even against unwise behaviour, not its imposition. Neither does this mean that individuals lack moral responsibility for their health, but this has to be differentiated in the name of fairness from what we owe each other. We could, for example, morally reproach someone for the foolhardiness of climbing a mountain without being sufficiently prepared, or ingesting excessive amounts of saturated fats, without this breaking our even more basic obligation to help people should such actions result in an accident or illness.

However, the main argument against the social exemption of responsibility for the health of *all* patients is deeply-rooted in the principle of solidarity. If we eliminate the concept of justice from solidarity (which has nothing to do with beneficence and charity) from the above example of the child with a serious congenital disease, the child is at grave risk of being unattended. Neither utilitarianism nor neoliberalism feels the obligation to help the child. The former, because the treatment may prove inefficiently cost effective. The latter, because those people prepared to care for the child might lack the economic resources to do so. Without the duty of solidarity, the child is abandoned to their fate and, consequently, society cannot say that it treats all its members with equal respect and dignity.

Solidarity, understood as the will of citizens to jointly face the avoidable risks of existence (poverty, illness and unemployment being the most important), should be considered part of social justice if we believe there is a duty to attend to the child that goes beyond individual will; in other words, if attending to the child is a unique obligation. Solidarity has been a mechanism by which social inequalities have been compensated and a founding principle of the welfare state since the second half of the 20th century. However,

its continuity is threatened on multiple fronts: the economic crisis affecting us over recent years; the growing trend towards an individualism that is indifferent to the needs and suffering of others, which includes the belief that individuals are those most responsible for their own fate; the preponderance of neoliberal ideology, which prioritises the right to private property over any other right; or the progressive deregulation of markets. This new scenario may well require a transformation of solidarity [22] if we wish to preserve the will to collectively share (between young and old, sick and healthy, rich and poor) the above-mentioned risks. Whatever the case, as long as its demise is not confirmed, its absence leads us to a distancing and final abandonment of what makes a society good or just.

The crisis of solidarity our liberal societies are experiencing is now going through a new, disheartening episode: the contractual interpretation of solidarity that says that people must behave according to a 'logical counterbalance' [23] in order to deserve the resources that may prove beneficial through solidarity. Solidarity then is no longer an unconditional right, a collective assurance unconditionally guaranteed by the State in the form of rights. It becomes a reward given only to those who deserve it, those who use their individual responsibility to look after themselves according to the parameters of health authorities, and those who, through their voluntary behaviour, prove to those financing the solidarity that their trust is not being abused. In this scenario, responsibility for the policy of solidarity is no longer public, but is ultimately moved to the recipient. Individual merit substitutes their rights as a citizen. In the classical conception of solidarity, the aid the sick citizen needs is also a way of aiding the community, of communal self-help, which strengthens the community. Social protection is constructed on a building of rights. Nonetheless, in the liberal or compassionate conception of solidarity, aid to the needy individual is a personal merit, a privilege that must be won through their own responsibility.

Conclusion

Healthcare prioritisation or, better said, rationing, must accept certain uncomfortable truths. The first and fundamental one is that rationing is not always avoidable, so we are forced to face this. In order to do so, what we must do first is recognise that healthcare prioritisation or rationing is an ethical issue that cannot be avoided. We must also accept that the ethics of healthcare rationing are linked to social justice and cannot only be limited to clinical ethics.

Unfortunately, we do not have an ethical criterion or a combination of ethical criteria that serve as a magic wand to ease our conscience after each prioritisation, even though there are procedures that are fairer than others to determine how to achieve them. In general terms, the ethical criteria of prioritisation linked to need are fairer than those that place the emphasis on personal merit and responsibility for one's own health. This does not mean that they play no role in prioritisation. What it does mean is that its importance is secondary or peripheral.

Prioritisation means that some patients are not receiving the healthcare they need, and no ethical criteria of prioritisation can evade the resulting moral dissatisfaction. The ethics of prioritisation consist of the final decision being the most reasonable from the standpoints of social values and the information available, but the ethical conflict within society and the moral dissatisfaction of any sensitive decider will always be inevitable.

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EPILOGUE

After Prioritising, Implementation

Rafael Bengoa, Patricia Arratibel

*However beautiful the strategy, you should occasionally look at the results.
Winston Churchill*

There is broad agreement among governments and policy makers on the need to redesign the current model of the health system. It is a fragmented, reactive model that is no longer considered adequate for the challenges it faces.

Although the pressures on health systems vary from one country to another, all the same challenges can be recognised: funding pressures, population aging and chronicity, health and social service fragmentation, models focussed exclusively on reactive and acute care, lack of public health priority and prevention, plus problems related to the number, capacities and functions of human resources.

There is also general agreement on *what* the key components of a model change are. The priorities for this change have become clearer over the years. The evidence of recent years has been useful to prioritise ‘what’ to do. The following lines of priority action can be recognised in numerous health plans and health policies.

- *Reconfigure the care model to a more proactive and preventive one*
- *Conduct more effective management of chronic and complex patients*
- *Move towards greater focus on quality and clinical safety*
- *Give more voice to patients and advance the empowerment of patients and the community*
- *Define and prioritise patient populations and develop population health management*
- *Develop local integrated organisations*
- *Attack inequalities that still exist*
- *Make ambitious use of information and communication technologies*
- *Assign resources based on value and not just on volume*
- *Coordinate/integrate social and health services*

The evidence in favour of these changes is increasing in practically all of these interventions. For example, there is a growing consensus on the need to integrate health and social care, as well as the need to change the model of resource allocation between those who finance and those who provide services.

In Spain, the resource allocation model encourages more activity and volume than promoting value. It is true that an allocation of resources by value is more complex not only because of activity, but also because it is a fundamental intervention for the Spanish National Health System (NHS) if we want to identify a model that offers more quality and sustainability. It would be a model of resource allocation that promotes the coordination of care and quality, and develops more integrated care organisations.

These advances are already visible in several countries and the evidence confirms the positive impact of these changes; therefore, they are prioritised interventions in the majority of countries that seek a change of their healthcare model. For example, the pioneering model of Accountable Care Organisations promoted by Obamacare has generated savings of \$417 million for Medicare and prevented 150,000 hospital readmissions. European examples of new forms of resource allocation in Sweden and the Netherlands have also had very positive results.

Although the current evidence confirms these successful priority lines of action, their introduction in the Spanish NHS creates two important paradoxes in terms of implementation:

- There are numerous pilot experiences and although the majority have positive results, they do not ‘escalate’ or become generalised.
- These changes seem to be insufficient to move the health system towards a new model systemically.

Since the application of these priority lines of action is insufficient in itself, it is necessary to ask *what other conditions* are necessary to ensure their widespread implementation in Spain and other countries. Consequently, this epilogue focuses on analysing these additional requirements for successful implementation and *presents existing evidence* to succeed in this implementation.

This evidence is aimed at policy makers and macro decision makers who have the responsibility to initiate and lead a transformation of the sector. It is they who must create the right conditions for successful implementation of these ambitious priority actions. Consequently, this chapter is built on the notion of having to introduce ambitious large-scale transformation, and of identifying how to ensure successful implementation.

The definition of large-scale transformation that seems most appropriate is the one that comes from Best et al. [1]: *‘Large-system transformation in healthcare are interventions aimed at coordinated, system-wide change affecting multiple organisations and care providers, with the goal of significant improvements in the efficiency of healthcare delivery, the quality of patient care, and population-level patient outcomes’.*

Although not particularly new, this definition has the merit of being based on a realistic review carried out over a period of 6 months in 2010 by the project ‘Knowledge for Action and System Transformation’ (KAST). The KAST team conducted a rapid systematic review and a synthesis of knowledge on large-scale transformations for the Saskatchewan Ministry of Health in Canada.

Implementation of a Priority Intervention - Getting beyond the Operational Disconnection

The science of implementation offers a disciplined process rather than a recipe, and is an important ingredient in responsible government [2]. In their extensive review of

successive government mistakes in the UK, King and Crewe argue that the *disconnect between formulation and implementation* can be partial and sometimes complete [3]. What they call '*operational disconnection*' is an important feature of modern governments. One thing is to define and formulate a priority and another is to implement it. Spain also suffers from this operational disconnection.

At the heart of this notion is the asymmetric relationship between high-level policy makers and front-line workers. It is interesting to note that while those in the front line can do their job properly without taking into account considerations of a higher level, the opposite is not true. Those who operate at higher levels cannot succeed without having some understanding of what really happens on the front line. This is particularly true of medicine.

Occasionally, the proposed policy priority may be of symbolic importance and the implementation stage is not reasoned as necessary, nor are the appropriate conditions or investment provided to ensure implementation. In these cases, the government is content to *announce* a new policy and does not create conditions for its implementation. In these cases, the simple formulation and announcement of a policy are a substitute for action.

This comment begins with the idea that, in general, policy makers really want to see their policies operationalised on the ground. Consequently, this next section starts with the principle of responsible government.

The main factors facilitating successful implementation of priorities are described below in the context of each highlighted study. The science of implementation helps us address, in an organised way, some solutions to the abovementioned *operational disconnection* [2].

The Institute for Government (IFG) offers a series of lessons for a government in the areas of politics, vision, institutions, capacity and alignment. That group confirmed that health policies are not implemented alone, and that it is necessary to create a receptive environment to move forward. One wonders if in Spain one invests what is necessary in the creation of a receptive context when formulating a new health policy.

The review by Best et al. [1] provides examples of success in creating context for successful implementation. It includes conditions such as (i) the leadership styles required (a combination of top-down and bottom-up leadership); (ii) the appointment of a team exclusively dedicated to the implementation; (iii) a formal explanation of short- and long-term goals; and (iv) the participation of health professionals and patients in the change.

In the same vein, there is a more recent study on national and state leadership capacity for health reform in the US. The analysis was sponsored by the Milbank Memorial Fund and is based on interviews with legislators about their experiences developing the capacity needed for the transformation of the health system [4]. Again, the study identifies the importance of factors such as leadership, the existence of a transformation fund and the support of the public.

In the Milbank Memorial Fund study, several important issues emerged, including (i) the political mechanisms at the beginning of the reform process; (ii) the simple political capacity; (iii) the contribution of leadership style; and (iv) the availability of financial and technical resources for the development and implementation of new policies [4].

What also emerges strongly from these observations and analyses of transformational change (the Canadian study, the UK study conducted by Barber, the recent IFG review and the recent Milbank study) is the critical role of *ensuring constructive relationships* at all levels. It follows that a change will not likely be successful for long if there is no development of constructive relations, especially between the high-level policy makers and the front-line staff responsible for implementation.

This level, sometimes called ‘street bureaucrats’ (without pejorative intent by Lipsky), [5] controls a significant discretionary power and can be decisive in determining the success or failure of a policy. Furthermore, it seems very important to have a reliable, timely and dynamic evidence base in order to inform the change process as it progresses so that it can be modified as and when appropriate. This element of evidence is being instrumental in upholding and continuing to implement Obamacare in the US in the current hostile environment.

The need to involve patients and/or citizens in the redesign of health systems, since their support or, more likely, opposition to changes in the model, may be critical to progress. The key issue in this case, which is often neglected in transformation initiatives, is to dispel fears and suspicions that change is designed to reduce costs, reduce quality and lead to a general decline in care or service.

When efforts are made to involve the public and citizens in understanding change, all too often those changes are discarded as they are perceived as coming from politicians or managers. In contrast, there is a greater willingness to listen and understand when doctors are put in the position of leading the public consultation process. Therefore, it is necessary to invest more effort in identifying ways of involving the public – not just in helping them understand the reasons for the transformation of the health system.

There are two particular factors that need to be made explicit in the implementation of priority interventions. These include some of the steps recommended by Kotter for successful change [6]. First, the development of a sense of urgency so that the need for change cannot be ignored or postponed indefinitely. This emphasis on urgency is also a factor in the approach described by Barber and is behind the notion of a ‘burning platform’ that triggers large-scale change [7]. Second, achieving early wins and short-term results offers confidence and hope that change is possible in the long run. Barber refers to this as the ‘expectation of success’. Having quick results offers reassurance to politicians who may be attacked because of their policies, and this allows them to provide temporary evidence that their changes are working.

While rapid gains are needed to ensure continued political support and to demonstrate that the policy is working, it should be noted that a profound culture of change could take 5–10 years to be implemented and integrated.

The aforementioned Milbank Memorial Fund study concludes with a list for policy makers undertaking priority health system initiatives. This checklist consists of five dimensions:

- Leadership: this factor is paramount in policy development and implementation.
- External resources: these include funding, technical assistance and communication forums.
- A core of management: a group of political leaders with sufficient experience in managing change is critical.
- Analysis: relevant data and information are central to both monitoring the implementation of the policy and assessing its impact.
- Implementation: operational skills are critical and yet are often neglected with the consequence that recruitment and retention of staff receives insufficient attention.

In conclusion, in Spain there is still a lack of vision on the direction the NHS should take in order to remain sustainable and quality driven. Given the inevitability of this change – sooner rather than later – a new policy will be formulated that will bring about

the transformation of the NHS. That new policy will continue ambitious priority interventions. At that time, it will be necessary to identify *what* priority actions to take. This will have to be done methodologically as explained in other chapters of this book. However, identification of those actions will be insufficient, and it will be necessary to create the right conditions for successful implementation. In other words, it will be useful to have an implementation plan as well as a very detailed priority formulation. This will ensure there is less *operational disconnection*. Evidence and international studies on implementation have been presented in this comment. From these studies, there are common denominators whose aligned development will favour the implementation of the ambitious change required in the Spanish NHS.

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¿Priorizar los servicios sanitarios o «salir del paso»?

Resumen ejecutivo en español

Introducción

La solvencia y perdurabilidad de los sistemas sanitarios públicos de los países desarrollados están tocadas en su morfología actual. El envejecimiento, las enfermedades crónicas con epidemias tales como la obesidad, las enfermedades mentales, las adicciones de todo tipo, el desempleo crónico, la reducción de los porcentajes de población activa por la implantación de tecnologías sustitutivas de mano de obra, la vertiginosa innovación biomédica, las expectativas ciudadanas no siempre acertadas sobre lo que se puede esperar del sistema y un largo etcétera hacen que superen a la oferta de los servicios existentes, que se ven desbordados por esta demanda y con unos costes difícilmente asumibles con el crecimiento económico actual y posiblemente futuro. Es en este contexto en el que el establecimiento de prioridades toma carta de naturaleza y pasa a ser un imperativo para los responsables de la política y la gestión sanitarias. Perseguimos con este libro responder a las siguientes preguntas: ¿qué procedimientos se emplean para determinar si las nuevas tecnologías deben ser financiadas públicamente?; ¿cuál es el papel que tiene en la priorización cada agente del sistema?; ¿qué tipo de evidencia es necesaria para decidir prioridades?; ¿se tienen en cuenta en la fijación de prioridades los balances entre los distintos objetivos, perspectivas y valores del sistema?; ¿hay debate y transparencia en el proceso?; ¿qué podemos aprender de las experiencias internacionales que merecen la pena?; ¿cómo influye la arquitectura de nuestro sistema en la priorización del paquete de prestaciones básicas financiadas públicamente?, y finalmente, ¿cómo ayuda la evaluación de tecnologías sanitarias a todo esto?

Capítulo 1

Decidir sobre programas públicos: priorización y gobernanza, un todo inseparable

Autores: María Callejón, Carlos Campillo-Artero, Vicente Ortún

La priorización de tareas y programas ocurre en cualquier campo, público o privado, colectivo o individual, y siempre se hace mejor o peor, explícita o implícitamente. La priorización de las intervenciones que el Estado realiza se justifica tanto para corregir las fallas del mercado como para favorecer una cierta redistribución (el tándem eficiencia-equidad de la política pública). Esto se puede abordar dentro del contexto de las limitaciones de la acción pública y desde la perspectiva de la Economía Política (la teoría de la Elección Pública). Independientemente de si las recomendaciones para la priorización están basadas en la evidencia o no, no debemos ser tan ingenuos como para creer que la mejor «Economía» necesariamente se traducirá en la mejor «Política»; para que esto suceda la gobernanza debe prevalecer, y esto es válido para todos los ámbitos sociales.

En términos de gobernabilidad, la evidencia internacional muestra para España una creciente viscosidad en varios indicadores, como el índice de competitividad global del Foro Económico Mundial, los *Worldwide Governance Indicators* del Banco Mundial, el *Transparency International* o el *Rule of Law Index*, que tienen resultados altamente concordantes. España tiene un problema con su gestión pública. Será muy difícil mejorar la gestión pública o introducir reformas que aumenten significativamente nuestra productividad sin una mejora en la calidad de la política y las instituciones que la condicionan. Los requisitos para un mejor gobierno del Estado son tan conocidos como ignorados: (i) revisar la financiación de los partidos políticos limitando los gastos y controlando las contribuciones privadas; (ii) racionalizar las regulaciones electorales para acercarse al principio de «una persona, un voto», y (iii) permitir la independencia de los medios de comunicación públicos. Solo un Estado efectivo que facilite la existencia de instituciones transparentes e imparciales, tomando por ejemplo a los países escandinavos o a muchos países de la Europa Central, permitirá que España se fortalezca después de la crisis. No habrá una mejor gestión pública sin un mejor gobierno.

Respecto a la gestión pública, las decisiones no pueden regirse exclusivamente por umbrales en la disponibilidad social a pagar (DAP) por años de vida ajustados por calidad (AVAC), en función de proporciones de coste-efectividad incremental. Primero, porque los encargados de tomar decisiones están preocupados por otros objetivos además de maximizar la salud (la equidad, el impacto en la opinión pública o el déficit comercial), y segundo, porque a los ciudadanos también nos preocupan otros objetivos. Vale la pena intentar recopilar, ponderar y evaluar científicamente otros objetivos, como evitar futuros daños, alentar la innovación científica y técnica, tratar a las personas socialmente desfavorecidas, cuidar el «final de la vida» o ser sensible a las enfermedades raras.

En España ha llegado el momento de introducir la idea y la práctica de la competencia a partir de la comparación por calidad (por ejemplo, universidades, centros educativos o centros de salud), con un horizonte de 30 años. No habrá mejor gestión pública sin una mejor política y una mejor gobernanza: un concepto complejo que incluye, entre otros, la revisión del financiamiento de los partidos políticos, la necesidad de transparencia, la rendición de cuentas, la regulación apropiada de los conflictos de intereses, y la profesionalización e independencia de las funciones ejecutivas de la administración pública.

Capítulo 2.

Priorización en salud pública: objetivos, métodos, problemas y experiencias prácticas

Autor: Beatriz González López-Valcárcel

La priorización en la salud pública es más compleja que en los servicios de salud, con una tensión permanente entre «puristas y pragmáticos». Se encuentran dos tipos de dificultades: la primera, la de desentrañar y medir los valores de la sociedad; en segundo lugar, las dificultades técnicas de determinar las consecuencias esperadas o probables de diferentes acciones. El problema no solo es técnico, sino que también nos exige abordar los conflictos de intereses entre las organizaciones y, por lo tanto, tener en cuenta los problemas de implementación y las reformas organizativas. Como la salud no es el único objetivo de las políticas de bienestar social, el marco en la priorización de la salud pública debe ser amplio. En última instancia, se debe tomar la decisión de si la priorización debe limitarse a la salud o, más bien, debe abordar objetivos más ambiciosos y más difíciles en el campo del bienestar social.

Al realizar el acto de priorizar, estamos alimentando la propia cultura de la priorización, que es esencial para su aceptación social. Del mismo modo que existen medicamentos huérfanos, también existen políticas huérfanas, cuya evaluación ninguna organización está dispuesta a pagar. Los dos métodos de priorización explícita más comúnmente usados son el de Programación Presupuestaria y Análisis Marginal (PBMA, *Program Budgeting and Marginal Analysis*) y el Análisis de Decisión de Criterios Múltiples (MCDA, *Multiple Criteria Decision Analysis*). Las dimensiones que se aplican con mayor frecuencia a problemas de salud o programas forman una lista larga y variada, y los pesos o valores asignados a cada una de estas dimensiones son de crucial importancia en la clasificación final obtenida.

Los planes de salud son intentos bien intencionados de priorización, pero generalmente no tienen éxito debido a los problemas técnicos y políticos descritos anteriormente. En general, estas iniciativas tienden a dar más prioridad a los problemas que a las soluciones, y han evolucionado hacia planes basados en el paradigma interdepartamental y hacia la «Salud en todas las políticas».

Una lista de verificación de consideraciones pragmáticas en el establecimiento de prioridades debe incluir cuatro aspectos: (i) objetivos claros y bien estructurados con un horizonte temporal claramente definido; (ii) una organización equipada para el cambio; (iii) seleccionar a las personas adecuadas para llevar a cabo el cambio, y (iv) la viabilidad financiera y organizativa del cambio. A partir de una revisión de experiencias prácticas, este capítulo concluye que, en muchos casos, los ejercicios de salud pública siguen siendo más didácticos que pragmáticos.

Capítulo 3.

Priorización basada en el valor en la Atención Sanitaria

Autor: Juan M. Cabasés

Establecer prioridades en la toma de decisiones sobre salud es una práctica que incorpora valor para la sociedad, valor medido en términos de salud y bienestar, tanto dentro como fuera del ámbito del sistema de salud. Esto puede resultar en negarle a un individuo o grupo algo que podría ser beneficioso para él/ellos. En términos económicos, esto significa tener en cuenta el coste de oportunidad; es decir, los beneficios perdidos como consecuencia de la elección. Puede tener un impacto distributivo importante y un efecto en la eficiencia, lo que requiere de un mecanismo explícito en el que todas las partes involucradas afectadas puedan tener voz. La priorización requiere primero definir un marco; segundo, establecer criterios explícitos ponderados entre sí, y tercero, elegir los métodos para su implementación. En este capítulo se revisan tres aspectos: (i) el estado de los métodos utilizados; (ii) su potencial y limitaciones, y (iii) los agentes involucrados en este ejercicio cargado de valores. El foco se centra en los métodos y criterios utilizados en la medición de la eficiencia y la equidad. Además, reconociendo que establecer prioridades requiere de un proceso de deliberación en el que participan varias partes interesadas, se enfatiza en el crucial papel de los pacientes y el público en general.

A partir de la revisión de estos tres puntos, se concluye que todavía es escasa la evidencia de que el establecimiento de un marco de valores para la priorización haya tenido un impacto en la política sanitaria y de que los ejercicios de priorización hayan llevado al ideal de participación ciudadana en la toma de decisiones. Los principios, en abstracto, no tienen mucha influencia en la política. Ocasionalmente se dan conflictos entre criterios; los *ranking* resultantes no siempre son operativos a nivel individual; hay problemas conceptuales y prácticos a la hora de definir las necesidades; también hay resistencia a eliminar servicios de la oferta pública. Los casos de éxito se están produciendo en países donde se desarrollaron recomendaciones para guías clínicas, como Inglaterra y Gales con su *National Institute for Health and Care Excellence* (NICE). El futuro de la priorización en tiempos de restricciones presupuestarias consiste en garantizar que estos procesos se basen sólidamente en evidencias y sean transparentes.

Capítulo 4.

¿Qué evidencia del análisis de Evaluación de Tecnologías Sanitarias se precisa para la priorización y la toma de decisiones?

Autor: Iñaki Gutiérrez-Ibarluzea

Desde su inicio, el enfoque de la Evaluación de Tecnologías Sanitarias (ETS, o HTA por sus siglas en inglés) ha sido multidisciplinario y multidimensional, con el objetivo de ayudar a los responsables de la toma de decisiones a decidir dónde invertir o desinvertir cuando existen diferentes alternativas disponibles. Aquí, el uso racional de los recursos es crucial. Obviamente, la ETS ha desarrollado y perfeccionado sus métodos para tratar de responder preguntas complejas, en las que otros componentes diferentes a aspectos clínicos tienen un impacto aún mayor en los resultados de salud y económicos. En muchas ocasiones, la evidencia sobre aspectos organizativos, éticos, legales o sociales relacionados

con el contexto en el que se implementará la tecnología es fundamental para recomendar o no la implementación o eliminación de esa tecnología, o para priorizar dónde gastar el presupuesto dentro de un Sistema de Salud. En las últimas décadas, se han propuesto diferentes modelos para determinar el valor de las diferentes tecnologías sanitarias, para poder compararlas y así priorizarlas. Si bien en la mayoría de los casos las decisiones se toman sobre la base de criterios no explícitos, se han propuesto diferentes modelos o metodologías para cambiar esta práctica. La transparencia, la replicabilidad y la solidez son los pilares de esos modelos. Aun así, los autores de esos modelos admiten que el contexto determina las preferencias y las prioridades y, por lo tanto, los modelos deben ajustarse en consecuencia, al tiempo que garantizan la transparencia y la toma de decisiones basada en la evidencia. Aunque no se han implementado ampliamente, los modelos económicos y, en particular, los ratios incrementales de coste-efectividad, han sido los más conocidos y discutidos. Estos modelos son atractivos por sí mismos, ya que incluyen los dos componentes de la ecuación: por un lado, los beneficios (medidos de diferentes maneras) y, por otro, los costes. Además, ofrecen un enfoque cuantitativo al problema. A este respecto, los sistemas de salud y las organizaciones internacionales, incluida la Organización Mundial de la Salud (OMS), han propuesto umbrales para determinar cuánto es justo pagar por una tecnología concreta y cuánto no. Sin embargo, estos modelos han sido criticados por diferentes autores, ya que no logran capturar todas las dimensiones del valor. Otras propuestas han ganado importancia durante la última década para superar estos problemas, e incluir las preferencias y prioridades de los diferentes sistemas y contextos. Entre ellos, el Análisis de Decisión de Criterios Múltiples (MCDA, *Multiple Criteria Decision Analysis*) y las metodologías sugeridas del proyecto INTEGRATE-HTA han sido los últimos en ser propuestos y debatidos. En este capítulo, se aborda la diferencia entre la priorización de temas que evaluar y la priorización de tecnologías que financiar. Finalmente, se discuten los métodos para medir el valor y su relación con la generación de evidencia ETS.

Capítulo 5.

Prioridades en la Gestión Clínica moderna

Autor: Jordi Varela

La práctica clínica moderna está fuertemente presionada por el deseo consumista de la sociedad y la industria dedicada a la provisión de servicios. Además, este fenómeno subsiste con un cambio profundo y persistente de la casuística hacia la cronicidad compleja y la fragilidad geriátrica, que requiere una oferta de atención personalizada en lugar de acciones fragmentadas.

Con todo esto, los sistemas de salud sobreviven en un entorno perverso; por lo tanto, necesitan una visión transformadora global y mucha tenacidad. Este capítulo se centra en la necesidad de que la práctica clínica actual agregue más valor a la salud de las personas, y por esta razón, se proponen cuatro líneas estratégicas que, si el «malvado problema» ha de abordarse, deberían ocupar las agendas de los decisores:

1. Más estrategias para promover la atención centrada en el paciente, basada en una mayor capacitación de los médicos en materia de entrevistas motivacionales y decisiones compartidas. Es fundamental que los médicos dediquen más tiempo a la discusión clínica, una auténtica fuente de valor.

2. Más debate profesional en entornos académicos para reducir el sobrediagnóstico y el sobretratamiento. Es necesario aumentar la comprensión del riesgo por parte de los dos principales agentes clínicos: médicos y pacientes.
3. Más recursos para evaluar las prácticas clínicas que aún no están respaldadas por suficiente evidencia. Existe mucha práctica clínica que se mueve en territorio de áreas grises, con evidencia inconsistente o áreas desérticas, y con pocos estudios rigurosos de coste-efectividad. Se estima que el desperdicio en prácticas de valor dudoso puede ser del 25 al 33% de los recursos y, por esta razón, se alienta a los médicos a analizar las fuentes de información correctas y a pensar en términos de triple meta: simultáneamente reducir el coste per cápita, mejorar la atención al paciente y mejorar la salud de la población.
4. Menor fragmentación y mayor alineación de los objetivos de atención sanitaria entre los profesionales que atienden a pacientes con complejidades sociales y de salud, y una mayor implicación de los pacientes en el ajuste de los servicios y los recursos clínicos a sus necesidades. Uno de los principales males de la medicina fragmentada se da en el tratamiento de pacientes crónicos y frágiles. La forma de combatir la fragmentación es fomentar el conocimiento de la experiencia de los pacientes, como motor para integrar los cambios en los servicios y promover la continuidad de los planes de atención.

Capítulo 6.

¿Debería el Sistema Nacional de Salud ser más explícito en la priorización de los servicios de salud?

Autores: Salvador Peiró, Juan del Llano

El establecimiento de prioridades, un sinónimo de asignación de recursos y racionamiento, ocurre en cada nivel y en cada rincón de cada sistema de salud, en dos formas básicas (y no exclusivas): el racionamiento implícito y el racionamiento explícito. El establecimiento explícito de prioridades se refiere a situaciones donde las elecciones adoptadas sobre la asignación de recursos se aclaran. También, pero no siempre, se revelan las bases sobre las cuales se tomaron esas decisiones. Por el contrario, el establecimiento implícito de prioridades se refiere a las decisiones discrecionales tomadas por gerentes, médicos y otros profesionales de la salud bajo una restricción presupuestaria. La priorización implícita se puede ejercer fundamentalmente en el nivel micro de toma de decisiones clínicas (racionamiento de cabecera), mientras que la priorización explícita debe ser, sobre todo, una responsabilidad de los encargados de tomar decisiones de la meso y la macrogestión o política sanitaria.

Es necesario resaltar la importancia del racionamiento implícito llevado a cabo por profesionales sanitarios. Es probable que donde existe un conocimiento suficiente del paciente y de sus necesidades clínicas, como para tomar las adecuadas decisiones de racionamiento, sea solo en el nivel micro. De hecho, si estas decisiones fueran perfectas, no estaríamos hablando de racionamiento (subutilización) ni de uso excesivo: todos los pacientes recibirían la atención necesaria para su condición clínica. Sin embargo, reconocer el papel esencial que desempeña el racionamiento implícito llevado a cabo por los profesionales

sanitarios no excluye la necesidad urgente de un mayor y mejor racionamiento explícito por parte de nuestras autoridades sanitarias. La explicitud tiende a mejorar la rendición de cuentas haciendo que la asignación de decisiones sea transparente (y el papel de los grupos de presión para obtener recursos adicionales para sus prioridades); sin embargo, sobre todo, las decisiones macro y mesoexplícitas son necesarias para un rendimiento adecuado de nuestro Sistema Nacional de Salud (SNS). Una gran cantidad de evidencia muestra que el SNS tiene un problema importante con su uso excesivo (que surge precisamente de la toma de decisiones implícita a nivel clínico en un marco de toma de decisiones explícito deficiente en los niveles macro y meso). Los estudios de variación de la práctica médica española, junto con estudios sobre el uso inadecuado de fármacos (por ejemplo, antibióticos, entre otros), pruebas diagnósticas, hospitalizaciones, intervenciones quirúrgicas y derivaciones a atención especializada, sin mencionar el uso de urgencias hospitalarias, sugieren que uno de cada cuatro a cinco servicios proporcionados por el SNS podría ser innecesario. Es probable que estas cifras no difieran de las de otros países de nuestro entorno, pero deberían preocupar lo suficiente como para tratar de definir mejor, mediante el establecimiento explícito de prioridades, la máxima variación admisible en los juicios clínicos. El establecimiento explícito de prioridades requiere, a su vez, experiencia técnica, participación social y responsabilidad política. Estos tres elementos son muy escasos en nuestro contexto.

En conclusión, en el establecimiento adecuado de prioridades, no se trata de elegir entre perderse con el racionamiento implícito, o ser encorsetado por una estructura intervencionista exhaustiva, rígida y explícita en los niveles macro, meso y micro de toma de decisiones. Esta dicotomía no logra capturar la complejidad del establecimiento de prioridades en la práctica. Necesitamos más y mejor configuración de la priorización explícita, no para sustituir, sino para mejorar la configuración de la priorización implícita.

Capítulo 7.

Bioética y evaluación de tecnologías sanitarias: una pareja no tan extraña

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El papel de las agencias de evaluación de tecnologías sanitarias (ETS) ha evolucionado desde su auge en la década de 1980. Con la creación de la Oficina de Evaluación Tecnológica (OTA) en 1972, nació una corriente crítica e independiente de análisis y síntesis de nuevas complejidades científicas y técnicas, dirigida a ayudar a los políticos, los gerentes y la administración pública a tomar decisiones informadas. En reacción a los cambios epidemiológicos, sociales, tecnológicos y económicos de los últimos años, las agencias han asumido nuevas funciones, como lo ejemplifica la Agencia para la Calidad y Evaluación de la Salud de Cataluña (AQuAS, por sus siglas en catalán).

Este capítulo proporciona una breve revisión de los principios de la bioética:

1. El principio de Autonomía.
2. El principio de No Maleficencia.
3. El principio de Beneficencia.
4. El principio de Justicia.

A su vez, considera cada uno de estos principios en el contexto de proyectos con datos de la vida real que se están llevando a cabo actualmente en AQuAS.

La conclusión principal de este capítulo es que algunos de los proyectos actualmente en curso en AQuAS están bastante alejados de la ETS clásica. Estos son mucho más amplios y complejos, y con una participación intensiva de médicos y pacientes/ciudadanos. Eso sí, tienen en común un fuerte antecedente de la Medicina Basada en la Evidencia. Además, todos ellos están relacionados con los principios de la bioética, uno de los elementos clave de la evaluación ETS.

Por otro lado, también se señala que, dado el alto desarrollo de las Tecnologías de la Información y Comunicación (TIC) y la disponibilidad de herramientas analíticas de *big data*, lo más probable es que un área de desarrollo futuro en torno a la ETS sea el uso intensivo de datos rutinarios (bases de datos administrativas), que se digitalizarán en gran medida con una información clínica cada vez más rica, y serán enlazables entre áreas, es decir, consumo de drogas, hospitalizaciones, uso de atención primaria y registros específicos (accidente cerebrovascular, infarto de miocardio, cáncer, etc.). Estas técnicas se emplearán para evaluar la efectividad de los medicamentos, dispositivos y políticas sanitarias. No obstante, el uso de estas bases de datos también tiene implicaciones éticas, que deberán analizarse.

Capítulo 8.

Las verdades incómodas de la priorización de la atención sanitaria

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Un enfoque correcto para la priorización de la atención sanitaria requiere aceptar ciertas verdades éticas y políticas ciertamente incómodas. La primera y fundamental es que el racionamiento no siempre es evitable, por lo que nos vemos obligados a enfrentar esta verdad. Para hacerlo, lo que debemos hacer primero es reconocer esto mismo, que la priorización de la atención sanitaria, o el racionamiento, es un problema ético que no se puede evitar. También debemos aceptar que la ética del racionamiento de la atención sanitaria está vinculada a la justicia social y no solo se puede limitar a la ética clínica.

Desafortunadamente, no tenemos un criterio ético o una combinación de criterios éticos que sirvan como varita mágica para aliviar nuestra conciencia después de ejecutar el ejercicio de priorización, aunque hay procedimientos que son más justos que otros para determinar cómo lograrlo. En términos generales, los criterios éticos de priorización vinculados a la necesidad son más justos que aquellos que ponen el énfasis en el mérito personal y la responsabilidad por la propia salud. Esto no significa que no jueguen ningún papel en la priorización. Lo que significa es que su importancia es secundaria o periférica.

La priorización significa que algunos pacientes no reciben la atención médica que necesitan, y ningún criterio ético de priorización puede evadir la insatisfacción moral resultante. La ética de la priorización consiste en que la decisión final es la más razonable desde el punto de vista de los valores sociales y la información disponible, pero el conflicto ético dentro de la sociedad y la insatisfacción moral de cualquier decisor sensible siempre serán inevitables.

A lo largo de este capítulo, se analizan cada una de estas incómodas verdades, además de ver cómo se relacionan con la gestión correcta de la priorización de la salud. A modo de resumen de lo anterior, estas son:

1. Que la priorización de la salud es inevitable.
2. La negación de recursos a pacientes que los necesitan para algún tipo de beneficio para su salud.
3. La priorización es una cuestión de justicia social y no de un mero acceso equitativo al sistema de salud.
4. También es una cuestión ética, que no se resuelve mediante un mero razonamiento clínico o económico, y no se resolverá mediante la aplicación de un criterio ético moralmente indoloro.
5. Exige un compromiso de solidaridad por encima de la libertad individual.

