EDITORIAL



Seeking efficiency gains outside drugs and diagnostics

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The tsunami of the COVID pandemic has shown more clearly some of the pitfalls of health care systems and processes in the effective and efficient management of patients. New pharmaceuticals for complex diseases, such as tumors and orphan conditions, provide improvements in progression free survival (PFS), many of them in the range of 2–5 months, and some even manage to show few additional months of overall survival (OS) [1]. These are two common metrics for assessing the therapeutic value of new products. When estimating the quality of life associated with these gains (the famous quality adjusted life year-QALY-used in many jurisdictions), the results are generally a little better than the simple PFS and OS outcomes, but still limited in the total amount of additional gain of QALYs. As the prices of new highly engineered molecules and other inhibitors used for these treatments are high, their cost-effectiveness ratios are becoming astronomical (easily over 100,000 euros per QALY).

Since the 1980s, health care systems have witnessed an increase in economic evaluations targeting new health technologies, namely new drugs, and, on fewer occasions, other technologies involving certain electronic devices or medical procedures [2, 3]. There are guidelines on how such evaluations must be made as well as several scientific journals that publish mostly this kind of studies. We have invested lot of resources in economic evaluations of medical interventions based on drugs and diagnostic procedures, to understand their efficiency. The information on the efficiency of new drugs is a helpful decision-making tool, such as in the cases of price and reimbursement, formulary inclusion, medical practice guidelines, and hospital protocols, among others [4].

Health care systems struggle in making decisions to reimburse new technologies and maintain the efficiency and equity of public health care, as they come under the increasing pressure of the industry providing new products; in some cases, there are many uncertainties about their added value with regard to the aforementioned metrics. As one target of health care systems is to increase the number or volume of QALYs provided to society, which is subject to yearly budgets, they should also seek to obtain QALYs from sources within their own systems, which are more affordable and easier to find.

According to the World Health Organization, health technology is "the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of life" [5]. Therefore, in a broad sense, health technology is also the organization and management of healthcare systems, hospitals, primary care, etc. However, the latter part of the definition of health technology has received little attention in the economic evaluation applied to the healthcare sector. Let us review some data to illustrate this point. In the last year, only about 10% of the systematic reviews of cost-effectiveness studies concerned the evaluation of management alternatives in the health system; the rest mainly belonged to the area of drugs (according to an ad hoc search performed by the authors of this article). There hasn't been an in-depth analysis of the reasons for the scarce volume of care organization assessments. One of these reasons may be the absence of stakeholders interested in understanding the efficiency of new ways to organize and manage healthcare systems and processes. An additional reason may be the lack of commercial interests behind new managerial technologies that would benefit from the results of economic evaluation, as compared to what happens with drug companies and device manufacturers, for instance. There are also difficulties in identifying resources and health outcomes of new organizational technologies, and a lack of

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clear guidelines for their evaluation, as they are not based on tangible products (i.e., drugs and devices). Moreover, the time frame or time horizon of these technologies may be rather fuzzy.

Diagnostic process

For many diseases, the case of diagnostic process is paradigmatic. As we know, clinical drug efficacy trials impose strict entry criteria. Recruited patients have already a well-defined diagnosis and the therapies are tested versus other options of care, or just a placebo. Next, through data analysis, we may obtain the knowledge that product X is superior to a placebo by a certain number of months of incremental OS. Such a result may lead to the prescription of product X to patients whose characteristics are similar to those who participated in the trial, with the expectation of achieving similar health outcomes. However, in real world medical practice, there is something missing from this analysis, which is the integration of the entire time from when patients experience the initial symptoms that trigger their decision to seek medical care up to when they are cured, or they die. Nowadays, more complex conditions are identified, and the taxonomy of the diagnosis has become more accurate and specific [6]. For example, some decades ago, it was just lung cancer, but now it must be classified by cell size, squamous type, staging, and other biomarkers, which will yield a more specific diagnosis to better target new therapies. Therefore, say a patient comes down with a chronic cough, the time between their first visit with a general practitioner and the final cancer diagnosis can easily take 4 months. To an external observer, this could seem like quite a long time, but it can be considered normal for a health care system. A patient is initially attended by the general practitioner. Should the cough persist, the doctor may prescribe X-rays in a second visit. This may take another week. Biochemistry and microbiologic tests could also be prescribed. In the meantime, the primary doctor would refer the patient to a specialist for a visit at a hospital. This may take days and even weeks to schedule, as there are long waiting lists all over the system. Subsequently, sophisticated imaging procedures such as a CT scan and MRI may be prescribed by hospital consultants who may be part of the process. By the time a biopsy is ordered and removed, and the results are obtained, a few months may have gone by. If a Positron Emission Tomography is advised, even more time will be needed, as this is a time-consuming test and there are few machines available. Clinicians do their best to follow a stepwise process, as advised in the protocols, but the issue here is the timing of all these logistic steps, which is not indicated in the protocol but rather left up to the system management. By

the time a patient is ready to start on a therapy, the time window for a better response and health outcome could be closing. If such a patient lives in a rural area and their initial point of reference is a small county hospital, then everything will be even more cumbersome. They will need to be transferred to a regional hospital, which may not receive previous tests, as coordination between centers can be difficult, which means that some tests may need to be repeated, consuming even more valuable time.

These reflections have driven a lot of the research in the last decades, pointing out variations in the interval of time from request for primary care to start of treatment, across types of tumors and countries [7, 8]. Many of the research papers state that there is room for improvement, especially when it comes to patient management within health care systems!

Interestingly, several private clinics are doing good business in EU countries; some of them are affiliated centers in the US specialized in the fast diagnosis of complex conditions, because they know about the unmet needs of patients in their own countries. Some of these private clinics even promise they will take care of the whole process in as little as two weeks! At this speed, we would observe an immediate increase in both OS since diagnosis and QALY gain, of course, almost no matter what therapy is finally applied. However, these diagnostic processes, despite their being health technologies based on organizational tools, are rarely evaluated from an economic perspective, which would facilitate their adoption, as is the case for other technologies, such as pharmaceuticals. As a result, diagnostic processes seem to maintain their rather slow status quo.

Cataract surgery

Again, the goal of better societal welfare and a longer and higher quality of life can be achieved by identifying other areas where modifying management could facilitate their implementation. We can see examples in some diseases that characterize an aging society. When we consider cataract surgery, we think of the elderly, and the problems they encounter as vision becomes weaker; they become more easily dependent, cannot drive or even walk without major risks, read or watch tv, and become more isolated and scared of potential blindness. In other words, if we apply the EQ-5D, several dimensions are directly affected by this sight problem, where effective technologies already exist. As Jain et al. [9] showed, QALY gains from a surgical operation are around 2.25, which is quite an attractive figure when it does not involve prolonging survival. The question is how long it takes before it is performed. There is no doubt about efficiency; some review studies [10, 11] showed cost-utility ratios between 200 and 20,000 USD; nonetheless, time is of great importance, and more QALYs could easily be obtained. Some public health care systems have long waiting lists for this non-urgent procedure, which implies a reduction of the potential welfare gains. Nowadays, the QALY gains obtained from this easy kind of surgery are likely superior to the gains achieved by sophisticated therapies in some disease areas such as oncology, which often at the time of launching only show a few months of PFS, non-inferior quality of life, compared to placebo and, rarely, data on OS, thus, yielding limited QALY gains.

What to do

Naturally, we cannot correct all these processes at once. We should identify the areas where significant QALY gains can be achieved, in both the diagnostic process and the implementation of therapies. There is a huge area of managerial health technologies that is still waiting for economic evaluation to shed light on their efficiency. This is the case for most of the changes in health care organization. We anticipate that the potential health gains are much greater than for many new and sophisticated technologies based on drugs and other devices. We observe that the target population of these managerial technologies will involve millions of people. If we really believe that efficiency matters, we cannot focus on scrutinizing the costs and outcomes of only one kind of health technology, overlooking other managerial innovations that are accepted without any assessment, or worse, with a simple budget impact analysis that fails to study the results in terms of health. Such an economic evaluation could support needed changes, sometimes requiring only additional specialized staff rather than more advanced drugs, when the latter may be used as a last resource to offset previous delays.

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