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EDITORIAL

Improving health care systems by building 'more Europe'

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Health results from a combination of different factors, but society tends to believe that health care systems have the highest responsibility to provide the inputs needed to increase quality of life and survival, the two major variables that allow us to quantify such an abstract and multifactorial concept as health. Health care systems require human resources, scientific knowledge and technologies to yield the expected output. A system is, by definition, a set of organized elements that interact among themselves to achieve a given target. But, so far, the context within which the interaction of the elements of health care systems has taken place has been national (or in some cases regional), rather than supranational. And that is the crucial issue we would like to address in this text.

The organization of a national health system, in order to efficiently achieve its goals, should consider the organization of other neighboring systems, especially when the country belongs to an international structure such as the European Union (EU). So far, the Member States (MS) are competent to organize their own care systems, and the European Commission has mainly limited its directives to facilitate a common framework regarding a few aspects of the inputs related to health such as the supplementary protection certificates for extending the patent protection of technologies (mostly drugs and medical devices), the design of the clinical trials for drug research, the creation of the European Medicaments Agency to assess the value of new drugs, and patient data protection issues. The mobility of human resources across countries is not yet straightforward in all countries, and we still lack an EU common title of medicine, for instance. Furthermore, the differences in access requirements that each health system has make difficult the provision of health care to those who are not citizens of a specific country, despite the fact that the majority of the European systems are mostly public.

To cope with all these issues several general policies are needed (educative, migratory as well as those related to the EU citizenship right to health care). These policies exceed the competence of the health departments of the MS and require a higher political consensus to be implemented. However, there are other policies that more directly belong to the area of influence of the health departments and could eventually be applied more easily. We will refer to them in the following paragraphs.

The target of efficiency, i.e., higher quality care for less cost, is aimed at by every system. New health technologies are continuously launched to markets and the systems incorporate them to improve the quality of their services. In the WHO document of Health for all in the year 2000 for the European region it was already clear that health systems had to perform assessments of new technologies to guarantee a good level of quality and efficiency. Accordingly, EU national systems implemented assessment mechanisms and created many agencies to analyze the value and characteristics of health technologies (national, regional, specific for drugs, general for all technologies, etc.). Contingent to the results of the assessments, health technologies are priced and reimbursed in some countries, are positioned in the treatments algorithm in others and, finally, are prescribed or restricted in health care centers depending on each jurisdiction too. However, the assessment processes and methods, and the influence of their results in the health care systems deeply differ across regions and countries. As an example, the recent paper by

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Heintz et al. [1] of the European Union Network of Health Technology Assessment (EUnetHTA) highlighted that in the area of health economic evaluations there is more than one guideline per country in several MS, while seven of them have no guideline at all. From the 51 collected documents, Heintz noticed that "28 were developed primarily for pharmaceuticals while 19 for all type of technologies." Then, the question is: how can efficiency be understood and later be achieved if the methods to measure it vary across countries? Furthermore, how can the efficiency results obtained by one agency be shared by another agency if their methods differ? How much are health care systems paying to obtain results that end up having a limited application? Still, in spite of generating information about efficiency, the results of the agencies are not mandatory in many systems, but just informative, as stated in the quoted article. Some of these results are not only and specifically due to the direct strategies and actions of the assessment agencies—that in fact are integrated in a network (EUnetHTA) to share their results, experiences and so on—but also to the specific legal frameworks where these agencies operate. Unless harmonization of the processes and methods is achieved in this area, the efficiency related to the implementation of innovative health technologies will continue being a nice message more than a reality across countries.

As mentioned, the legal framework of each health care system conditions how efficiency can be achieved in the process of implementing health technologies, mostly those based on drugs and devices. However, there is also an important area whose implications for the provision of medical care are expected to be important: the case of personalized medicine and its related future changes in disease management [2]. The application of this type of medicine is based on tests that allow the classification of patients according to some criteria, and on the administration of treatments that better fit their needs. The recent advances in genetic tests have pushed ahead this way of understanding medical practice. In this area there is a confluence of ethical, legal, organizational, epidemiological, regulatory and insurance related issues together with the more basic clinical ones.

In recent research on this topic funded by the EU (Health-F2-2009-223533; FP7-Health-2007-B), we highlighted the high heterogeneity with regard to the way decisions related to the implementation of genetic tests were taken across the EU. We identified several decision levels (there were regulatory agencies—not coming only from a single health department but from other governmental bodies—with conflicts of interest and contradictory messages whose tasks frequently overlapped), and we also observed that decisions were taken without almost any specific approval or control (i.e., just a laboratory in a hospital decided to implement a technique whose results were used by a given specialist within that center, and that technique was introduced without further considerations). We also noticed that depending on the structure of the health system, there existed special agencies dealing with regulatory issues for genetic testing approval and reimbursement. Another finding of that research was that economic assessments were scarcely applied for most of the techniques, although those whose purpose was population screening had usually been assessed in some way. Furthermore, the utilization of the tests varied among countries, some of them being mostly used for screening or alternatively as a part of the therapy based on drugs (pharmacogenetics).

We believe that the learning process derived from genetic identification is seldom shared among jurisdictions given the specific legal frameworks of each country or region. Hence, improvement in this area is more complex than initially anticipated and, again, there are efficiency losses.

Research on health technologies requires more and more big efforts to obtain powered statistical samples so that the conclusions are significant and sound. That requirement applies to drug research and in general to any other health technology. Taking the case of drugs, the crucial elements of their development are efficacy and safety. Multinational studies are commonly undertaken to analyze these issues; that requires a lot of administrative work to obtain the permissions from several national and regional legal and ethical committees, work that in the case of some decentralized countries, such as Spain, grows exponentially. In addition to these permissions, the design of the contracts signed with the research centers (usually hospitals) also requires further efforts as well as time delays. As a consequence, research costs rise and so do the prices requested by the manufacturers to reward their research and development. Our health systems are the intermediate payers because at the end of the process, the citizens/patients are the final bearers of that burden. To make these processes simpler and more harmonized, there have been two important pieces of legislation (Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 "On the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use"; and Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 "On clinical trials on medicinal products for human use"). The legal form of the latter implies that MS are obliged to apply this norm and modify, if needed, their national rules in this area. As a result, some simplifications have been produced, but still the MS are in the process of adapting the European legislation, of deciding on some organizational issues that still are left by the EU regulation to each country and, more

importantly, of updating the routine practices to finally implement the legal changes. Probably, the negative impact of the legal complexity on the economic benefits of the European pharmaceutical firms and their loss of competitiveness versus the American and Japanese laboratories made them pursue the intent of unification.

Furthermore, in this area of access to drug innovations, the creation of the EMA (European Medicaments Agency) in 1993 was also an important landmark; it had the mandate of coordinating the national efforts to assess the value of new drugs as well as drug surveillance—among other goals—and also had the capacity of approving new drugs in the EU, contingent on the previous assessment. The EMA represents a cornerstone of European consolidation in the area of health care.

As we have summarized, when there is a clear group of interest and some potential efficiency gains from the harmonization processes can be achieved—and easily be appropriated by a specific group—some pressures appear—lobbies—and regulatory initiatives take place (e.g., supplementary patent protection for drugs, simplification and unification of protocols for clinical trials, centralized approval of new drugs, CE mark for medical devices, etc.). However, this is not the case for some other organizational processes where the potential winners are fuzzier, less coordinated, and where the efficiency gains cannot be easily appropriated by a single group of actors but by the society as a whole. This can be the case with patients across MS that do not have a clear legal status to be eligible for health care in each system. It is also the case with health technology assessment agencies whose outputs are not mandatorily applied to the introduction of new technologies, which leads to fewer incentives for harmonization; and with public health research and policies, where there is no clear beneficiary but just the general population.

We would like to reflect a little more on this latter element which is present in each health care system. Public health is, by its own nature, an abstract concept—the health of a community—that does not know defined boundaries. Environmental quality, pollution, labor health, transport, nutrition, transmissible diseases, water supplies, genetics, and similar elements easily travel across countries, becoming crucial inputs for this intersectoral and multifactorial outcome that is our health. However, there are many actors in each one of these aforementioned areas having different and frequently conflicting interests, making it difficult to lobby in one strategic way, so that a clear regulation—perhaps resulting in loss of some national sovereignty—would yield improvements in public health and, consequently, in the efficiency of the health care systems. For instance, it is quite eloquent that the EU still lacks a European Institute of Public Health (it is not even expected) that should coordinate the initiatives in this area and perhaps, going further, orientate research and establish policies to promote better health for European citizens.

Again, without clear decisions in the area of public health, we are condemned to waste our apparently abundant resources in multiple coordination meetings at the EU level besides national and regional ones; similarly, regulations commonly overlap across the stakeholders, reducing the efficiency of the policies. The last recent examples of the Ebola crisis and Zika infection highlighted the shortages in the area of public health when facing a common enemy—in spite of all countries being transitorily united against the virus. We should also be aware that the growing mobility of EU citizens and migrants reinforces the necessity of better coordination of the involved still-national public health policies to prevent transmissible diseases from being spread out across Europe. These sporadic advertences of our pitfalls should be understood as nice warnings in favor of adopting a more aggressive, effective and efficient approach in this area of public health.

In summary, the construction of Europe has important implications in the efficiency of the national health care systems. There are clear areas related to information, considered as a public good, (e.g., information on the efficiency of technologies and their surveillance), to research on innovative technologies and to public health issues, where 'more Europe' clearly means more health at a lower cost. There are some other areas where 'more Europe' means simplification of health care management and more comfort for citizens, since an EU citizenship regulation could allow health care to be received across countries without as much bureaucracy as at the moment; and from the simplification of some requirements, such as the implementation of a common and unique European medical university degree that would facilitate working in any European national health care system. Finally, there are other areas where 'more Europe' would widen the reference context for knowledge exchange, data sharing from clinicians, institutions and patients, so that improvements in science and health management could be more efficiently achieved.

References

1. Heintz, E., Gerber-Grote, A., Ghabri, S., Hamers, F., Prevolnik-Rupel, V., Slabe-Erker, R., et al.: Is there a European view on health economic evaluations? Results from a synopsis of methodological guidelines usd in the EUnetHTA partner countries. Pharmacoeconomics **34**, 59–76 (2016)
2. Antoñanzas, F., Rodríguez, R., Juárez, C.: Is personalized medicine a panacea for health management? Some thoughts on its desirability. Eur J Health Econ **16**, 455–457 (2015)