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SCIENTIFIC CONTRIBUTION

The current status of decision-making procedures and quality assurance in Europe: an overview

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Abstract The 2005 Report on Social Responsibility and Health of the UNESCO International Bioethics Committee (Ibc) proposes a new approach to implementing the right to healthcare and suggests a number of Courses of Action to be followed in various fields. Based on the latest available data, we intend to present an overview of the current state of European health systems in two of those fields—decision-making procedures and quality assurance in health care—and to attempt a comparison of the situation with the Report's provisions, in order to pave the way for the identification of what still has to be done to bridge international recommendations and the reality of policy and practice in Europe's health care.

Keywords Health systems · Healthcare · Equality · Social responsibility · Solidarity · Europe · Basic goods · Health care rationing · Quality assurance · Health care · UNESCO

The Report on Social Responsibility and Health of the International Bioethics Committee (Ibc) of UNESCO proposes an innovative view of the problem of guaranteeing in practice the standard of health in the terms it had been previously formulated by the Universal Declaration on Bioethics and Human Rights (UNESCO 2005). This practical approach is best represented by the provisions contained in Part V—Courses of Action, that describes five domains in which action can be taken by health care systems to safeguard this standard of healthcare, and, in particular, sets forth the principles by which theory should be translated into action in accordance with the discussion carried out in the previous sections (UNESCO 2010).

Two of these domains, decision-making procedures and quality assurance, stand out for their comprehensive character, their intimate connection with the overall design of the health system they are referred to and with the policies guiding it, and above all their remarkable relevance to the most recent and the ongoing developments of healthcare reforms in Europe. Of the domains considered by the Report, they represent the ones more directly related to the design of health care systems in the traditional sense.

We intend to present an overview of the current status of the systems and policies currently in place in Europe concerning these two fields of action, so as to assess how European countries currently compare to the principles and the standards set by the Report, and to what extent their implementation is already present in the debate over health systems reforms, or rather requires to be upheld by promoting a more clearly defined and a better recognized definition of the right of healthcare in our continent.

Decision-making procedures

It should come as no surprise that "Decision-making procedures" is the opening topic of the section "Courses of Action" of the Ibc Report. The difficulty of enforcing the right to health care in its traditional definitions, and the practical value of the distinction between civil and social rights, stems exactly from the problem of the limited availability of resources, which makes it necessary to determine who is entitled to what.

This is why most European health systems have designed legal and institutional frameworks that include,

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under different labels and using different procedures, but with remarkable consistency, the definition of what is variably referred to as the *essential*, or *basic*, or *fundamental* level of healthcare: quite simply, a "basket" of the health care services guaranteed to either all of the population (in a perspective of equality) or to different categories of patients in need of care (in a perspective of equity).

Discussion of how this basic level of health care is defined and ensured in different European countries requires a preliminary consideration on the general organization and financing of health care in Europe.

European health systems are traditionally divided in two categories, or models. The first model is known as "National Health System" model, or Beveridge model (from Sir William Beveridge, the pioneer of the establishment of the British National Health System). Systems belonging to this model ensure universal health coverage to all citizens, and finance health provision through general taxation. In these countries, the State usually has a major role in the provision of health care as well, at least as far as hospital care is concerned. In Europe, this is the model followed by UK, Ireland, Spain, Portugal, Italy and the Scandinavian countries. The second model, often referred to as Bismarck model (from German Chancellor Otto Bismarck), includes health systems in which health coverage is not per se and a priori universal, but is linked to payment of premiums to insurance funds that can be private, public or any combination of the two, and operate within a regime with different degrees of competition, under the supervision of public authorities but without their direct intervention in either the financing or the provision of health care. This model or some variants of it are used in Germany, the Netherlands, Belgium, France, Switzerland, Austria, and in most Eastern European countries formerly belonging to the Soviet bloc (Stevens and van der Zee 2008).

Traditionally, the Beveridge model is considered to be more equal, but less efficient, because of lack of competition mechanisms, while Bismarck systems sacrifice the guarantee of equality and universal coverage to the advantages in efficiency provided by a more or less market-based organization (which involves both funders and providers; Van der Zee et al. 2004). However, over the last decades the differences between the two systems have been increasingly blurred by waves of reforms that have combined their features. Most Bismarck countries have now enacted systems that ensure universal coverage and promote equality, while Beveridge systems have been introducing systems of managed competition which use quasi-market mechanisms to exert pressure towards efficiency on health care providers (Wagstaff 2009).

How the minimum level of care is defined

The notion of "health benefit basket", that is, the range of medical services and pharmaceuticals guaranteed by the health system, is in some cases only implicitly defined, by formulas such as "all necessary medical services"; in other cases, it is defined explicitly through positive or negative lists, including all goods and services which are respectively covered or not covered by the national health system or by basic primary health insurance (Paris et al. 2010).

A centrally-defined positive list is used in 8 countries to define the benefit basket covered by the basic level of coverage: they include many insurance-based systems (Belgium, France, Luxembourg, the Netherlands, Poland and the Slovak Republic) and two of the national health systems (Italy and Spain). By contrast, a centrally-defined negative list, containing the procedures excluded from the benefit package, is used in four countries: the UK's National Health System and the insurance-based systems of Germany, Switzerland and the Czech Republic. All other countries, including the Scandinavian ones, do not explicitly define the benefit package, but may rather resort to finely-tuned mechanisms to regulate decision-making procedures at the peripheral level (see below).

The regulation for pharmaceuticals provided is more complex. Only Greece does not provide any lists; Germany and the UK define the package for pharmaceuticals only by negative lists, while the Czech Republic, Slovakia and Iceland use both negative and positive lists. All other countries use centrally-defined positive lists.

Lists are outlined by different institutions, the Ministries of Health usually having a prominent role. Most of the insurance-based countries involve the insurance funds in the process.

Founding principles

A study conducted in 2006 by a Dutch advisory committee, the *Raad voor de Volksgezondheid en Zorg* (RVZ), in the setting of a large-scale reform of the Dutch healthcare system, compared the approaches employed by different countries to take decisions regarding prioritization and the essential health care benefits to be guaranteed by the health systems.

The most significant attempts were conducted by the Scandinavian countries, and two cases are in this respect emblematic. In Norway, a first attempt conducted in 1987 identified five criteria and fives groups of care in decreasing order of prioritization, with a detailed listing of clinical conditions. A follow-up carried out in 1997 simplified the principles to three (patient's health status, benefits of interventions, equality) and the groups to four, but, above

all, established a well-defined four-step process for all future prioritization decisions, with key roles for scientific and financial advice. In the neighbouring Sweden, a Commission was set up in 1995 to establish a prioritization mechanisms that complied with the principles set by the 1982 Health and Medical Services Act (Universality, Solidarity, and Cost-Effectiveness), producing a set of three principles: human dignity, necessity, and social solidarity; and as many as two lists of hierarchically-organized patient groups, one for resource-allocation and one for clinical decisions. Interestingly, the commission explicitly refused to recognize the principle of efficiency.

The RVZ study concluded that a wide consensus appears to exist today as to the essential criteria that should form the basis of prioritization of care to be paid by collective means. While different terms are used, the recurring notions are *necessity*, *solidarity/justice*, *autonomy*, *effectiveness* and *efficiency* (Table 1), which are addressed one by one by the RVZ as follows (Ottes and van Rijen 2006).

Necessity: Those with the highest needs have the highest priority, where "need" is usually assessed by the acute and life-threatening character of the condition. However, there appears to be disagreements on the collocation of chronic patients: Sweden tends to consider them in higher priority than Norway and especially the Netherlands. Under the pressure or rising costs, the tendency of explicitly mentioning those categories that are not covered by public health care, e.g., the use of negative lists, has been spreading. Where the line is drawn usually depends on the interpretation of the notion of *solidarity*—basically, the simple notion: the healthy pay for the sick. Clearly, it is not unambiguous, and interpretations may significantly diverge. In the Netherlands, the definition moves from the counterpart of solidarity, that is, personal responsibility; and it was suggested that all care outside hospitals belongs to personal responsibility and is therefore, by definition, outside the domain of solidarity (Commissie Structuur en Financiering Gezondheidszorg 1987). The Swedes focused on the notion of *social solidarity*, and therefore on attention for the most vulnerable groups, while solidarity in the strict sense was included in the domain of human dignity, with the result that some criteria were explicitly named as inacceptable, such as age and personal responsibility—which, in contrast, is counted by Norwegians among the essential criteria. The RVZ observes that *autonomy* is strictly related to the field of solidarity. The obligation to subscribe the basic insurance limits the personal autonomy of citizens, but it also increases it from the standpoint of making treatments affordable to them that would not have been otherwise. In the same way, prioritization itself is on the one hand an obvious limitation of the autonomy of those patients that are denied care, but on the other hand an increase of the autonomy of those that are granted it. *Negative discrimination* is never accepted, whether it be on age, sex, race, ethnicity, social status and "own fault", but some forms of positive discrimination (based, for instance, on socio-economic background) are sometimes accepted. However, the implementation in practice differs significantly: sterility and sexual problems are given significantly different priorities in different countries. *Effectiveness* is everywhere a mainstay. A distinction between *clinical effectiveness* and *cost effectiveness* must however be drawn. The former refers to the assessment of the risk–benefit ratio of medical procedures or medicines. For both procedures and pharmaceuticals, these criteria can serve two purposes: to assess whether "benefits" deserve collective funding by basic primary health insurance (for instance, drugs just improving the comfort of patients with minor ailments can be excluded from basic benefits) or to assess whether a procedure/product brings more benefits than competing alternatives (comparative effectiveness assessment). Unlike clinical effectiveness, *cost-effectiveness* assessment requires economical techniques to compare incremental costs and benefits of therapeutic alternatives. Since this method is a quantitative one, it gives numerical outcomes, so clear cutoffs can be defined beyond which procedures or products are not covered: this is what happens in the United Kingdom and in Sweden. In Sweden, the 1982 Health and Medical Services Act even includes "Cost-Effectiveness" among the three funding

Table 1 Recurring principles in decision-making for healthcare

Necessity	Priority is given to those with the highest need (Ottes and van Rijen 2006)
Solidarity	Priority is given to the most disadvantaged in society, so that the healthy pay for the sick (Ottes and van Rijen 2006; Hoedemaekers and Dekkers 2003)
Autonomy	Self-determination that is free from both controlling interferences by others and personal limitations preventing meaningful choice (Miller-Kean Encyclopedia and Dictionary of Medicine 2006)
Effectiveness	Extent to which the intervention in question produces the desired effect (Maxwell 1992; Witter and Ensor 1997)
Efficiency	Extent to which objectives are achieved by minimizing the use of resources (WHO 2000)
Discrimination	Treating individuals differently on the basis of their properties of them (Lippert-Rasmussen 2006)
Affordability or budget impact	

principles of the that are stipulated to inform the provision of health care, the other two being "Equality" and "Solidarity". However, it is on the third place of the hierarchical order the three principles are expected to be considered in policy-making and in decision-making concerning health care.

Along with effectiveness, *appropriateness* is almost always mentioned, despite not being indicated as the most important criteria in any country.

Significantly, *affordability or budget impact* has been explicitly mentioned and clearly formalized only recently in the health policies of European countries, which could reflect a progressively increasing acceptance of the legitimacy of allowing cost constraints to influence provision of health care. Most countries still do not explicitly mention affordability among coverage decisions: Austria, the Czech Republic, Denmark, France, Germany, Italy, Portugal, Spain, Sweden, and Switzerland. Three countries, however, have run into the opposite extreme, by mentioning affordability as the single criteria for reimbursement decisions: Ireland, Greece, and Turkey. The Greek law even goes to the length of explicitly stipulating that covered benefits are defined by available funding resources.

From principles to process

Informal and implicit criteria seem to be bound to play a significant role in decision-making, and several reasons have been proposed for this: the political nature of the process, so that an acceptable compromise must be usually found between scientific and professional approval and social approval (Klein 1998); the liability to different interpretations when it comes to implementing criteria, even after they have been established; the unavoidable biases and assumption that always exist at the basis of the very scientific research that should represent the firmer basis of these decisions, especially as regards those technologies that are less liable to objective evaluation (Berg et al. 2004).

The recognition of the problems intrinsic to formulate and applying clear-cut criteria in forming benefit baskets has heavily influenced policy-making. Based on the RVZ's observations, a conspicuous trend can be detected when analyzing the historical evolution of the attempts to devise ethically sound procedures for the composition of the health benefits basket. The earliest ones, mainly those conducted in the late 1980s and in the early 1990s in the Scandinavian countries (Health Care and Medical Priorities Commission 1993; Calltorp 1999; Norheim 2003), went for a so-to-speak "top-down" approach: they drew specific criteria from general principles. In contrast, later attempts (Holm 1998; Swedish Parliamentary Priorities Commission 1995; Berg and van der Grinten 2003; Rawlins 1999; Sabik and Lie 2008), rejected this "mechanistic" approach: rather than trying to operate based on fixed principles and predetermined standards, they emphasized the *procedure* by which prioritization occurs, and the need to ensure that the procedure itself complied with ethically consistent criteria.

This progressive shift in focus by policy-makers has mirrored a similar development in the international debate in the same field. The formulation of rules that control the process of decision-making itself (Holm 1998) and the proposal of practical approaches to allocation of resources, such as Daniels' "Accountability for reasonableness" (Daniels 2000), had indeed already made the simplistic principle-standard approach outdated.

As a result, the goal of 'equity and quality in the creation and delivery of health-related services' set by the Report appears to be a realistic one: European policymakers have already moved in that direction.

Public participation and stakeholder perspective

An important consequence of the 'process approach' involves public participation. In the Netherlands, the 1991 Dunning commission proposed a set of principles for the choice of the essential benefits (Commissie keuzen in zorg 1991): first, a division into categories that allows all citizens to have access to the same services; second, choices should be as much as possible explicit rather than implicit and public responsibility should be taken for them; third, in the composition of the basket, along with professional and scientific arguments, social values should be taken into account. Moreover, the commission set four principles: necessity, effectiveness, efficiency, and individual responsibility. While the second and the third principle pertained to the domain of quality, and required the establishment of a systematic evaluation procedure such as Health Technology Assessment, the first and the fourth principles represented an explicit appeal for a broader involvement of relevant actors, that is, the subjects involved in some way in the health care system (Bal and van de Lindeloof 2006). This recommendation found a follow-up in the 2003 advise "Outlines of the basic basket" by the Gezondheidsraad that remarked that "the application of the criteria always requires a finely-tuned (*genuanceerd*) approach", with a recognition that the decision whether to include or not a provision into the basket ultimately depended not only on scientific considerations, but also social, juridical and ethical ones (Gezondheidsraad 2003).

The reasons why participation of citizens in decision-making is advocated are numerous: to comply with the democratic principle that everybody should participate in decisions that ultimately affect them (Hansen 2000; Daniels 2000); to increase the quality of the decision-making process (also by creating a connection between different

types of knowledge and experience, thus preventing hostilities between them; Harrison and Mort 1998; Charles and DeMaio 1993); to reduce political hostility and increase compliance (Goetz and Gaventa 2001; Wiseman et al. 2003; Daniels 2000; Rowe and Shepherd 2002; Mossialos and King 1999). In contrast, opposition to public participation also uses diverse arguments: the lack of knowledge on the part of the general public, with the danger that interest groups or distorted information make their way into the decision-making process (Harrison and Mort 1998; Mossialos and King 1999; Edgar 2000); public can be manipulated to hinder politically difficult decisions (Harrison and Mort 1998); and the public might actually not desire to be involved in the decision-making process, having already delegated others to take such decisions according to the principles of representative democracy (Harbers 1996).

Based on existing studies (Tenbensel 2002; Bal et al. 2002), the RVZ report distinguishes between deliberative and non-deliberative methods, the former being characterized by every part being able to express its view in an attempt to change the other part's opinion or clarify it, the latter using mediation roles to exchange information, and without any intention to change others' viewpoints. The "focus group" is an intermediate form, as it includes a deliberative stage, but the viewpoints are presented by a mediator. Also, some methods address the public as *patients*, other as *citizens*. It is apparent that the former definition entails their representation of a more particular interest than the latter, and that these two approaches can lead to differently oriented contributions. But, above all, methods vary as to the decision power that is bestowed upon the public: a widely used classification (Charles and DeMaio 1993) distinguishes "consultation", where participants can only express their view to those that will ultimately decide, "partnership", typical of the committees where decisional responsibility is shared more or less equally by all participants, and "dominant responsibility", where the opinions of the participants are directly converted into decision (e.g., in referenda). Of course, in practice more forms of public participations can co-exist in the same system, or in different stages of the same process, giving rise to mixed forms.

Public involvement at the highest levels of decision-making and health prioritization is still not common in Europe. Recent data show that patients are represented in decisions pertaining to the licensing of pharmaceuticals only in the Czech Republic, Denmark and Sweden, while they are represented in decisions relating to the coverage of health services in the Czech Republic, Denmark, the Netherlands, and Switzerland (Paris et al. 2010). In all other countries, they have no involvement or only a marginal one, with no significant responsibility in decision-making.

The effect of financial pressure

If we leave the field of principles and go on to consider the practical factors that appear to influence the actual scope of benefits guaranteed, it becomes plain that the evolution of the former has been heavily affected by the development of the latter.

Since the definition of the structures of most European health systems after the Second World War, health costs have been increasing steadily. With regard to high-income countries (which all European countries are), the main factors on which responsibility for this trend is blamed are demographic changes leading to population ageing (with increased co-morbidity), advances in technology with introduction of increasingly expensive equipment, and growing expectations on the part of the population on the efficiency and the quality of care.

It is therefore not surprising that cost containment figures prominently in the agenda of health care policymakers. The first consequence of cost pressures is indeed the increase in health care institutions' deficits; other common consequences are also purely financial, with no significant impact on health care delivery itself, e.g., partial refunds from health care providers and/or the pharmaceutical industry to health insurance funds or the government, or reductions in physician fees.

However, increase of out-of-pocket payments has today become the most widely employed measure to address increased costs, which has been considered one of the most worrying trends in European health care policy of the last two decades, because of its impact on access to health care. Out-of-pocket payments increase the exposure of households to financial losses associated with health care, preventing which should be one of the main goals of health systems. Significant evidence exists on the undesirable effects of user charges in this respect (Robinson 2002). The RAND Health Experiment, conducted in the United States in the 1970s, found that while higher cost-sharing decreased utilization, this phenomenon involved at the same time effective and ineffective or inappropriate procedures, and that higher cost-sharing was also associated with lower health status (Newhouse 1993). These undesirable effects from the utilitarian viewpoint were also shown to be accompanied by negative effects on equity, as decreased access to effective interventions seems to disproportionately affect lower-income groups, children, the unemployed and the homeless, both in high-income (Rubin and Mendelson 1995; McLeod et al. 2011) and in developing countries (Schieber and Maeda 1997), and availability of health services requiring payments appears to represent one of the major preconditions for catastrophic financial payments in different country settings (Xu et al. 2003).

Lastly, direct effects on the level of care are reported increasingly often: in recent years, waiting times for a number of services increased in many Eastern European countries, while delisting of goods of services from the health benefit package was reported in Belgium, Czech Republic, France, Germany and Italy (Paris et al. 2010).

The effect of market mechanisms

Along with constraints originating from increased costs, trends in reform of the structure of health care systems themselves appear to be severely affecting the "essential care". This is especially notable in countries with Bismarck systems, that have been undergoing more and deeper-reaching reforms than Beveridge countries over the last few years (Hassenteufel and Palier 2009).

Among the countries with an insurance-based system, three, France, Austria and Greece, have introduced a long series of reforms pressing for greater equality, transforming their systems into *de facto* national health services. Citizens are automatically assigned to an insurance fund based on their job, which means that there is no real competition between insurers. Still, there is divergence in how the "essential care" is defined: at one extreme, Greece, where insurers determine themselves benefits, level of coverage and contribution rates. At the other one, France, where contributions and benefits are uniform and determined by state laws. Halfway between them is Austria, where insurers are required to cover "all necessary services", but these are not explicitly defined, leading to variations across health insurance funds.

The remaining five countries with systems based on multiple insurance funds have a true competition between insurers, because citizens are allowed to choose their insurance fund. How the "basic benefit" provided by insurers is defined, however, varies from country to country. In Slovakia, both contributions and benefits are uniform, and competition is supposed to rest solely on quality of care. There is a somewhat greater flexibility in the Czech Republic, where insurers are required to offer a uniform benefit basket defined by law, but they are allowed to extend the scope of coverage but not to alter premiums or the level of coverage (percentage of the costs paid by the insurer). In Switzerland, a uniform benefit basket is also defined that cannot be modulated by insurers, but lower premiums can be offered to those enrollees that accept "managed care plans" or higher cost-sharing (Leu et al. 2009).

The health systems of the Netherlands and Germany underwent in recent years carefully designed reforms aimed to maximize competition and market-based mechanisms, also by raising the flexibility of the benefits basket, while at the same time ensuring universal coverage and counterbalancing market failures. In the Netherlands, insurers can modulate the basic benefit basket set by the Government only by adding more services, and not by removing or replacing the standard ones. They have also significant room for competition on costs: premiums may vary by type of contract (single vs. collective; collective for single employers or by consumer groups) and by coverage model (in-kind benefit vs. reimbursement). In Germany, a reform that entered into force in 2009 grants funds extreme flexibility in the definition of the benefits covered: higher benefits in exchange for higher cost-sharing or acceptance of a set of constraints, such as restricted provider network, or specified health care pathways; same benefits, lower premiums but higher cost-sharing; no-claim bonuses (financial advantages for those who do not seek care for a certain time). If the insurance fund has a financial surplus, additional benefits or premium rebates are allowed; if the fund has a financial deficit, it is compelled to charge their enrollees an additional premium (Cheng and Reinhardt 2008).

These five systems have therefore been granting their insurance funds a constantly increasing number of instruments variably defined as "levers" to "steer the demand for health care" or "ensure appropriate use of the health services". While the use of such instruments appears consistent with the market approach, it should not escape our notice that their introduction has ethical implications that go well beyond their effects on competition and efficiency. Such instruments entail an explicit trade-off between, on one hand, the costs paid by the citizen, and, on the other hand, the number of benefits, the frequency of recourse to health care, and the choice of providers or health care pathways—in short, the provision of health care. In other words, financial advantages are increasingly given a value in terms of sacrificed health care, at least as long as the non-compulsory component of healthcare insurance—which has a different weight from country to country and never includes, of course, the basic package—is concerned. Acceptance of this trade-off equals to the implicit admission that not all health care is guaranteed as such, but that the provision of at least a part of it is in some way related to the money every citizen is willing to spend on it. As a result, the extensive provisions these States introduce to ensure a *minimum* level of health care for everybody only appear to ensure *some level* of care for everybody. What care each citizen actually affords is unclear, lost as it is in tangle of insurance policies provisions and State regulations and limitations (Maarse and Paulus 2003).

The coverage of the "average" citizen

The above discussion makes it easy to understand why it is difficult to analyze the actual level of health care guaranteed as basic or essential: the details of insurance policies,

State interventions, financial mechanisms make it possible for significantly different levels of health care to be provided to different groups of people within the same countries, both in terms of scope of coverage (which benefits are provided) and depth of coverage (which percentage of costs of each benefit is covered). An attempt can be made, however, to evaluate the health care benefits guaranteed to the "average" citizen of each countries (Paris et al. 2010).

On the whole, most countries guarantee a high level of coverage for acute inpatient care and medical services, as well as for laboratory tests and diagnostic imaging. In France, the share of costs covered for outpatient physicians' services is 60%, bur complementary health insurance, held by 92% of the population, covers virtually all cost-sharing. In Ireland, basic primary health insurance does not cover primary care services for people eligible for Category II (the wealthiest two-thirds of the population). Pharmaceuticals are usually covered at lower levels than other health services. Only in Italy and the Netherlands does coverage of pharmaceuticals reach 100% of costs: the Netherlands, Italy and the United Kingdom, even if mechanisms of cost-sharing partially distort this provision in the latter two countries.

At the bottom of the "hierarchy of services" are dental care and eye products, covered in most cases at a lower level than all other types of care or not covered at all.

It should be considered, however, that what is theoretically covered by basic health coverage is distorted by limitations to access to care that only become evident in practice. For instance, people may be entitled to health services "free at the point of care" but nevertheless be obliged or tempted to turn to private providers with copayments or to lay out informal payments for different reasons (lack of supply, long waiting times). For instance, in Belgium, patients pay extra-billing and supplemental fees for inpatient care leading to high levels of private payments (23.8%), exceeding "official" copayments (Lecluysea et al. 2009). A similar phenomenon occurs in Hungary, where hospital and primary care should in principle be fully covered by basic health insurance. On the other hand, in many countries the actual level of private funding is below the level predicted by cost-sharing arrangements; this happens because some population groups benefit from partial or total exemption of cost-sharing requirements.

Quality assurance

While no policy-maker or health professional would ever refrain from confirming their support to initiatives aimed to ensure and increase quality in health care, a shared definition of what we actually mean by quality does not exist. Different European countries and, within them, different institutions and interventions confer on this word a variety of meanings, which need to be carefully taken into account as we consider what quality assurance policies are currently adopted.

The most widely accepted definition of "quality" is the one given by the Institute of Medicine in the United States in 1990, which reads as follows: "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge; IOM 1990). It is remarkable that this definition mentions both individuals and populations as the addressees of health services, and, above all, that their "desires" are mentioned, which reflect acknowledgement of the central role played by the values and the expectations of those interested and involved in the performance of the health system.

While this definition is carefully designed, attempts to implement and pursue the notion of quality in practice require it to be broken down into components more liable to be referred to visible actors and activities—the so-called *dimensions* of quality. A study by the European Observatory on Health Systems and Policies (Legido-Quigley et al. 2008) has found quality to be defined by a variable array of dimensions including *effectiveness*, the ability of a certain care measure or intervention to result in the intended effects; *efficiency*, that is, the ratio between output and input; *access*, the extent to which those in need of care can actually obtain it; *safety*, the reduction of risks associated with the measure or intervention itself (medical errors, side-effects of medicines); *equity*, the availability of the same services to everybody, with the possibility of grading the intensity of care based on the degree of need or the ability to benefit from care (Whitehead 1991); *appropriateness*, the correspondence between the intervention and the needs of the patient; *timeliness*, provision of the intervention in an adequate time; and *responsiveness to patients*, one of the dimensions most variably defined, but of particular interest here, because it usually includes the acknowledgement of patient' and society's preferences and values.

Article 86 of the Report specifies the requirements of quality assurance in health care in the following terms: "(1) adequate prevention and/or treatments, based on sound evidence, are applied at right time; (2) primary or secondary harm are avoided or reduced; (3) patient dignity and rights are respected". Accordingly, the elements of quality that more directly referenced are Effectiveness, Appropriateness, Timeliness, Safety and, and Responsiveness (sometimes referred to as Patient-Centredness).

From the international level to the national level

As we go on to summarize how these dimensions are pursued in practice, we have to first remark the attention of international organizations on this matter. One of the first

frameworks on quality of care specifically regarding Europe was provided by the Council of Europe with the Report "Dimension of Quality Improvement Systems" (Council of Europe 1997). That report triggered a number of initiatives, mainly at the level of the European Union, which included the issue of quality in the 2000 Health Policy by advocating the diffusion of best practices (Shaw and Kalo 2002). In 2008, the European Commission presented a number of non-legislative proposals pertaining to the quality of health care, among which the Recommendation on Patient Safety and Quality of Health, which explicitly states as its goal that of providing the necessary and relevant practical and legal tools and mechanisms for the Member States, as well as the key stakeholders, to take appropriate actions to improve safety and quality of care (European Commission 2008).

On the national level, several strategies exist. Oevretveit (2001) and the 2008 Report of the European Observatory of Health Systems and Policies (Legido-Quigley et al. 2008) distinguish three levels at which policy development in the field of quality takes place: the health system level; the organizational level; the level of services.

Health system level strategies

At the level of health systems, the most obvious type of intervention is the introduction of legislation and the initiation of policies especially directed to the quality of care. Legislative activity is, however, quite heterogeneous, probably also as a consequence of differing views about formal legislation, rather than more decentralized instruments such as negotiations or agreements, being the most suitable tool to this end. In general, lack of systematic legislative approaches to quality assurance is mainly notable in Eastern European countries, with some notable exceptions such as Czech Republic with its National Quality Policy, adopted in 2000 (Health Systems in Transition. Czech Republic 2009). Countries with a longer history of membership of the European Union already have long-standing strategies in place of which Sweden with its 1990 National Strategy on Quality is the most significant example. In the other countries, approaches seem to differ: while dissemination of guidelines seems to be common everywhere, France focused on training and accreditation, Germany progressively shifted from a system based on professional self-regulation to legal obligations to introduce quality management programmes and quality indicators, while Spain and Italy have been gradually delegating quality management (along with several other responsibilities) to Regional governments, which led to yet more fragmentation. A small group of countries, namely the United Kingdom, Denmark, the Netherlands, Austria and Belgium, are envisioning substantial reforms that mainly follow the "top-down" approach—possibly also as a consequence of evaluation of previous "bottom-up" strategies, like the 1993 National Strategy for Quality Improvement in Health Care in Denmark, that led to a number of initiatives that were largely local, ad hoc and informal (Legido-Quigley et al. 2008).

Policies on patient safety in Europe recognize a pioneering role in the 2001 UK NHS Report *An organization with a memory* (Department of Health 2000), and by recommendations on patient safety issued in 2005 by both the EU and the Council of Europe (Legido-Quigley et al. 2008; Council of Europe 2006). The most remarkable ones are the Danish system, based on a confidential, non-punitive but mandatory system for reporting adverse medical events, collected in a national database, and the British one, coordinated by the National Patient Safety Agency mainly operating with management of information on adverse event (also by means of Confidential Enquiries) and with subsequent interventions, including alerts and confidential advice.

Patient safety was the primary concern in the development of the well-refined regulations on the approval of pharmaceuticals and medical devices, the former being approved either by the European Medicines Agency (EMEA) or by Member States, the latter being regulated by a number of EC Directives and through national legislations.

The label *registration and licensing* is used to refer to the activities aimed to ensure that health professionals or health care providers meet minimum standards of competence. They therefore include activities such as training, registration, certification and revalidation. While there is a striking variability and lack of coordination in the training of professionals across Member States, the problem has been made more compelling by increasing attention on the issue of mobility of professionals across Europe and the need for mutual recognition of professional registration. A number of innovative approaches have been attempted in this field: one is the instrument of medical revalidation, a regular, compulsory review of the competences of professionals, necessary for renewal of the permission to practice. The introduction of quality of care in the setting of the education and training of medical professionals has also been attempted, but only in a sparse and fragmented way, on the initiative of diverse subjects (public authorities, government agencies, professional associations, single universities) and implemented to variable degrees.

The most systematic—and probably most promising—approach to quality assurance at the level of health systems is Health Technology Assessment (HTA), a methodology to evaluate the conditions for and the consequences of using any health technology, that takes into account four dimensions—the technology, the patient, the organization and the economics (DACEHTA 2007). The main advantages of HTA are its quantitative basis, which allows for standardization and comparability, and its global scope,

that accounts for all of the stakeholders of health care. Nevertheless, the label of HTA is used with a variety of meanings, and its application varies from unsystematic to well-developed, the pioneers being Sweden, Netherlands, France, Germany, Belgium, Denmark, UK, Spain, Italy (the latter two countries displaying no unitary national policies for HTA because of their regionalized structures, but still counting a good number of institutions and initiatives active in this field).

Organizational and service level strategies

Organizational quality assessment schemes evaluate the providers of health care on an either voluntary (in which case they are usually carried out by private subjects, in most cases professional organizations) or compulsory (usually by public authorities or agencies) basis. This distinction entails a difference in approach: voluntary assessments are oriented to self-development and improvement, while compulsory assessment has a more judgmental, standard-oriented character. Two popular models of organizational quality assessment originated in an industrial setting, but were later applied to health care by the private international organization owning them. The International Organization for Standardization ISO 9000 model series is devoted to healthcare; along with countries where it is popular as a basis for voluntary accreditation, there are cases of countries that have used ISO standards as a model to develop their own public, compulsory accreditation criteria: they include the Netherlands (since 1994), Finland, and Spain. The European Foundation for Quality Management (EFQM) model has a different perspective, as it is oriented to improvement and the pursuit of excellence in customer and employee satisfaction, giving providers the tools for quality management and continuous improvement rather than evaluating their adherence to pre-set standards. It is, however, less commonly used than the ISO model in the health care sector.

The level of clinical quality assurance is undoubtedly dominated by clinical practice guidelines, the traditional instrument designed to improve clinical practice. Corporations of health professionals are usually called upon in this process, as the traditional autonomy of physicians poses difficulties for attempts to influence their professional behaviour by constraints (Hulst 1999). This also represents the key weak point of this approach: evaluating adherence to guidelines is difficult, as is assessment of their effectiveness in influencing quality. Again, we stand before a fragmented situation (Shaw et al. 2010). On the one hand, this type of instrument is so mature that it has given rise to international frameworks (Council of Europe's Guideline Recommendation 2001; Guidelines International Network 2007), and, above all, to some impressive achievements.

The method of *peer review* or *visitation* is based on on-site surveys conducted by medical professionals, who therefore assess the organizational features and the activity of care provided by fellow physicians and health professionals, and advise them on how to improve (ExPeRT 1998). This model is not widespread, but in what countries it exists it has been integrated into the set of regular, compulsory activities.

A number of approaches exist that are focused on collection and management of information. Availability of transparent data on quality is considered as a means to enhance quality and efficiency (Canadian Health Services 2006), even in the absence of control mechanisms. In most European countries, information on quality of services supplied by individual providers is available, but different aspects are monitored in different countries, with a prominence of data on hospitals and a relative lack of data on primary care. In the Netherlands and in Slovakia, insurers and the media (in Slovakia, also the government) publish information on clinical outcomes, use of appropriate processes, patient satisfaction and patient experience. A particular type of information is represented by surveys of health care users and the public, which, however, lack of systematic implementation, with some few exception at the international (the Eurobarometer series) and at national level (like the National Survey of Patient and User Experience in the UK). Most other experiences are one-off initiatives; still, it should be observed that Eastern European countries have displayed a remarkable liveliness over the last few years: well-organized patient satisfaction surveys have been carried out in a number of Eastern European countries (CPSS 2007).

Lastly, a promising approach is represented by the use of quality indicators. While setting up this kind of procedure is difficult from both the organizational and the financial standpoint, what countries have used this has done so with success. Denmark's National Indicators Project (Health Systems in Transition. Denmark 2007), Germany's national system for performance measurement of medical and nursing services in hospitals (BQS 2007) and the national health care quality registers of Sweden deserve to be mentioned in this respect.

How does this landscape compare to the recommendations contained in the IBC Report? Two points stand out clearly. The "international cooperation" the Report calls in for better "information and training to clinicians, agreed best practice guidelines" (Art. 85) was poorly developed in the 1990s, but the recent tendency for the internationalization of guidelines demonstrated by the 2001 Council of Europe's Guideline Recommendation and the GIN and by the publications of the Council of Europe and the EU on patient safety is promising in this respect. The diffusion of HTA appears to be an adequate response to the Report's warning on the

Table 2 Historical landmarks and open problems of approaches to quality assurance in Europe

Strategies	Landmarks	Open problems
Health system level		
National legislation or policy for quality	*1990 Sweden*: National Strategy on Quality	Persisting West-East divide; Czech Republic, Slovenia, Lithuania recovering
	1993 Denmark: National Strategy for Quality Improvement in Health Care (Health Systems in Transition. Denmark 2007)	
	2006 Netherlands: experience from the 1993 Individual Health Care Professions Act (BIG) and the 1996 Care Institutions Quality Act (KZI) embedded in the 2006 health care reform (Health Systems in Transition. The Netherlands 2009)	
Specific institutional structures to ensure patient safety	*2001 UK*: NHS Report An Organization with a Memory; establishment of National Patient Safety Agency	In 2005, only the UK, Denmark, the Netherlands, Germany and Spain had set up specific institutional structures for patient safety (Somekh 2007)
	2004 Denmark: the Patient Safety Act includes a database collecting mandatory reports of adverse medical events (Health Systems in Transition. Denmark 2007)	
	2005 EU and Council of Europe independently issue recommendations on patient safety	
Approval of pharmaceuticals and medical devices	*1995 EU*: foundation of the European Agency for the Evaluation of Medicinal Products, later European Medicine Agency (EMA)	
Registration and licensing; revalidation	*1993 Netherlands*: the BIG (Individual Health Professions Act) activates medical revalidation	
	2008 UK: The Report of the Chief Medical Officer for England's Working Group sets the principles and next steps for implementing revalidation in the UK	
Quality in training and education	*1995 Belgium*: the RIZIV-INAMI (National Institute for Sickness and Disability Insurance) introduces a system of voluntary accreditation for physicians and dentists including training for the promotion of quality of care (Health Systems in Transition. Belgium 2010)	
	1996 Sweden: The SALAR (Swedish Association of Local Authorities and Regions) starts initiatives to promote the integration of quality into health professional education at all levels	
Health Technology Assessment	*1991 United Kingdom*: the Department of Health publishes the report on *Assessing the effects of health technologies* (Department of Health 1991)	Persisting West-East divide
	2006: Launch of EUnetHTA (European Network for Health Technology Assessment)	
Organizational and services level		
Organizational quality assessment schemes	*1987*: First publishing of the ISO 9000 series	
	1988: Initiation of the EFQM frameworks by 14 representatives of European multi-national companies, the European Commission and the European Organization for Quality.	
Clinical guidelines	*1988 Finland*: the Finnish Medical Society produces the first electronic guidelines for primary care (Kunnamo 2005)	
	1999 UK: creation of National Institute of Clinical Excellence (NICE)	
	2002 Germany: translation of clinical guidelines into the National Disease Management Programme. (Ollenschlager and Kopp 2007)	

Table 2 continued

Strategies	Landmarks	Open problems
Quality indicators	*1999 Denmark*: establishment of the National Indicators Project (www.nip.dk)	
	2000 Germany: foundation of the BQS-Instituut (Institute for Quality and Patient Safety) by insurances and multiple healthcare-related government agencies (BQS 2007)	
Peer review or visitation	*1967 Netherlands*: first introduction of the "visitatie" model in teaching hospital (Klazinga 2000)	Only used in the Netherlands, UK and Slovenia
	1980s Netherlands: frameworks for visitation developed by associations of specialists	
	2011 Netherlands: visitation becomes compulsory for General Practitioners	
Surveys on health care users and the public	*1973*: The European Commission sets up the Eurobarometer as a means of conducting surveys of public opinion.	Eastern Europe (Poland, Slovakia, Slovenia, Romania) displaying dynamism (CPSS 2007)
	2002 UK: the Department of Health initiates the National Patient Survey programme (www.nhssurveys.org)	

Source: Authors' elaboration on Assuring the Quality of Health Care in the European Union. A Case for Action. European Observatory on Health Systems and Policies 2008

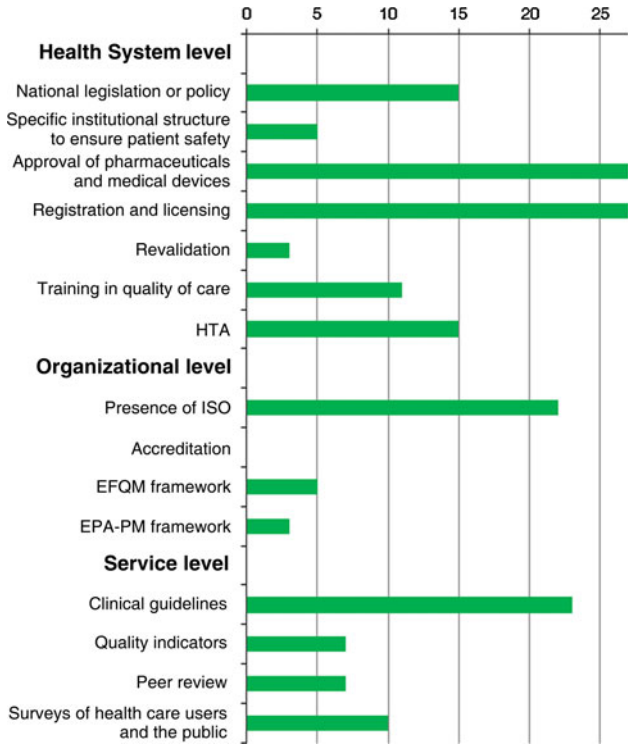

Fig. 1 Diffusion of approaches to quality assurance in health care in the EU-27. The diagram shows the number of countries adopting each approach to quality assurance in healthcare. Approaches to accreditation lack homogeneity and cannot thus be compared. *Source* Authors' elaboration from Assuring the Quality of Health Care in the European Union. A Case for Action. European Observatory on Health Systems and Policies 2008

danger of "drugs and techniques of uncertain efficacy and unclear adverse event profiles" and call on "research on effectiveness". The diffusion of quality assurance practices and the main historical landmarks in the process are summarized, respectively, in Table 2 and Fig. 1.

Definition and enforcement of patients' rights

Quality is almost always mentioned in documents and law provisions specifying patients' rights. In most European countries, patients' rights are formally defined in some way at the national level, except for Ireland, Sweden and Switzerland. In most countries (but, notably, not always in central-northern Europe), an obligation exists for hospitals to have a patient desk to register patients' complaints, and all except Denmark and the Netherlands have an Ombudsman investigating patients' complaints.

It has been observed that a requirement for guarantees on patients' rights and guidelines to effectively exert pressure toward quality is the possibility of suing them as basis for legal action, in the form of a torts system or class actions (Hulst 1999). In this respect, in all countries but Finland, Iceland and the Slovak Republic, patients can seek redress in courts in case of medical errors, and almost everywhere class action is possible against health providers and pharmaceutical companies. Denmark is an extreme case, in that health providers' liability does not even have to be proven to grant indemnification to the victim, but can be "presumed" under certain conditions. There is also a

basis for "no fault compensation" in a number of countries, including Austria, France and the Scandinavian countries: patients may obtain compensation even when the adverse outcome was not predictable according to the state of medical knowledge.

The attempts to include patients' representatives at the decision-making level has involved the field of quality as well, but is still an exception. Patient are represented in health technology assessment bodies in Australia, Denmark, Norway and the United Kingdom; in hospital planning in Denmark, Iceland, Norway and the United Kingdom and in the definition of public health objectives in Denmark, France (through regional consultations on public health), Hungary, Iceland, Norway, Portugal, and the United Kingdom. The significance of involvement of the public in processes pertaining to quality assurance can be better appreciated if two aspects are considered. From the legal and ethical standpoint, with a view to ensuring the right to health care, it represents the only possible solution for the proper consideration of *all sectors of society*, as well as for shifting to the stakeholder approach in healthcare. From the practical and technical viewpoint, with a view to maximizing the health status and patient satisfaction, it has been observed that a variation exists across cultures as regards what is "important" in healthcare: a further confirmation that solving the problem of what is quality requires individual values to be taken into account (Groenewegen et al. 2005).

Do these provisions match the Report's calls for "protection of patient rights and dignities" (Art. 85) and the "cooperation of all institutions and members of society" to improve "the quality of health care systems" (art. 88)? A comparison of the approaches to quality described here with the dimensions of quality addressed by the Report (see above) suggests that these policies might not be sufficient. The most developed strategies still seem to be in fact those that embrace a notion of quality as effectiveness and cost-effectiveness, and that can thus be referred to an utilitarian ethical framework, while those that reflect a communitarian approach—such as the inclusive and collective character of decisions—or a liberal one—such as provisions to ensure the respect of individual freedom—are still limited; yet, a tendency of development in the latter direction does seem to exist.

Conclusion

Over the last two decades, the European health systems have shifted from the problem of ensuring health care to everybody to the problem of determining what healthcare—in scope and in depth—to ensure to every single patient. This has forced them to ponder, for the first time, what meaning they attach to the notion of minimum essential healthcare, and how to make the collocation of limited resources socially and ethically acceptable.

The reliance on technical dimensions such as effectivity and cost-effectivity that characterized priority-setting in Europe until the beginning of the Nineties reflected an attempt by policy-makers to avoid directly addressing ethical choices (Martin and Benatar 2008). Such an approach is only consistent with one ethical dimension at most, the utilitarian one, and incompletely so, as it does not necessarily take into account the aggregate gain of the population.

The subsequent evolution has seen the gradual diffusion of the notion of equality as implied by the principle of solidarity, both in terms of contractual/risk solidarity and in terms of humanitarian solidarity (Hoedemaekers and Dekkers 2003). This notion of equality represents a step forward relative to previously common forms of equality that did not explicitly reflect a clear ethical standpoint: for instance, the principle of "avoiding the worst outcome" typical of medical triage and the one of "avoiding undue burdens" that justifies the decision to exempt the immunocompromised from inoculation of some vaccines already contained elements of egalitarianism and solidarity, while the provision of services and public goods of vital importance to well-being implicitly reflected a communitarian viewpoint (Rhodes 2008).

In fact, egalitarianism and solidarity do not represent the only ethical perspective that has gained ground in this process. Many European States today appear to embrace the notion of self-determination of individual typical of liberalism and that of social functioning typical of communitarianism. The ongoing process should therefore be considered as a recognition by policy-makers and experts that considerations of value cannot be avoided when addressing the issue of resource allocation, priority setting and definition of essential care—a recognition long called for by literature in the discipline, in an attempt of which the UNESCO Report on Social Responsibility is but the most recent chapter (Hoedemaekers and Dekkers 2003).

The next step in this process, one called for by the UNESCO Report, will be shifting from a national to an international and from a European to a global perspective in the diffusion of good practices for ensuring respect of the individual choices and values of patients—a shift in perspective made necessary by the existing burden of health inequalities the next few decades will compel us to face.

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