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**RESOURCE ALLOCATION AND PRIORITY SETTING
IN HEALTH CARE SYSTEMS**

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ABSTRACT

The combination of constrained resources and increasing demands in health care is making priority setting a crucial factor for health policy, and as choices on the allocation of resources are required to be increasingly explicit, priority setting and rationing drift away from a straightforward process. This chapter aims to review the main challenges regarding prioritization. The first section describes the concepts and normative economic grounds of priority setting. The second section maps out a review of sound practical experiences with priority setting. The third section provides thoughts on the development of prioritization mechanisms and the policy implications and limitations of these mechanisms, as well as the potential use of priority-setting concepts for allocating resources and for informing decisions about issues such as coverage and cost sharing.

1. INTRODUCTION

From many points of view, healthcare systems are improving their capacities to heal and to extend lives. Innovation and improvements in health care systems, together with many other factors, have helped improve health indicators worldwide. However, healthcare expenditures are under increasing pressure. Governments are struggling to keep healthcare budgets under control, especially in some developed countries, as health care budgets are often increasingly restricted by economic downturn and the costs associated with aging populations. Moreover, in all countries, the gap between technological innovation and health care expenditure capacity is likely to remain or increase in the future.

Thus, in most of the Organization for Economic Cooperation and Development (OECD) public health care systems since the 1980s, there has been a need to ensure that any additional resource spent on health care is worth it. It is not just an issue of cost minimization, but of making choices between alternatives, which is what economics is about. Outputs, throughputs and outcomes are the focus as well as the key to the efficiency goal. Defining these parameters becomes the most relevant challenge for priority setting in health care systems.

This chapter aims to review the core concepts behind priority setting. The first section describes the concepts and normative economic grounds of priority setting. The second section maps out a review of sound practical experiences with priority setting. The third section provides thoughts on the development of prioritization mechanisms and the policy

implications and limitations of these mechanisms, as well as the potential use of priority-setting concepts for allocating resources and for informing decisions about issues such as coverage and cost sharing.

2. CONCEPTS REGARDING PRIORITY SETTING

a. Rationing, priority setting and economic evaluation

There are several key concepts and terms that should be defined in our discussion of priority setting: these are rationing, economic evaluation and cost-effectiveness. Rationing (the action) and priority setting (the tool), are terms that are quite close and even sometimes used interchangeably. However, rationing usually implies the withholding of resources from individual patients, whereas priority setting has a less negative connotation, referring more to populations than to individuals (Dickinson et al. 2011), and to a means for rationing. Although strictly speaking, these two terms have different meanings, they are closely related in terms of their policy implications. For that reason, they will be used in this chapter to refer to the process by which resource allocation decisions are both made and implemented in health care systems.

Economic evaluation, which is defined as “the comparative analysis of alternative courses of action in terms of both their costs and their consequences” (Torrance & Drummond 2005), when applied to the health sector, provides a systematic framework to assess the relative costs and benefits of alternative health care interventions. A health care intervention that is “cost-effective” is one in which additional health benefits have been leveraged against their additional costs, resulting in a more efficient healthcare provision. Economic evaluation is hence used to inform resource allocation decisions.

Economic evaluation can be applied at different levels in the decision-making structure of health care organizations. At an aggregate level, economic evaluation may be applied to assess the relative value of building additional capacity into the system (health care service facilities), promoting health actions among alternatives (either from inside or outside of the health care sector) or even the allocation of funds to sectors other than health care (such as education or income support). On a lower level, once an initial health care spending capacity has been determined, we can implement economic evaluation to choose among more disaggregated health care areas such as procedures or types of services or among different beneficiaries. This is often made on an isolated or marginal basis, despite the need to recognize the existence of intersections among alternatives.

When used to determine a package of services and procedures to be covered under an insurance policy, whether public or private, the typology of the selected treatments and services may be of two types (i) those included in a “basic package” (guaranteeing “right to access”), usually with the filter of a medical agent, perhaps some “enforceable” rules (legal entitlements or citizens’ charts), or (ii) those considered beyond the basic package, under the constraints of either “hard” or “soft” rationing, dependent upon the role of the public regulator for private complementary care (community premiums, tax deductibility, etc.).

Applying economic evaluation to healthcare rationing is not exempt from controversy. As an example, controversy may arise on the question of including a certain treatment in the covered package of treatments and the consequent need to replace that new treatment with another previously covered due to budget constraints (investing and disinvesting), or increasing the extent of currently funded treatments (by adding to the covered package specific indications that were not previously considered). We will later discuss the extent of these controversies in health policy.

Economic evaluation is nowadays used not only for rationing health care coverage but also for measuring the performance of a whole health care system relative to other countries' or regions' health care systems. These measurements may be a means to attract more or less resources to the sector. In such analyses, the most common measures of output are mortality and morbidity, such as life expectancy, and impairment-free life expectancy (Field & Gold 1998), or even improved versions of the Quality Adjusted Life-Year (QALY) by incorporating data on health-related quality of life to produce estimates of Quality Adjusted Life Expectancy (QALE). An interesting example of economic evaluation applied to international measures of performance is Bloomberg's ranking of countries based on the efficiency of their health-care systems.¹ Each country² has been ranked on three criteria: life expectancy (weighted 60 percent), relative per capita cost of health care (30 percent); and absolute per capita cost of health care (10 percent). Countries were scored on each criterion and the scores were weighted and summed to obtain their efficiency scores. Relative cost is health cost per capita as a percentage of GDP per capita. Absolute cost is total health expenditure, which covers preventive and curative health services, family planning, nutrition activities and emergency aid. Finally, economic evaluation is used to estimate the cost of illness or burden of disease, with the aim of assessing the overall scale of one specific health problem compared with other health problems (Mooney & Wiseman 2000). Disability Adjusted Life Years (DALYs) have been extensively used in economic evaluations to monitor the burden of disease in both developed and developing countries (Lopez & Murray 1998). However, such a use of economic evaluation is considered to be useful to size the problem associated with a disease, but does not provide any recommendation as to how many resources (including a measure of the opportunity costs) are worth being invested to fix it.

b. Welfarism and extra-welfarism in economics

A common fallacy in health and health care is that if universal access to health care, or low financial barriers to health care, can be achieved, then fairness can be reached by using patient needs as the main driver of resource allocation (Culyer 2010a). However, to the extent that budgets are binding, adopting a new intervention that "works" (cost-effective) and is needed

¹See results at this link: <http://www.bloomberg.com/visual-data/best-and-worst/most-efficient-health-care-2014-countries>

² Included were countries with populations of at least 5 million, GDP per capita of at least \$5,000 and life expectancy of at least 70 years.

will necessarily entail reallocating resources, leaving other needs unsatisfied. That loss is the opportunity cost of the adopted intervention – that is, what is foregone by making one decision rather than another in the allocation of resources. In order to minimize opportunity costs, interventions that work better than others need to be identified. That is, evaluative techniques need to be applied for setting priorities. When opportunity costs are taken into account, an extra-welfarism approach is adopted, where decisions take a community perspective, allowing comparison of relative effectiveness among different interventions. It can even enable tradeoffs to be made, for example, by comparing the welfare losses from taxation to the benefits from increased public revenues and expenditures.

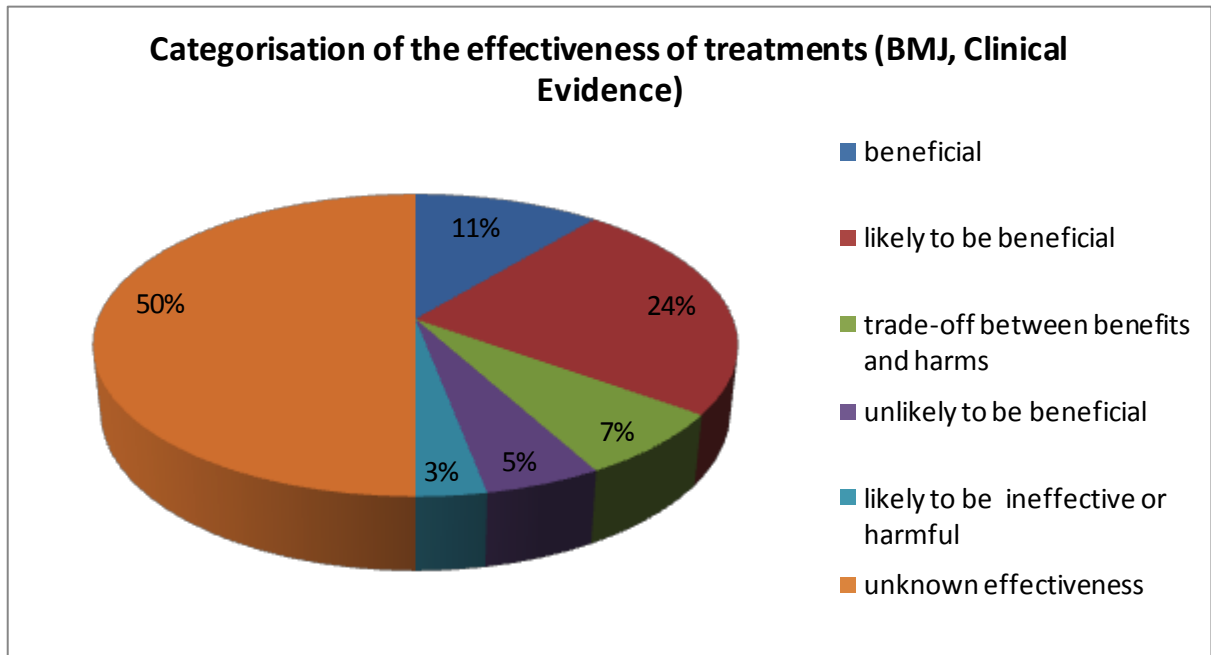
However, this is a less straightforward exercise than in a welfarist approach (Culyer 2012). Indeed, a welfarist approach builds on individual preferences of the members of society, where actors are rewarded for arrangements they dislike and are willing to pay for things they want. Economic transactions between parties would, by these means, be reached on Pareto criteria, and willingness to pay (WTP) would be used as the main criteria for allocating resources in the health care arena (Musgrove 1999). In an extra-welfarism approach, economic evaluation becomes the main tool to assist decisions regarding which interventions are preferred for the community in terms of health, given both the scarcity of resources and the need to make choices among alternative initiatives. For further reading, the book by Culyer (Culyer 2012) is a perfect introduction to these concepts.

c. Uncertainty and decision-making in practice

There are, as just mentioned, many difficulties in decision-making that arise from the evidence of relative effectiveness or value under an extra-welfarism approach. For instance, one difficulty arises from the existence of uncertainty in the decision-making process. It is, in spite of increased evidence, still an unavoidable component of decision-making. Indeed, the British Medical Journal *Clinical Evidence* (Clinical Evidence), calling on the knowledge of information specialists, editors, peer reviewers, and expert authors, highlight how evidence-based treatments are, for certain indications, based on randomized controlled trials. They find that more than 50 percent of the treatments have an unknown effectiveness, and an additional 15 percent have harmful or unlikely benefits at all. Only 11 percent of the treatments have a beneficial effect and 23 percent are likely to be beneficial.³ The following figure illustrates these results:

³ As noted by the authors, “these data reflect how different treatments stand up in light of evidence-based medicine and are not an audit of the extent to which treatments are used in practice or for other indications not assessed in *Clinical Evidence*.”

Figure 1: Categorization of the effectiveness of treatments

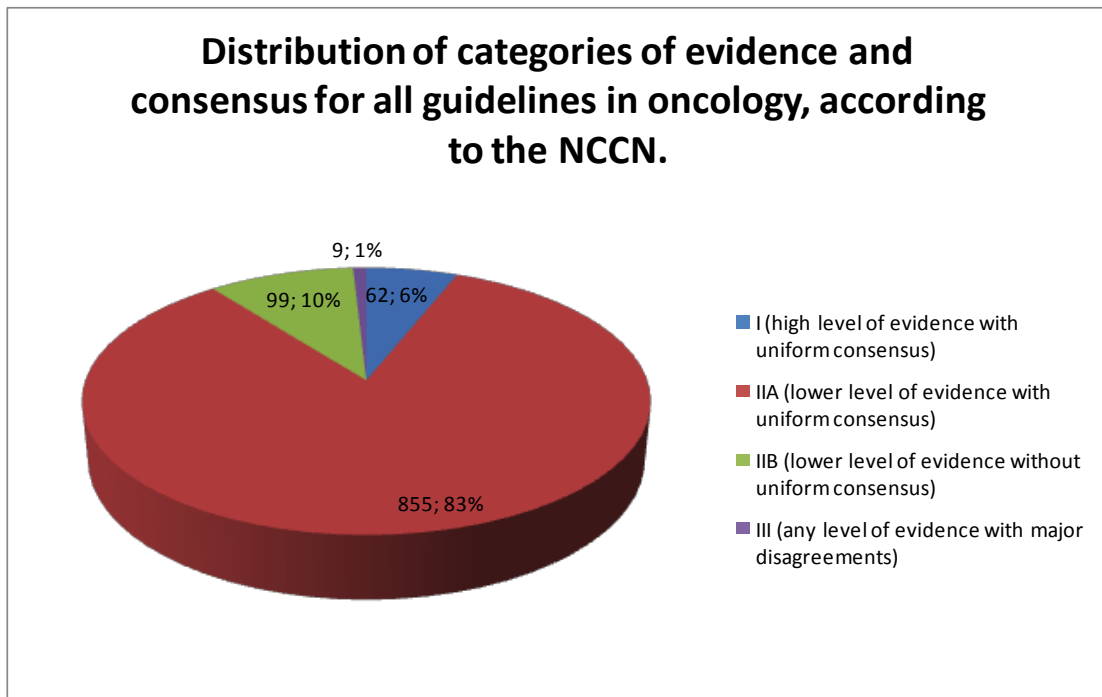


Source: BMJ, 2011

Comparable results have been found in the U.S. (Poonacha & Go 2011). The National Comprehensive Cancer Network (NCCN), a not-for-profit alliance of 21 comprehensive cancer centers designated by the U.S. National Cancer Institute and dedicated to improving the quality and effectiveness of care provided to patients with cancer, categorized evidence from I (highest degree of evidence, with consensus) to III (lowest level of evidence).⁴ They found that the majority of the recommendations (83 percent) were based on category IIA and a minority (6 percent) were based on category I (the highest level of evidence with uniform consensus), as illustrated in Figure 2.

⁴ The NCCN definitions for Evidence and Consensus are as follows: category I, high level of evidence with uniform consensus; category IIA, lower level of evidence with uniform consensus; category IIB, lower level of evidence without a uniform consensus but with no major disagreement; and category III, any level of evidence but with major disagreement.

Figure 2: Distribution of categories of evidence and consensus for all guidelines in oncology, according to the NCCN.

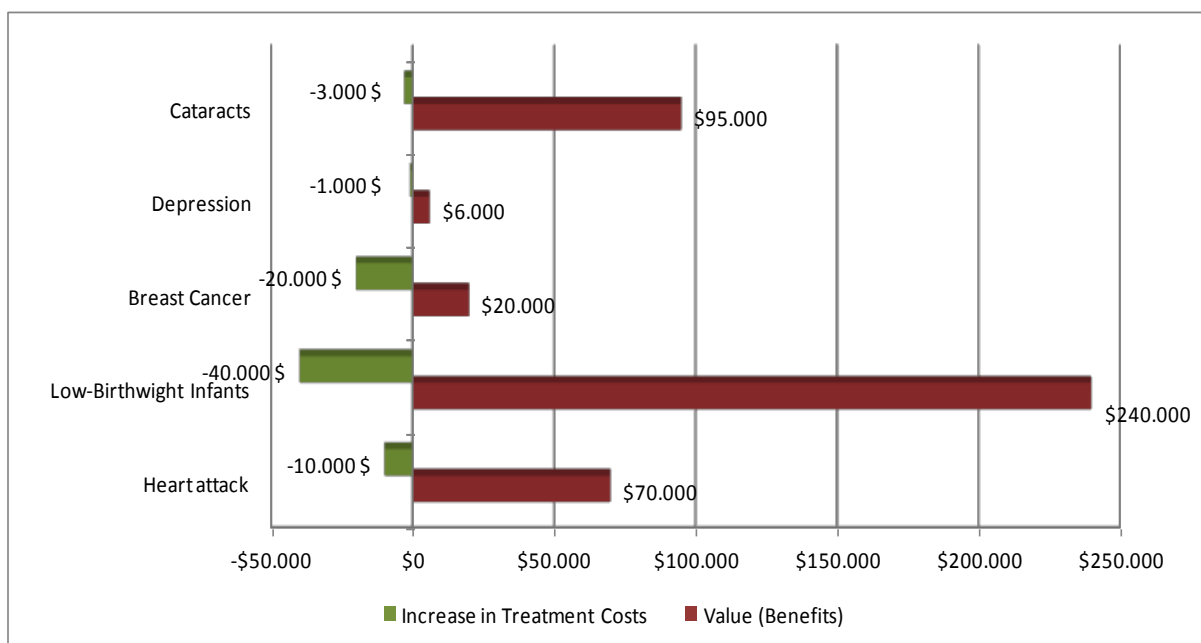


Source: National Comprehensive Cancer Network

As a result of unavoidable uncertainty in decision processes, the alternative of doing nothing is often considered the baseline case, converting the analysis of decisions into an analysis of incremental costs and consequences of any action. Being that uncertainty is an inherent ingredient in these analyses, the central question becomes how much uncertainty there is and how much can a decision process bear. In some circumstances, technology changes are worth their cost, in spite of the fact that they might be expensive and in spite of uncertainties. Cutler and McClellan (Cutler & McClellan 2001) report on the benefits of technology changes produced in the treatment of heart disease, low-birth weight infants, breast cancer, depression and cataracts. As illustrated in

Figure 3, extracted from Cutler and McClellan, in all of these cases but breast cancer, benefits from technological changes are so large that they dwarf all of the uncertainties one may think of in such analyses.

Figure 3: Medical innovation: value and costs



Source: Authors' elaboration based on (D. M. Cutler & McClellan 2001)

d. Priority setting and fairness

Priority setting is not exempt from controversy since there is no single, generally accepted way of undertaking it. Priority setting may be done on an efficiency basis (as a “health maximand” function), but other criteria could also be used for priority-setting purposes. For instance, the degree of the negative externality that a health care condition may cause on the patient’s relatives or caregivers could be considered as a criteria for priority setting. The existence of significant catastrophic costs associated with treating a disease may also count as a criteria for priority setting (Musgrove 1999). Adding social and equity concerns (that is, looking for a “fair” distribution of health); taking categorical constraints into account (by defining, for example, a threshold of minimum entitlements per individual); or considering criteria to be used on a case-by-case basis for a limited number of cases where a trade-off exists (for instance, across treatments for a common illness) are frequent additional considerations and criteria used for priority setting in practice.

In order to evaluate progress toward presumed social goals in allocating resources under explicit priority setting principles, it is important to know who accrues these social benefits and under what distributional weights. Using cost-effectiveness and QALYs for priority setting implicitly compares the value gains of alternatives irrespective of other characteristics (unless otherwise specified), such as the nature of the disease, beneficiary characteristics or social implications. No equity concerns are explicitly taken into account, but rather, all QALYs are considered equal. However, maximizing population health (efficiency) may not yield equitable

solutions (distributive fairness), neither in the horizontal sense (that is, equal treatment of people in equal situation), nor in the vertical sense (unequal treatment of those unequal). There is no consensus about what “treatment” or “situation” may implicitly be taken into account for equity purposes (Culyer & Wagstaff 1993).

There are, however, a variety of proposals on the table regarding equity concerns. Some authors link equity to morbidity or mortality, which are the closest concepts to medical “need” (or need understood as absence of health) (Williams 1962). However, *health* absence and *health care* absence are sometimes confounded: much health care may have low productivity or effectiveness to achieve better health conditions. Health indicators may signal a lack of health care resources and/or many other flaws the health care sector cannot fix. The only health care that might be “needed” is that which is effective.

For some others, equity is regarded as equal “capacity to benefit” from a health care intervention (i.e., the difference between a person's predicted health with and without health care). However, this criterion for measuring equity does not take into account the starting point, that is, current health differences among people. Indeed, individuals who are initially relatively healthy might benefit more than those in poor health, even though the latter might be those with higher health care deficits. So, this criterion might eventually increase differences.

Despite these nuances, in practice, allocative targets usually consist of maximizing total outcomes, with or without accounting for initial health endowments and with or without accounting for an individual’s capability to benefit from health care, which affects their relative maximum benefit achievable (Culyer & Wagstaff 1993). The approach adopted will affect the precise amount of resources to be allocated, either in terms of equal resources (input values, expenditure levels) for equal access, equal consumption, or in order to achieve equal health.

Besides the set of economic criteria involved in economic evaluation, one may find other ways of rationing based on some concept of need, such as the Rescue Principle (McKie & Richardson 2003). These alternative criteria do not include any economic rationale, since they do not account for the relative effectiveness of the intervention nor for its costs. Implicitly, there are logical inconsistencies. For example, the Rescue Principle assumes somehow that death might be avoided, not just postponed, as a consequence of health care interventions. Something similar can be concluded from a Needs Assessment, a kind of analysis consisting of prioritizing health care services on the basis of need in such a way that it can clearly lead to an inefficient use of resources, because it overlooks the potential for patients to benefit from healthcare interventions and ignores the costs of interventions. In summary, it does not offer a realistic mechanism for trading off different alternatives in a binding budget context.

e. The critical role of economic evaluation and its different forms

As mentioned before, economic evaluation in health provides a systematic framework to assess the relative costs and benefits of alternative health care interventions. By choosing to provide interventions that are deemed cost-effective, health care provision should be made more efficient while health benefits could either remain the same or increase.

There are three main forms of economic evaluation. Cost-effectiveness analysis (CEA) focuses on the consequences of an intervention as measured in terms of natural units on a one-dimensional scale: that is, *effectiveness* in terms of mortality rate decreases or some other measure of results expressed in natural (non monetary) units. Cost-Utility Analysis (CUA) applies when consequences of an intervention are measured as units of a cardinal utility function that maps the multi-dimensional concept of health onto a scalar index. QALY (quality-adjusted life year) is the most frequently used measure of utility used in such analyses. Finally, Cost-Benefit Analysis (CBA) is used when *monetary units* prevail as the unit of measurement and evaluation technique for both the costs and benefits of an intervention.

There are, additionally, partial evaluation methods that are worth mentioning. Firstly, *cost-description analysis or cost-of-illness studies*. These generally rely on the estimation of the economic burden of a specific disease to society (for example, to the health care system, government, or employer) and allow attention to be drawn to particularly high-cost disease areas. They inform decision-makers on the absolute and relative magnitude of the burden of a disease and offer an indication of the amount of resources that could be saved if the disease were eradicated. They are hence useful for guiding future research that aims to stimulate better utilization of healthcare resources. However, a clear limitation of cost-of-illness studies is that they say nothing about outcomes or efficiency, and, consequently, different alternatives cannot be really compared.

Secondly, *cost-minimization analysis* is a partial approach to economic evaluation and is used in circumstances where there is already good existing evidence to suggest that the interventions under consideration are equally effective. Given equal outcomes, the evaluation involves the comparison of costs alone to determine the lowest-cost alternative. In other words, the aim is to minimize the cost of producing a certain level of outcome, with the cheapest option being the most efficient.

Specific developments on the methodologies for economic evaluation have reached a high level of sophistication. Very recently, the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement (Husereau et al. 2013) was developed by a task force supported by ISPOR (International Society for Pharmacoeconomics and Outcomes Research), as part of a broader initiative to facilitate and encourage the exchange of expert knowledge and develop best practices. The statement is an attempt to consolidate and update previous health economic evaluation guidelines into a single document for researchers reporting the outcomes of economic evaluations and editors and peer reviewers assessing them for publication.

Table 1 summarizes the CHEERS statement and the variety of recognized evaluation options (Husereau et al. 2013). In spite of such a varied menu of options, many academics still believe that full economic evaluation analysis for priority-setting purposes must be done through one of the three methods: *Cost Effectiveness Analysis (CEA)*, *Cost Utility Analysis (CUA)* or *Cost Benefit Analysis (CBA)*.

It is worth noting that, besides identifying and defining the various forms of economic evaluation, the aim of the CHEERS Committee was to provide recommendations, in the form of a checklist, to optimize reporting of health economic evaluations. Their checklist of items to include when reporting economic evaluations of health interventions has been published in more than 10 scientific journals, becoming an unavoidable international reference for professionals in this field.

Table 1: Forms of economic evaluation, according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Committee

Approaches	Definition
Cost consequences analysis	Examines costs and consequences without attempting to isolate a single consequence or aggregate consequences into a single measure
Cost minimization analysis (CMA)	The consequences of compared interventions are required to be equivalent, and only relative costs are compared.
Cost effectiveness analysis (CEA)	Measures consequences in natural units, such as life years gained, disability days avoided, or cases detected. In a variant of CEA, often cost utility analysis (CUA) , consequences are measured in terms of preference-based measures of health, such as quality adjusted life years or disability adjusted life years.
Cost benefit analysis	Consequences are valued in monetary units
Note: Specific forms of analysis reflect different approaches to evaluating the consequences of health interventions. Health consequences may be estimated from a single analytical (experimental or non experimental) study, a synthesis of studies, mathematical modeling, or a combination of modeling and study information.	

Source: Husereau et al. 2013

Cost effectiveness analysis (CEA) insights

Returning to the main evaluation method, CEA, the outcome of interest is health or health-related quality of life. CEA measures outcomes in natural (physical) units which are often disease specific (e.g., infections or cancers prevented, lives saved, cases detected, patients correctly treated, or life-years gained). CEA always compares two or more interventions (not a stand-alone analysis). Health is sometimes compared to an alternative average situation, and the resulting difference between these two situations yields an average cost-effectiveness ratio (ACER); for example, if effectiveness is measured as length of life, ACER would give a measure of increased costs, in units of money, against benefits in life years gained. If two alternative interventions are compared and are mutually exclusive, however, the resulting comparative index will be the so-called incremental cost-effectiveness ratio (ICER). The ICER of an intervention is defined as the ratio of incremental costs and incremental benefits compared

to the next most effective intervention; that is, to compare additional costs to additional benefits in natural units.

CEA puts interventions side by side on the basis of their cost for each unit of outcome. It is hence a method of comparing the opportunity costs of alternative interventions which have a common desired benefit or outcome (Torrance & Drummond 2005). Although the health outcome measured in a CEA makes this analysis different from CBA – which measures outcomes in monetary units – according to Culyer (Culyer 2010b), the monetary value of a CEA's outcome measure is left implicit and, "in a budget constraint system motivated by health maximization, it is the shadow price of the budget, or incremental cost-effectiveness ratio (ICER)."

All in all, on the one hand, CEA is a helpful analytic tool when outcomes are difficult to value monetarily, when those that are measurable are not commensurable, or when the objectives are set in terms of health itself. On the other hand, however, CEA has some important limitations.

Firstly, CEA fails to account for non-health outcomes. Additional analysis, sometimes called cost-consequence analysis, where aspects other than health outcomes are also taken into account, is required, or CBA may be a solution.

Secondly, an important limitation of CEA arises when one needs to compare interventions across different medical conditions, because CEA addresses only a single dimension of disease-specific outcome. Moreover, it may be difficult to capture all possible effects of an intervention on a single outcome, as in the case of life extension when the quality of the life changes together with other side effects. CEA is more useful when effectiveness has a single dimension of interest. Some of the measures may be soundly different, as for instance the increase in Forced Expiratory Volume in spirometry, the number of cases hospitalized for a specific diagnosis, the number of symptom-free days, the number of fractures prevented, cardiovascular events avoided, pain-free days, life-years gained, disability-days saved, percentage of vision gained, and so on. CEA becomes useful when consequences can be captured in a single measure of outcome and the decision concerns how to achieve that particular outcome. It then allows for alternative interventions or actions to be sorted out in relative, not absolute, terms.

Thirdly, CEA deals with intermediate output data that cannot be directly compared across different areas of health care (e.g., detection of allergies vs. mammography) or between different moments in time (whether an individual's health has improved or declined), and this information is necessary in order to be able to compare changes in health.

Finally, CEA deals with health indicators without taking into account individuals' or patients' preferences in health states, even though preferences in health states may differ greatly across patients.

Consequently, CEA appears to be useful only under restricted circumstances. Some of these problems are tackled with another evaluation methodology, Cost-Utility Analysis (CUA).

Cost utility analysis (CUA) insights

In CUA, the outcome measure is utility instead of a natural measure of health. That utility indicator may be used to measure a single effect or multiple effects. CUA is more demanding from a methodological point of view, but a more valuable technique, with a common numerator to match up several alternatives by healthy years or, more typically, measured as quality-adjusted life years (known as QALY's). The QALY is a measure of overall health calibrated over one year. More specifically, it represents one year of life, adjusted for health-related quality of life. It incorporates both length of life and health-related quality of life into a single index (Williams 1995). The QALY accounts for both changes in the number of years lived (mortality) and the changes in quality of those years (how well). By using QALYs, we identify health state outcomes. They are described as the number of years alive (T) of each individual, weighted by a valuation of that health (W). The quality adjustment to life is made by assigning a value of 1 to "full health," and a value of 0 to the state of "death." Intermediate values represent intermediate states. And then we can calculate average outcomes (W.T) and differences before and after interventions.

All methods for obtaining quality weights start with a health state description (e.g., a general health state, or a condition-specific description). Note that these descriptions involve judgments about the important characteristics of different health states, but they tell us nothing about how different states are valued. The quality adjustment is a proxy for satisfaction/well-being. It reflects consumers' judgement about what they consider good and bad in relation to their health. They are necessarily subjective: they elicit an individual's preferences for, or value of, one or more health states. Nonetheless, there is some confusion about the term utility, which has, for some, a materialistic connotation, given the use of this term in other areas of economics. T. Culyer states that, regarding CUA, "modern confusion about the 'utility' of quality of health related life has arisen because it is entirely appropriate to use the theory of utility measurement also to measure other entities such as health. But that does not mean that what is being measured is a *utility*, at least not in the usual sense of an indicator of the strength of a preference...It is a pity that the term "cost-utility analysis" ever came to replace the much more neutral "cost-effectiveness analysis." (Culyer 2010b).

The most delicate part of computing QALYs is quantifying the above-mentioned adjustment to life years. This requires measurement of an individual's health-related quality of life for a period of time and giving it a quality of life score on the ratio scale mentioned previously, with 1 representing full health and 0 representing the state of death. Data from individuals is hence an input of the QALY. The most popular survey-based methods are Visual Analogue Scale, Time Trade-Off and Standard Gamble. The resulting value of the adjustment may vary according to the method used. For instance, the Time-Trade Off method asks individuals how many years of life are they willing to give up in order to enjoy full health rather than remaining in their current ill-health state, which can be a challenging question to answer. In a pilot study, (Dolan 1997), it was found that respondents cannot be expected to compare a large number of health states using that method. When direct interview methods such as these are not available or complete, indirect methodologies can be used, which are based on mapping procedures, expert judgment, and regression methods to estimate lacking information.

QALY arithmetic is based on three simplifying assumptions: (i) the value of life years is assumed to be linear, a convenient simplification; (ii) a multiplicative combination of life duration and health adjustment is postulated, and (iii) for non-chronic health states, values of different periods with different health states are just added up. The first of the assumptions on linearity is sometimes relaxed by introducing discounting possibilities or risk aversion. Other limitations of QALYs are frequently mentioned (Culyer 2012). Firstly, it is only a measure of health outcomes. It does not reflect the potential social outcomes of an intervention that are not taken into account in the questionnaires nor in the increase in years lived). It also does not reflect the processes (the means) related to the intervention. Too much emphasis is sometimes allegedly placed on the results of the health intervention under analysis. Secondly, the dependence on human inputs to get answers to the questionnaire may make some groups' answers less reliable, such as young children and the mentally ill. Their preferences are consequently less well reflected.

QALYs fit into an extra-welfarist approach, or the so-called "societal decision-making view." This approach takes as exogenously defined a societal objective and a given budget constraint for health care. It then considers CUA as a technical tool to solve a constrained optimization problem. This is, however, a much more complex exercise due to the required specification of an objective (QALY maximization) and the means to measure the achievements (under QALY assumptions). When used for priority setting, the aggregate QALY value obtained, as a result of either a linear or weighted process, is not universally accepted. Moreover, the conversion of the cost per QALY as a tool for setting priorities among services or indications, given a binding budget, requires an explicit decision on a threshold that is critical for the process. All these aspects clearly need the strong external legitimacy of public representatives in order to award them with a normative content. The deliberation process becomes even more important than the parameters and the goals to be achieved.

In contrast, Cost Benefit Analysis stays in the field of traditional welfarism, where health care interventions are to be judged in the same way as any other proposed welfare component. That is, according to whether they represent a potential Pareto improvement⁵ (as measured by a compensation test), and not just according to whether they improve health outcomes or preferences. On the other hand, for most developed countries' health systems, there is a clear reluctance regarding the prescriptions of the welfare theory to health care. The conditions of rationality and consistency required of individuals with respect to maximizing their utility have shown to be repeatedly transgressed, and the acceptance of the current distribution of income as the starting point of a willingness to pay method is widely rejected.

f. Social value judgments and ethical dilemmas

As mentioned previously in this chapter, rationalizing health care, by whatever means including a rigorous explicit system of priority setting, results in some form of rationing which,

⁵ Pareto optimality is a state of allocation of resources in which it is impossible to make any one individual better off without making at least one individual worse off.

in its most negative sense, implies exclusion or rejection of some procedures, services, or technologies. These rationing decisions might be very difficult to take and to be accepted by beneficiaries. For that reason, decisions need to be grounded on sound and explicit ethical principles. Otherwise, a lack of legitimacy of the decisions is bound to become the Achilles' heel of the whole priority system.

The deliberative process, defined as the process by which conclusions are reached and recommendations are made, is a key component (Shah et al. 2013) of success. Basically, this process must, firstly, be accountable with regard to beneficiaries involved in the health care initiative under evaluation and, secondly, preserve individual freedom and autonomy so that excluded health care procedures or devices from the benefits' package should not be prohibited. Individuals should be given the option of acquiring any rejected intervention that is deemed effective, under their individual responsibility. Thirdly, processes and criteria are to be explicit and clear. In addition, need (in the sense of fairness as perceived by the community) is a value to be held, as it opens the participation process to the community from a social perspective, with priorities based on common good and not on individual wants.

Although legitimacy is a crucial aspect of rationing processes, an adequate process does not preclude decision-makers from facing more fundamental judgements involved in priority setting, such as whether more health is always better, or whether public preferences violate monotonicity. In standard social welfare functions, a gain in efficiency should always overcome any loss due to potential increases in inequality. How efficiency and equity are leveraged depends very much on the distribution and on the extent of social aversion to health inequalities.

Priority setting is not just about applying a methodology. It needs to be anchored in a given social context, and this context is a determinant for the process. In fact, the results of the process and the decisions made depend very much on the social context. In other words, social costs are reflected not only by the additional costs held in public budgets when an intervention is selected to be covered by the public benefits package. An intervention may alternatively be covered through specific regulation, copayments and complementary community premiums, and produce other kinds of social costs. For example, an excluded treatment due to a poor cost effectiveness ratio is equivalent to a covered treatment with a "one hundred per cent copayment," in which case, social costs are appear at the individual level. Fiscal expenditures (tax deductions) are a form of copayment too, and charging a mandatory premium on employers is also a form of tax. All these alternatives, however, show different political strands, social culture, and a different tolerance of disparities between or within cohorts, ordered either by income, age or type of illness.

In summary, the issues at stake in priority setting are, firstly, the value given to health – that is, whether we are getting aggregate good value for money in health care. Secondly, one should consider how value differences that may arise within sub-groups of individuals should be addressed, and how these differences affect results in delivering and financing health care. Thirdly, it must be determined where the threshold should be for an intervention to be publicly covered. That is, what magnitude of incremental cost-effectiveness (cost increase per each health outcome or QALY gained) is excessive to justify the inclusion of a treatment or

intervention into the benefits package? Is the £30,000 per QALY gained, as defined by the NICE in England, an optimal threshold? Finally, explicit decisions should be made regarding equity. There needs to be consensus on the desired distributional effects of the interventions, that is, consensus on either setting equal weighting of benefits or some other form of categorical equity concept.

The difficulty in dealing with these issues from the pure political arena has led some countries to delegate priority-setting processes to independent agencies. These independent agencies have relieved policymakers from the suspicion of political bias in the priority setting process, and, at the same time, from implementing unpopular cost reduction decisions or disinvesting from new or existing procedures. We shall, in the next section, explain how specific agencies that are considered to be references worldwide are addressing priority setting processes.

3. INSTITUTIONS FOR PRIORITY SETTING IN HEALTH CARE

Here, we review the realities of priority setting processes in six different countries, four of which are known for being precursors for establishing explicit priority setting mechanisms. Table 2 summarizes the study cases and their main characteristics.

Table 2: Summary of case studies: Health technology assessment (HTA) agencies and their basic characteristics

	Healthcare system	Independent agency	Role	Method for priority setting
(a.) USA⁶	Private providers and Obamacare	The Institute of Medicine	Advice	CER (comparative Effectiveness Research)
	Medicaid (Federal and state coverage)	The Oregon Health Services Commission	Responsibilities on the package definition	Some form of CEA
(b.) England & Wales	Tax-financed	NICE – National Institute for Health and Care Excellence- (publicly funded)	Clear responsibilities linked to decisions on pricing and coverage	Economic evaluation
(c.) Germany	Social Insurance with competing	IQWiG - Institute for	Advice to the Federal Joint Committee	Efficiency frontiers

⁶ The U.S. offers a large set of examples regarding health technology assessment (HTA) initiatives. The CER is illustrative of a very idiosyncratic and innovative view which is worth analyzing, for the sake of its influence on other health care systems. Although only two initiatives have been described in this chapter, the CMS (Centers for Medicare and Medicaid Services) experience could have also been added, as an example of a government agency with more similarities to European experiences. For those interested in the CMS experience, see the information at these links: http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html?redirect=/cfcsandcops/16_asc.asp

<https://www.healthcare.gov/glossary/minimum-essential-coverage/>.

	companies	Quality and Efficiency in Health Care- (paid by sickness funds)		
(d.) France	Social Insurance with competing companies	HAS- Haute autorité de santé- (publicly funded)	Advice	Economic evaluation
(e.) Sweden	Tax-financed	SBU- Swedish Council on Health Technology Assessment- (fees from the industry)	Do or explain why not to do it	Economic evaluation
(f.) Netherlands	Social Insurance with competing companies	CVZ - National Health Care Institute (Publicly funded)	Clear responsibilities linked to decisions on pricing and coverage	Economic Evaluation

a. United States: Comparative Effectiveness Research

Among all the countries chosen for analysis, the U.S. is the country where private insurance and welfarism approaches are more dominant in the health care system.

Comparative Effectiveness Research (CER) became a focal issue in the U.S. during the 2009-2010 health reform debate (Luce et al. 2010) as a means for priority setting. In its hope to expand coverage while limiting use of treatments that did not work well, the Obama Administration decided to invest \$1.1 billion on CER, portraying it as the first step to government rationing. The Institute of Medicine (IOM), an independent, non-profit organization that works outside of government, to provide advice to decision-makers and health care stakeholders, defined and endorsed CER as follows: “CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition, or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policymakers to make informed decisions that will improve health care at both the individual and population levels.” (IOM 2009). CER is a different term from CEA. An important component of CER is the concept of Pragmatic Trials. These clinical research trials measure effectiveness (the benefit the treatment produces in routine clinical practice). This is different from regular clinical trials, which measure efficacy (whether the treatment works or not). CER is closer to Health Services Research techniques and does not necessarily include economic evaluation. CER was not meant for decision-making, but as an input for Health Technology Assessment analysis (Luce et al. 2010).

The U.S. Congress, in the American Recovery and Reinvestment Act (ARRA) of 2009, tasked the IOM to recommend national priorities for research questions to be addressed by CER and supported by ARRA funds. In its 2009 report (IOM 2009), the authoring committee established a working definition of CER, developed a priority list of research topics, and identified the necessary requirements to support a robust and sustainable CER enterprise.

It is a limited version of other countries' agencies. It is grounded on research that evaluates and compares health outcomes and the clinical effectiveness, risks and benefits of two or more medical treatments, services or related items. The IOM "identifies what works best for which patients under what circumstances. And provides doctors and patients with the information they need to make the best medical decisions" (IOM 2009). However, "implementation of CER must preserve patient access to a wide array of medicines, rather than limiting choice by using the resulting data to mandate coverage or payment levels" (IOM 2011). The Director of Public Health Systems, Finance, and Quality Program in the Department of Health and Human Services explains, "The social budget is limited — we have a limited resource pool. It makes terribly good sense to at least know the price of an added benefit, and at some point we might say nationally, regionally, or locally that we wish we could afford it, but we can't." (Honoré et al. 2011)

CER has some limitations as a priority setting tool. It does not consider costs, nor does it consider concerns about efficiency. CER analysis is affected by issues such as the heterogeneity in the patient effects of treatments (like pain, nausea, incontinence) that cannot make for a single outcome index. Moreover, these effects are sometimes exogenous (gene type, at the static level, or gene mutation at the dynamic one); sometimes, they are endogenous (spillovers from other treatments, user behavior, heterogeneous provider skills and know-how, scale economies). This is certainly a common problem to all economic evaluation but it reminds us that CER is less than perfect, too.

Finally, according to the IOM (IOM 2011), "if cost considerations were added, the endogeneity of prices for alternative treatments should be accounted for, and CER would resemble economic evaluation tools to a greater degree". In any case, CER, especially in the context of the Patient Protection and Affordable Care Act (ACA), signed into law on March 23, 2010, certainly opened a door to assign a role for public subsidies and copayments based on comparative effectiveness, perhaps for some variation in the treatment effects on the supply side, or on the patient benefits on the demand side, and more controversially, on how the benefits are valued by patients.

Indeed, the ACA stipulated that a set of qualified health plans (QHPs) would cover an "essential health benefit" package, to be defined by the Secretary of Health and Human Services (HHS) based on the scope of benefits offered by a typical employer plan. At the request of HHS, the IOM undertook a study to make recommendations on the criteria and methods for determining and updating the essential health benefits (EHB) package. The committee was not to specify the details of the package. The IOM report was issued by the end of 2011 (IOM 2012). The IOM saw two main questions: (1) how to determine the initial EHB package and (2) how to update the EHB package.

In considering how to determine the initial EHB package, the IOM committee “was struck by two compelling facts: (1) if the purpose of the PPACA is to provide access to health insurance coverage, then that coverage has to be affordable; and (2) the more expansive the benefit package is, the more it will likely cost and the less affordable it will be. How to balance the competing goals of comprehensiveness of coverage and affordability was key.”

The committee concluded that it was best to begin simply by defining the EHB package as reflecting the scope and design of packages offered by small employers. The committee considered four policy domains—economics, ethics, population-based health, and evidence-based practice—in determining the EHB package in general. From these policy foundations, the committee recommended criteria to guide the aggregate EHB package.

Benefits mandated for insurance coverage by individual states should be subject to the same review and criteria. Products and services that do not meet the criteria should not be included, according to the report. The report also described specific criteria to guide methods for updating the EHB, for inclusions and exclusions. It recommended that HHS officials should gauge potential services and products against a set of criteria including medical effectiveness, a good evidence base, safety, improved outcomes, and cost-effectiveness.

Besides the IOM recommendations based on CER, the experience of priority setting in Oregon’s Medicaid program starting in the early 1990’s represents the most explicit, as well as one of the most controversial, and innovative at that time, examples of priority setting in health care (Ham 1998). The goal of the program was to limit coverage to a bundle of services according to a cost-effectiveness ranking. A Quality-of-Well-Being Scale was first obtained, which had to be abandoned due to criticisms on the methodology, and substituted by another where expert knowledge and intuitive judgments about appropriateness were added. Since then, the Oregon system keeps updating the methodology. It represents an example of the potential difficulties of implementing explicit priority setting mechanisms in a context like the U.S. (Sabik & Lie 2008).

b. England and Wales: The NICE

The National Institute for Health and Care Excellence (NICE) is a [non-departmental public entity](#) of the [Department of Health](#) in the [United Kingdom](#), serving both the [English NHS](#) and the [Welsh NHS](#). It was established in 1999, redesigned in 2005 (NICE 2005), and finally renamed the National Institute for Health and Care Excellence in April 2013 (The Health Service In England, 2012), as a result of its new responsibilities on social care. It also changed from a special health authority to a non-departmental public body. As such, NICE is “accountable to our sponsor department, the Department of Health, but operationally independent of government. Its guidance and other recommendations are made by independent committees” (NICE, 2014).

The standard approach of NICE to technology appraisals takes one of two forms: A single technology appraisal (STA) which covers a single technology for a single indication, or a multiple technology appraisal (MTA) which normally covers more than one technology, or one technology for more than one indication. MTAs are very common and take 54 weeks from the initiation of the process to issuing guidance. STA is a faster process. As proof of its relevant activity, until the February 2014, NICE Guidelines amounted to 413 regarding interventional procedures, 303 on technology appraisals, 184 on clinical guidelines, and 49 on public health. Among similar organizations elsewhere, NICE is unusual in that it publishes details of evidence and reasoning.

From a methodological point of view, the Incremental Cost Effectiveness Ratio (ICER) from CUA plays a crucial role in helping NICE to reach a recommendation. NICE makes recommendations regarding the adoption of new health technologies by reviewing evidence on clinical effectiveness and cost-effectiveness. Each technology appraisal may contain more than one recommendation. Recommendations are classified into 4 categories: recommended, optimised, only in research, and not recommended. If NICE recommends adoption, clinical commissioning groups (CCG) [previously, Primary Care Trusts (PCTs)⁷] are expected to make the treatment available. If NICE does not make a positive recommendation, the CCGs are less likely to commission the treatment.

NICE defines an ICER threshold as the cost per QALY above which a product or a service is recommended not to be publicly funded. The threshold limit has been at the heart of many debates. One suggestion is to set the threshold to “optimally exhaust” (in maximizing the health gain) a fixed budget. However, NICE does not use a precise ICER threshold that automatically defines a technology’s cost effectiveness (Towse & Pritchard 2002). Cost per QALY gained ranges commonly from £20,000 to £30,000 per QALY. Below £20,000, usually the treatment is recommended; above £20,000 the decision would not be taken exclusively on the grounds of cost-effectiveness but could be accepted for a “particular feature of the condition and the population using the technology,” that is, for example, for an innovation that changes quality of life adjusted-years, in such a way that it has not been appropriately captured in the QALY measure. Above a most plausible ICER of £30,000 per QALY gained, the benefits would need to be identified as an increasingly stronger case.

The guidance within NICE’s first edition Guide to the Methods of Technology Appraisal (NICE 2003) established that “...an additional QALY is of equal value regardless of other characteristics of the individual such as their socio-demographic details, or their pre- or post-treatment level of health.” However, this was in fact a reflection of the absence of a consensus on how to deal with differences that were explicitly recognized by NICE (Shah et al. 2013). A period of research on how to deal with different weight considerations yielded a second edition of the Guide to the Method of Technology Appraisal (NICE 2008) so that, “The Institute considers equity in terms of how the effects of a health technology may deliver differential benefits across the population.” In January 2009, supplementary guidance was issued and NICE

⁷ A **primary care trust** (PCT) was part of the [National Health Service in England](#) from 2001 to 2013. PCTs were largely administrative bodies, responsible for commissioning primary, community and secondary health services from providers. Until 31 May 2011, they also provided community health services directly. Collectively, PCTs were responsible for spending around 80 percent of the total NHS budget. Primary care trusts were abolished on 31 March 2013 as part of the [Health and Social Care Act 2012](#), with their work taken over by [clinical commissioning groups](#).

was instructed to give special weighting to the health gains of individuals in the later stages of terminal illness. Between January and April that year, nine technologies were considered that fit into this context (Longson & Littlejohns 2009). Three criteria are required in order to qualify for this exception: (i) the treatment is indicated for patients with a short life expectancy, normally less than 24 months; (ii) there is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional 3 months, compared to current NHS treatment, and finally (iii) the treatment is licensed or otherwise indicated for small patient populations. This is equivalent, in practice, to a threshold increase.

Given the ethical issues involved in priority setting, the aim of NICE is to make criteria publicly accessible, reasonable (applying relevant principles) and challengeable through appeal. The threshold works at any rate as a numerical line which allows for comparisons across treatments. It avoids accepting unfavorable cost-effectiveness ratios in some areas simply because existing alternatives (the “going rate”) are relatively inefficient, as in comparative effectiveness. But from an ethical perspective, there remains the question of whether a “QALY is really a QALY,” or if more weight should be given to QALYs accruing to patients with relatively severe illnesses or which impose a relatively high burden of disease; patients in the later stages of disease with a short life expectancy (less than 2 years); or additionally whether more weight should be given to treatments to be licensed for small patient populations and to treatments for which no alternative treatment with comparable benefits is available through NHS. In these circumstances, the rescue principle is a powerful human impulse.

The principles are explicit, but there are plenty of caveats. For instance, NICE cannot in principle discriminate according to the cause of illness or how “deserving” of a treatment the individual may be. This includes even those conditions that may have been contracted or exacerbated due to the individual’s lifestyle or occupation. However, if the behavior is likely to continue and can make a treatment less cost-effective or clinically less effective, then it may be appropriate to take into account those features for treatment differentiation. Notice that it is often impossible on an individual basis to determine whether a condition may be fully dependent on a person’s own individual behavior.

The 2010 Equality Act (Equality Act, 2010), a Parliament Act to require Ministers, when making strategic decisions, to have regard for the desirability of reducing socio-economic inequalities, is another caveat. It urged NICE to actively extend health equality efforts regarding sex, age, race, disability and socioeconomic status, despite the fact that NICE was not initially expected to make recommendations on the basis of individuals’ income, social class or position in life. Nor were individuals’ social roles at different ages expected to affect the decisions about cost effectiveness. Indeed, NICE has been very reluctant to depart from the criterion of “a QALY is a QALY.” It is legitimated to increase overall population health, regardless of whether differences among groups remain the same or increase. According to a utilitarian approach, the overall increase in health may cause deterioration in terms of its distribution, meaning potential for greater disparities between groups. But now NICE may take these distribution effects into consideration, on a case-by-case basis and make decisions that produce overall health improvement – focusing on all levels of the health and socioeconomic gradient – and a targeted focus on the most disadvantaged. These hybrid decisions, despite being more difficult to achieve, depart from a “QALY is a QALY” policy.

In addition, weighting health gains for severely ill patients implies that fewer resources will ultimately reach preventive and public health programs which are meant to favor the healthiest groups. The justification to apply smaller weights to potential health gains among more economically advanced populations is, however, far from obvious from a universal perspective.

The cost effectiveness (C-E) threshold in itself is an estimate of health forgone, as other NHS activities are displaced to accommodate the additional costs of those technologies recommended by NICE. It will change as circumstances and the NHS change. It represents the implicit values from past NICE decisions. It does not necessarily reflect society's willingness to pay for health improvements. The overall threshold will, in reality, depend on the programs of care where disinvestment takes place or how expenditure on particular programs change with the overall budget; a sort of average marginal elasticity of spending with respect to income. Changes in budgets are, in practice, incremental and it may be the case that the elasticities of program expenditure in time of budgetary increase (when new initiatives are added) are not the same as in times of budgetary decrease (when the focus is on disinvestment). Estimates of the cost per life-year gained when disease-specific mortality changes were transformed into life-year gains were (for the years 2006/2007) £15.837 for cancer; £9.974 for circulatory problems; £5.425 pounds for respiratory problems; £21.538 for gastro-intestinal and £26.428 pounds for diabetes (Dakin, et al., 2013)

On the cost side of the ICER, there are also important methodological challenges. Indeed, there is a variety of methodological options in the economic evaluation process, such as parsing out the pecuniary versus non-pecuniary costs as well as the direct versus indirect, tangible versus intangible, medical and non-medical, related and unrelated, and present versus future costs. Non-pecuniary costs and benefits are those such as an earlier return to work after healing, which increase well-being to society; pecuniary costs and benefits are those such as the cost of drugs substituting for inpatient care treatments. They cannot be considered, out of their net difference, since otherwise it is a purely redistributive effect; opportunity costs such as days lost after being treated (if they would have been lost anyway being untreated) should not be accounted for either. Direct costs are viewed as those "ingredients in a recipe" while indirect costs refer to secondary costs related to other productive activities. Different time horizons imply the need to use some given discounting factors; and indications must be provided on how to offset resources when they approach average or marginal costs, with full capacity, in the short or long term.

NICE Guidelines (NICE, 2008) offer indications regarding these methodological issues:

- 1- The analysis has to be made from the NHS perspective, that is, the implication of an innovation on other aspects of society are ignored; in principle, neither production nor consumption-related costs are included.
- 2- Relevance first: aspects regarding treatability, progression, duration, incidence, prevalence, and budget impact need to be explained;
- 3- The analysis is to capture direct medical-related costs. Preventing adverse effects and avoidable admissions are considered to be direct effects;
- 4- Adopt unit (full) costs (training costs included);
- 5- The time horizon is in the range of 3-5 years;

- 6- The appraisal should include some sensitivity analysis, searching for robustness, if possible;
- 7- “Double counting” is to be avoided, regarding some aspects of costs and benefits already measured into QALYs.

The most controversial issue remains the need for increased government accountability to Parliament through tighter monitoring of the threshold application. There is still little acceptance among medical professionals and patients that healthcare resources are limited (Drummond et al. 2013). As a consequence, rationing and the NICE lack popularity, and separate budget funds have started to emerge where ICER criteria are not required to the same extent as in the general NHS budget, as in the case cancer and musculoskeletal diseases.

c. Germany: the IQWIG

The *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (IQWIG), the Institute for Quality and Efficiency in Health Care, was created in 2004. IQWIG is the German agency responsible for assessing the quality and efficiency of medical treatments, including drugs, non-drug interventions (e.g. [surgical procedures](#)), diagnostic and screening methods, and treatment and disease management (IQWIG 2014). IQWIG also supplies health information to patients and the general community. The organization is independent of private industry, contracted solely by the Federal Ministry of Health and the German [Joint Federal Committee](#).

The design and methodology used by the IQWIG was designed by an external panel of international experts (IQWIG 2009). One of the stated pillars was that: “IQWIG should only address the determination of a ceiling price at which a superior health technology in a given therapeutic area should be continued to be reimbursed.” Comparisons across diseases were to be avoided and this, as will be detailed later, brought the need to implement the “efficiency frontier approach.” An important reason for focusing on a single therapy was, according to the commissioned experts (Caro, et al. 2010), that the German health care system, based on social insurance, is not bound to a fixed national budget and therefore need not consider funding priorities across therapeutic areas, but should instead make sure that the system offers a portfolio of health care benefits that maximize health outcomes for a given level of invested resources. This characteristic made the IQWIG significantly different from other similar institutions worldwide, and has received strong criticism among academics (Brouwer & Rutten 2010), some of whom consider this to open the door to inefficient interventions and to accepting unfair situations produced by the use of different thresholds across interventions or cases (Drummond & Rutten 2008).

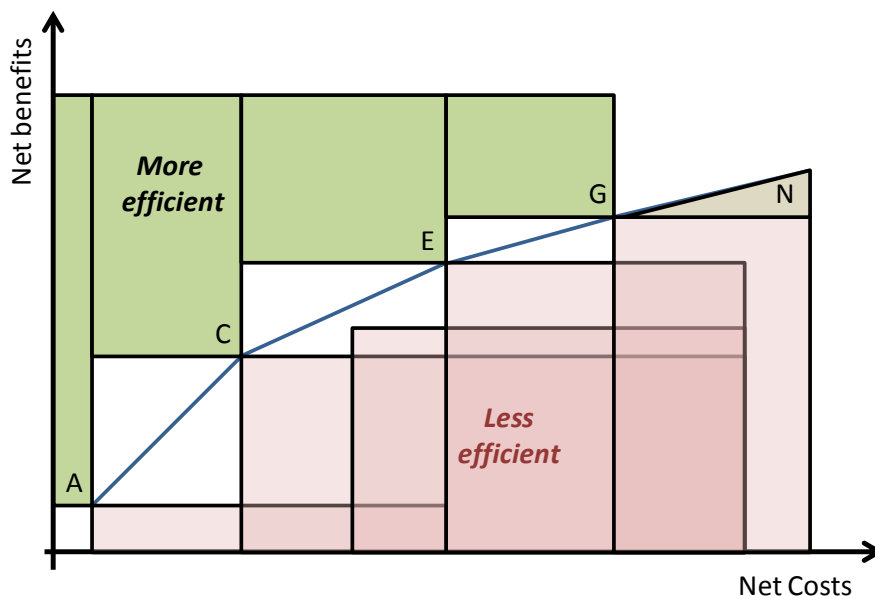
Unlike NICE, the IQWIG methodology is not based on CUA nor ICER, but on *the efficiency frontier approach* and on the establishment of price ceilings. The methodology consists of a comparison of benefits and costs among different alternatives. On the benefits side, evidence-based clinical measures are used. The advantage of this source of information is that clinicians are familiarized with it (Caro et al. 2010). The disadvantage is the limitations in successfully obtaining good metrics out of these measures, especially within the constraints imposed by

IQWIG: they need to be cardinal and aligned with the prerequisites of clinical trials (with a time horizon, end-point, etc.)(Drummond & Rutten 2008).

Costs are assessed primarily from the perspective of the insured individuals, and out-of-pocket costs must be included. Total net expenditure is the measure of interest: therefore, any savings produced by the intervention should be considered too. The no-intervention alternative is rarely expected to have a total net expenditure of zero. The time horizon under examination has to be sufficiently long to cover all the significant costs and not necessarily those included in the clinical trial periods, and the production gains and consumption effects should be subtracted from the costs of extending survival.

Benefits and costs combined yield the efficiency frontier representing the trade-off between costs and benefits and identifying the interventions that provide the most value for any given level of investment (Caro et al. 2010). Caro et al. display this trade-off graphically (see Figure 4) by plotting the interventions at their estimated net cost (horizontal axis) and benefits (vertical axis) and drawing line segments linking the options that are dominant.

Figure 4: The efficiency frontier approach to economic evaluation of healthcare interventions



Source: reproduced from (Caro et al. 2010)

IQWIG's concept of efficiency involves not only health-related morbidity and mortality and quality of life, but also time and effort invested and patients' treatment satisfaction. This may go into a single scale (i.e., experience utility), including a unique cost per outcome threshold. For this purpose, a relative efficiency frontier may be considered as the information basis along with the value of the benefits and total net costs, the estimated budget impact and the uncertainty around all the estimates. The aim is then to approach quality and efficiency.

IQWIG's conclusions can be used by the German sickness funds to cut reimbursement for drugs declared to be ineffective. However, it is a requirement that no patients should be excluded on cost grounds alone.

IQWIG's responsibilities were expanded in two health care reforms in 2007 and 2010. With the 2007 Act to Promote Competition of statutory health insurance, the IQWIG was commissioned to weigh the costs of drug therapies against the benefits previously determined. Prior to that, the assessment of drugs was restricted to health care beneficial effects (i.e., to the evaluation of benefits and harms of drug interventions). With the 2010 Law on the Reorganization of the Pharmaceutical Market, it became the responsibility of the Federal Joint Committee to assess the effects of newly approved drugs. If a health improvement had been established, the price of the new medicine needed to be negotiated between the Central Federal Association of the Health Insurance Funds and the company concerned. The assessment is performed on the basis of information the manufacturers are obliged to submit to the Federal Joint Committee, which then generally commissions IQWIG with the assessment of the dossiers.

IQWIG reports on specific topics as requested by the Federal Joint Committee or the Federal Ministry of Health, following the principles of evidence-based medicine. IQWIG also undertakes projects and research on its own initiative. The work of its staff is supplemented by projects which are contracted externally, and these projects are advertised publicly. Work on these projects must be conducted according to IQWIG's current methods.⁸ Stakeholders and the interested public can also get involved in IQWIG's work. IQWIG publishes all of its results online, and interested persons and parties may submit written comments on report plans (protocols) and on preliminary reports. Comments are considered and may even lead to changes in the final report.

IQWIG provides support rather than making decisions. It follows Health Services Research techniques, those used for evidence-based health care, focusing on specific therapeutic groups. As a result, funding priorities make sense among alternatives that fall within one therapeutic area, in contrast to a more global analysis of priority setting, intending to set priorities across very different types of therapies and innovations. The result of the analysis takes the form of a "maximum reimbursement" for specific treatments that are found to be better than existing treatments from the insurance company perspective.

d. France: La Haute Autorité de Santé

The Haute Autorité de Santé (HAS) - or French National Authority for Health - was set up in August 2004 with the aim of "improving the quality of patient care and guaranteeing equity within the healthcare system." The HAS performs a wide range of activities including assessment of drugs, medical devices, and procedures; publication of guidelines; accreditation of healthcare organizations; and certification of doctors. The HAS is an independent public body with financial autonomy. It is mandated by law to carry out specific missions on which it

⁸ <https://www.iqwig.de/index.925.en.html>

reports to the government and the Parliament. It liaises closely with government health agencies, national health insurance funds, research organizations, unions of healthcare professionals, and patients' representatives.

Its scope includes assessing healthcare technologies (including drugs, devices, and diagnostic and interventional procedures) for pricing and reimbursement, developing clinical guidelines and public health guidance, performing hospital accreditation, accrediting patient information websites, creating disease management models, continuous professional education, and developing guidance and recommendations on the most effective healthcare strategies.

Technology assessment reports regarding an innovative initiative in health care, at HAS, include a comparison with other medical and non-medical strategies. They address clinical and community benefits measured in terms of medical effectiveness (real-life), health economics (efficiency), impact on the organization of care, and some aspects of social choice and other relevant ethical issues. HAS follows a multidisciplinary approach that includes members from the fields of economics, ethics/philosophy, and social sciences, as well as patient associations, general practitioners and specialists, and it adopts a societal perspective.

Since the constitution of the *Commission d'Évaluation Économique et de Santé Publique* (CEESP), in July 2008 (Lise Rochaix & Xerri 2009), HAS has also addressed the assessment of risks due to inappropriate decisions taken in the health care system, due to excessively delaying market access of innovations or due to introducing technologies that turn out to be inefficient, not cost-effective or with a low benefit-risk ratio.

All new drugs must be assessed by HAS before inclusion in the compulsory benefits package, called *Service Médical Rendu (SMR)*. Once considered to be a reimbursable drug, regulated prices are set following a separate negotiation, by the Economic Committee for Health Care Products (CEPS). HAS's technical report on the clinical value-added of a drug is a fundamental ingredient in the price determination. To determine the price, they primarily take into account the clinical added value of the medicine, the prices of other medicines serving the same therapeutic purpose, the forecast or recorded sales volumes of the new drug, and the actual and foreseeable uses of the new drug.

The HAS reports on incremental effectiveness, and reimbursement recommendations may be positive or negative opinions with full or restricted indications for certain situations or subpopulations. Drugs are compared to existing therapies, and recommendations depend on the clinical added value or ASMR (*Amélioration du SMR*): Major clinical improvement (ASMR I), important clinical improvement (ASMR II), moderate clinical improvement (ASMR III), minor clinical improvement (ASMR IV), with ASMR V for no clinical improvement. According to ASMRs's categorization, reimbursement decisions are taken: (i) Level V is only reimbursable if it is cost-saving; (ii) Most innovative drugs Level I, II and III are eligible for faster access at a European price (price notification instead of negotiation). On the assessment of added value, the question to be answered is what is the added value and for what population. This leads to a target population and recommendations for use in clinical practice. Uncertainty may force the HAS to ask for additional data collection and studies.

Currently, *SMR* only considers efficacy and safety to define a relative position of a new drug with respect to other available therapies, taking into account the severity of the condition the drug is indicated for, whether the drug prevents, cures or relieves symptoms, and the benefit the product may have for public health. For the future, a relative therapeutic index is expected to be implemented, and pharmaceutical companies will have to put more emphasis on portraying the total economic benefit of a drug, not just its clinical superiority, or ASMR.

e. Sweden: The Swedish Council on Technology Assessment in Health Care (SBU)

In 1987, the Minister of Health formally established and funded the Swedish Council on Technology Assessment in Health Care (Statens Beredning for Utvardering av Medicinsk Teknologi, SBU). The Government's instructions to SBU in 1987 were as follows: The agency must provide evidence-based information on matters of health technology to advise health policy and practice and to inform the general public, without regulatory functions (Jonsson 2009). The SBU reviews the benefits, risks and costs of methods used in health care delivery, with the aim of identifying which method is the most appropriate for treating a specific disease and patient group, but also to determine which methods are ineffective or not cost-effective, so that they can be avoided. The SBU also identifies important knowledge gaps, that is, areas in which further research is urgently needed (Anell et al. 2012). The Government's instructions to SBU are not much different today: "SBU is mandated to make scientific assessments of new and established health technologies from a medical, economic, societal, and ethical perspective."

The SBU has no regulatory power, and its first challenges were to "establish proper incentives to make clinicians use the findings from the SBU, \ to build a strong collaboration with the medical profession, and to develop a level of trust in SBU that its findings would be viewed as an integral and fundamental part of professional practice" (Jonsson 2009).

SBU assessments include a systematic review based on protocols for inclusion and exclusion criteria and for grading evidence presented in all relevant studies in the international literature (i.e., clinical studies, economic evaluations, and studies addressing other issues on subjects such as nursing, ethical, and social aspects). The assessments also include a synthesis with recommendations for health policy and practice. Assessment of pharmaceuticals has not been a priority at SBU, because the Medical Products Agency in Sweden has a mandate to assess the safety, efficacy, and effectiveness of drugs. However, an important issue for HTA generally is the appropriate indications for use. Although SBU has focused its assessments on that issue in a few projects on pharmaceuticals, it may want to consider further efforts in this regard.

During the major economic downturn of the Swedish economy at the beginning of the 1990s, an important priority agenda was established in the Parliament regarding most areas of policymaking. A Priority Setting Commission was appointed in 1992 comprised of members of Parliament and expert advisers. The Commission accomplished its task in the health care arena by 1995 and published a report entitled "Priorities in Health Care—Ethics, Economy,

Implementation” (Swedish Government, 1995). The key components of the Commission’s proposals were: (i) a so-called “ethical platform” and (ii) practical advice for priority setting in the form of two lists, one for political and administrative priority setting and another for clinical priority setting.

The ethical platform sets forth the principles that should form the basis of medical prioritization:

- (i) Human dignity – all humans beings have equal dignity and the same rights, regardless of their personal characteristics and their functions in the community,
- (ii) The principle of need and solidarity – with need meaning that resources should be committed to fields where needs are greatest, and solidarity meaning paying attention to the needs of groups less able or inclined to exercise their rights, and
- (iii) The cost-efficiency principle, which is that one should aim for a reasonable relation between cost and effect, measured in terms of improved health and improved quality of life. The cost-efficiency principle should only be applied in comparisons of methods for treating the same disease, since where different diseases are involved, a fair comparison of the effect is impossible.

Priority setting was defined as dealing with (i) the treatment of life threatening, acute diseases and diseases which, if left untreated, would lead to permanent disability or premature death; (ii) the treatment of severe chronic diseases, palliative terminal care and care of people with reduced autonomy, and (iii) prevention, with a documented benefit for habilitation/rehabilitation as defined in the *Swedish Health and Medical Services Act*.

A National Board of Health and Welfare (the NBHW) was then appointed by the Parliament to develop guidelines in accordance to that framework. The guidelines are produced in collaboration with other actors, such as the SBU or the TLV (regarding pharmaceutical and dentistry products and services). The NBHW developed a national model for explicit priority setting. (See Table 3, where the first row shows analytical categories and the second row shows measures used.) The model is based on the ethical framework, with the ultimate outcome in the form of a ranking ranging from 1 to 10, where 1 is the highest and most prioritized and 10 is the lowest and least prioritized. In addition, instead of a rank, the labels “don't do” or “do” can be assigned in cases where there is no proof of benefit or harm or when something needs to be further evaluated (Waldau 2010). To simplify the list, the rank order can be divided into three larger groups, where rank 1-3 represents what needs be done and is considered to form part of the core activities of the health care system, rank 4-6 is what ought be done and is perceived as expected services, and rank 7-10 is what could be done if economic circumstances allow.

Table 3 : The prioritization model in Sweden

Health condition/ intervention	Severity level of health condition	Patient Benefit/ Effects of intervention	Evidence of effect	Cost per life years Gained /QALY	Health economic evidence	Rank order
Condition and actual state/ Action or intervention	Level of severity: Very high, high, moderate or low	Benefit/effect: Very high, high, moderate or low	Evidence grades 1-4, or: very good to insufficient scientific evidence or standard clinical practice	Low, moderate, high, very high or cannot be appraised	Good, some calculated or estimated	1-10 "do not do", R&D ₁
<p><i>1-One is the highest, 10 is the lowest priority rank. "Do not do" = "no medical benefit or harmful". The "R&D" label was used for interventions of unknown benefit and in need of evaluation.</i></p>						

Source: (Waldau 2010)

This model is designed to work in most cases of vertical prioritization regarding treatment alternatives on the basis of clinical evidence (need), but when and how it should be carried out is left to local and regional authorities. In February 2011, the NBHW announced a working process to revise the national model. Recently, the NBHW started to use the model to develop national guidelines for all levels of health care decision-making and prioritization. Guidelines are being developed for use in resource-demanding areas, for example, for large patient groups with chronic diseases, such as breast, colorectal and prostate cancer; dementia; depression and anxiety disorders; and diabetes. The guidelines are based on thorough literature reviews and health economic calculations. But a bit of imprecision exists regarding the treatment of less severe acute and chronic diseases and care related to cases other than treating a disease or curing an injury.

The extended time it takes for SBU to complete its assessments, sometimes reaching a period of 2 to 3 years, is a source of concern and critique. Indeed, in 1996, SBU developed a special program called Alert to rapidly (usually within 6 to 12 months) assess specific, mostly new, innovations in health care. Except for the Alert program, SBU generally does not assess a single technology at a time, but all technologies surrounding a specific health problem—often including prevention, diagnosis, and treatment and always including both established and new technologies, which is much more time-consuming.

The situation today (Waldau 2010) regarding priority setting is such that the National Parliament keeps an authority to define a "framework" through legislation, based on the interpretation of the "ethical platform," and further developments or more concrete priority setting decisions, with actual priority setting in practice, in hands of the County Councils at a more decentralized level. Several County Councils have developed their own specific models for priority setting within the framework set by the National Parliament. The National Priority Commission is in charge of disseminating information on Parliament's priority-setting

decisions, developing methods to promote implementation of those decisions, monitoring and evaluating the effects of the decisions, and comparing the Swedish situation with international experience. The Commission holds meetings with local groups on ethical matters within County Councils or Municipalities .

f. Netherlands: The Dunning Report

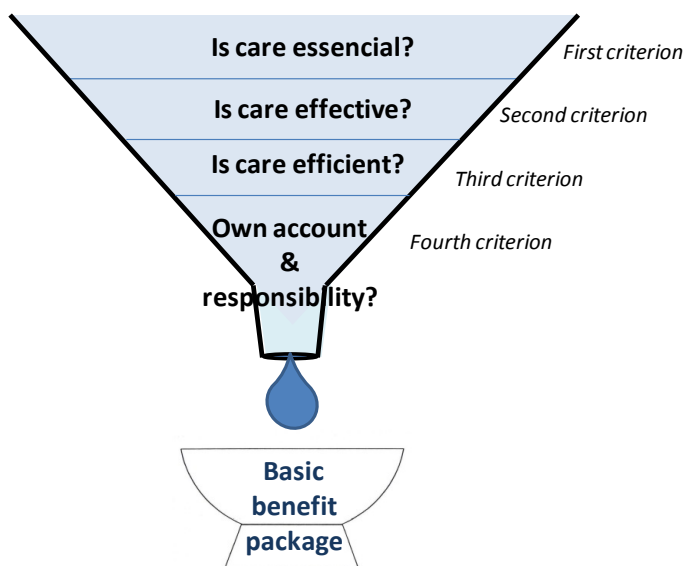
Since the 1980s, priority-setting has become a key issue in making choices in health care in the Netherlands. The 1991 Dunning Report, in order to give a response to the political concern on what the health care system should cover in the Netherlands, established four criteria for the definition of the Dutch basic health insurance package: necessary care (a purely political criteria), effectiveness (more technical criteria), efficiency (measured in terms of cost-effectiveness), and individual responsibility (leaving room for individual responsibility to pay for some benefits, again a political criteria). These priority-setting criteria could result in an exclusion of medical treatments from compulsory health insurance coverage and/or in the development of protocols and guidelines for inclusion and the selection of patients by health professionals. The discussion on the introduction of in vitro fertilization into the basic health insurance package and the exclusion of dental care for adults has shown that, on the basis of the Dunning criteria, it is not easy to leave services out of the basic health insurance package. The second strategy - the application of the Dunning Committee's criteria by the use of protocols, guidelines, and budget restrictions - seems to be even more difficult to realize. More patients assert their right to health care benefits before courts. The courts' decisions have shown that it is difficult to prove that government is responsible for non-delivery due to *force majeure*. Courts attach much importance to the Dunning criteria and, in particular, the criterion of necessity.

The Dunning criteria received support (and still do) for necessary care under three alternatives (i) if individual necessity equals individual demand; (ii) under a medical approach with doctors establishing necessity of care, and (iii) under a community approach, meaning care necessity established from the point of view of the community.

The Central Government makes decisions on the basic health insurance package relying on advice from the Health Care Insurance Board (CVZ). Ministerial proposals for changing the benefit package have to be approved by Parliament. Decisions about the composition of the benefit package are guided by an algorithm, which is known as the "Dunning's Funnel," represented in Figure 5 (Schäfer et al. 2010).

The Committee indeed defined four cumulative criteria: (1) services should be essential, (2) effective, (3) cost-effective and (4) unaffordable for individuals. "Essential" refers to the capacity to prevent loss of quality of life or to treat life-threatening conditions. The affordability criteria is political and open, and states that some services might not need to be included in the basic package in case they are considered to be affordable for individual citizens and for which they can take responsibility.

Figure 5: The Dunning's Funnel⁹



Source: Reproduced from Schäfer et al., 2010

Although the Funnel was a step forward, in practice, the criteria are not always easy to apply. For instance, what constitutes “essential care” is arguable, or decisions can be hampered by lack of information on the efficiency of the service. Other problems may arise with regard to treatments of diseases resulting from unhealthy behavior or when pharmaceuticals covered by basic health insurance are used by those other than the intended patient groups. Critics of the process say that the criteria are too general. It is difficult to indicate which benefits are or not essential and hence would be excluded from the basic package, that affordability for individual patients differs from case to case and cannot therefore be readily determined at the macro level, and that only a few services can be said to be entirely ineffective or inefficient, since effectiveness and efficiency depend on the medical indication, which again cannot be properly determined at macro level (Linander 2011).

The fact is that a Dunning's Funnel effort was made to remove the contraceptive pill from the basic benefit package and failed. The same happened regarding IVF treatments, long-term psychotherapy, transportation by taxi, speech therapy and home-help, dentistry for adults, long-term physiotherapy, incontinence pads, colostomy bags and hearing aids. Today, the basic package is very comprehensive, including 95 percent of present health care services. Indeed, it proves difficult to eliminate existing services from the basic package on the basis of the Dunning Committee criteria. Instead, the alternative to constraint the basic package

⁹ In practice, an example of the decision rationale for excluding a service from the basic package could be, for in vitro fertilization (IVF): (1) Regarding “necessity” from a community point of view, likely exclusion, and from a professional and individual's point of view, likely inclusion. (2) On the “effectiveness” criterion, inclusion. (3) On the “efficiency” criterion, the cost would need to be calculated and leveraged against effectiveness. (4) On the “individual responsibility” criterion, inclusion. Therefore, as a result of combining the four criteria, IVF would result a , out of the basic package.

comes from curtailing the treatment to specific cases, instead of just eliminating it. Despite its limitations, the Dunning's Funnel process has been generally accepted.,

4. FINAL THOUGHTS

High-income countries are struggling with the question of how to cope with the growing pressure of health care expenditures as a result of a combination of budget constraints and advances in technology. We have reviewed a number of approaches developed and tried in a variety of countries, but there is no clear hegemonic system. There is no single best way to allocate resources nor is there a sole way to set priorities. Rather, it varies from country to country.

Priority setting is the process by which health care decision-makers make choices about competing expenditure alternatives within a budget constraint. Hence, all forms of priority setting create rationing and, consequently, an exclusion. In the case of allocating public resources under budget constraints, this exclusion (the opportunity cost) needs to be more explicit. Although in the academic literature, there are clear methodological limitations for making opportunity costs explicit (Birch & Gafni 2003), in a public policy arena, individuals or patients who lose resources are likely to step forward, and political controversy is likely to arise from the inclusion of new technologies and the exclusion of others. How these challenging aspects of priority setting processes are successfully handled depends on many factors, such as the context (Culyer 2010b), the culture, the deliberative process (Shah et al. 2013), the level at which the decisions are made (Tso et al., 2011), leadership (Dickinson et al. 2011), and other contextual factors. At the end of the day, similar methodologies may yield different prioritization results.

Besides the context, economic evaluation (specifically, cost-utility or cost-effectiveness analysis), are at the root of priority setting in all the experiences reviewed. Economic evaluation, however, has important limitations regarding both the economic methodologies and their applications in real-world circumstances. One limitation of economic evaluation has to do with its tight-fitting application to trade-offs concerning health care services and lack of comparability of utility measures regarding health care versus other public services competing for funding. Moreover, cost-effectiveness analysis is based on the assumption of perfect divisibility and comparable size programs. This means that no economies of scale or differences in size are ignored in such kinds of analysis (Birch & Gafni 2003), and decision-makers cannot purchase individual units of QALYs. Each program is supposed to produce a package of QALYs and the average price per QALY may differ by program size. Consequently, a threshold incremental cost-effectiveness decision rule is unable to determine whether a program represents an efficient use of resources.

Another limitation of economic evaluation has to do with the assumption that "a QALY is a QALY," meaning that QALY gains are implicitly valued equally irrespective of the beneficiary or the disease. Such practice has been an issue of debate because evidence tends to show that the public may prefer some QALY gains to others (Dolan et al. 2008). In practice, although explicit QALY weighting is still uncommon, it seems it does implicitly exist. Recent

developments in the U.K. illustrate such need to weight QALYs, for example, for those cases addressing end-of-life-prolonging drugs (NICE 2009). The Netherlands has also responded to equity concerns by developing a framework that is primarily concerned with some idea of need, in particular, based on the controversial “proportional shortfall” (Van de Wetering et al. 2013). Dealing with equity is not a straightforward task. Finding a systematic approach raises two important questions: (i) Which equity principle(s) are used to determine QALY weights? (ii) How can we derive practically applicable QALY weights that are in line with the chosen principles? These difficult and inherently normative questions complicate the formalization of methods to deal with equity concerns (Shah et al. 2013)(Musgrove 1999)(Culyer 2014).

Maximizing social benefits should imply, from a welfarist viewpoint, maximizing utility, not only as far as health is concerned but also accounting for other trade-offs. The utilitarian approach, consisting of the allocation of resources in order to maximize the health of the community as a whole versus some restrictive notion of egalitarian goals remains an open question. For example, “fair innings” is one of the many equity principles one may need to trade off against efficiency (Williams 1997). It captures the feeling that everyone is entitled to some “normal” span of health (usually expressed in life years) and anyone failing to achieve this has been cheated, while anyone getting more than this is “living on borrowed time.” Productivity gains from health care spending are likely bounded by *fair innings* types of arguments from individual entitlements to health care access.

In spite of the limitations of economic evaluation, economic thinking has much to offer in the context of making decisions between competing claims on scarce health care resources. On the one hand, equity concerns are increasingly taken into explicit consideration in most priority setting processes (Culyer 2012). On the other hand, although much is still to be accomplished, efforts are being made to provide frameworks for easier application of economic evaluation tools, like the controversial PBMA or Program Budgeting and Marginal Analysis (Donaldson Cam & Mitton 2009); or the Generalized Cost-Effectiveness analysis, designed to allow policymakers to evaluate the efficiency of the mix of health interventions currently available and to maximize the capability to generalize results across settings (Torrance & Drummond 2005); or the use of integer programming when data requirements are accomplished (Birch & Gafni 2003) for constraint maximization problems.

Moreover, economic evaluation is receiving increasing attention as a means of setting regulated prices of goods and services provided within the benefits package boundary in most of the countries reviewed: *Value Based Prices* in **France** with higher therapeutic value (*Service Médical Rendu*), advocating greater coverage and higher prices. In **Germany**, reference pricing strategies have to follow the indication of the value as identified in cost effectiveness analysis. In **Sweden**, a new commitment for better therapeutic value is to be reflected in prices. In general, the idea that more risk-sharing contracts should be agreed upon for drug approvals with larger budget impacts is increasingly being accepted. Finally, the **UK**, in 2014, has tried to implement Value-Based Pricing and recommendations for treatment removal and delisting. Hence, the complex objectives faced by decision-makers, far from limiting the role of economic analysis, represent the challenges that economic models intend to accommodate.

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