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Sustainability of the Health System: Beyond Cost-effectiveness Analyses



Sostenibilidad del sistema sanitario: más allá de los análisis de coste-efectividad

To the Editor,

We have read the editorial on cost-effectiveness analysis by Campillo-Artero and Ortún¹ with great interest and are in complete agreement with their views. Spain can boast of a universal public health care system; although its major drawback may be the sometimes long waiting lists, the level of training of its professionals is excellent and they have access to technology comparable to that of any of the leading countries. However, alarms are beginning to be sounded with regard to its sustainability. The authors propose analysis of its cost effectiveness along the lines of the appropriate use criteria (AUC)² being developed in the United States and Japan. Together with the measure outlined by Campillo-Artero and Ortún,¹ the present situation demands additional actions.

The pharmaceutical industry and device manufacturers are essential in the design of the technology without which we would be unable to work. In cardiology, both have provided advances that have often been extrapolated directly to other specialties, such as vascular surgery or neurology. Moreover, the industry has always sustained our continuing education, which is especially important in Spain because of the always insufficient funding inherent in a system of universal coverage. The opportunity cost model implies that the needs of patient care limit public funding for continuing education. Thus, for us, support for this training is considered necessary. In addition, we should not overlook the growing tendency to channel investment toward other more profitable sectors, such as cancer drug development.³

We feel that sustainability requires an understanding between authorities, health professionals, and industry. In this respect, we believe that there is room for improvement in the application of study results and how they are reflected in clinical practice guidelines. A class I recommendation must be supported by randomized studies and meta-analyses and, according to evidence-based medicine, post hoc analyses only serve to generate hypotheses for a future study, which often is not carried out because, once the main outcome of the core trial is obtained, the sponsor's interest disappears. However, we should not lose sight of the fact that the guidelines should never contemplate costs, since health systems differ widely from one country to another; moreover, some patients might want to pay for their treatment, regardless of the cost.

The truth is that the public health system is often unable to fund treatment for every class I indication (in fact, it is probably not cost-effective in all of them), and that is where tensions arise. On the one hand, the manufacturer's marketing department defends this class I indication, regardless of the number of patients needed to treat to prevent one event; on the other hand, some professionals defend this universal indication, at times, too adamantly, which stands in the way of communication with the administration, which becomes impervious to the opinion of the physician. Moreover, managers usually take a short-term view, depending on the political system at the time, and consider the request for therapy only in economic terms. This usually generates rejection of the new treatment and of its advocates, including the refusal of or delay in its acquisition.

Keeping in mind that the purpose of guidelines is not to deal with economic aspects, we feel that the solution requires understanding among the 3 stakeholders. First, marketing departments should understand the situation and not design strategies based on achieving treatment for every patient and, second, as professionals, we should make the administration's job easier by promoting therapies and innovations in the subgroups that could derive the most benefit from them and limiting them in the rest.⁴ Finally, if this all comes about, the administration itself should acknowledge these actions and take a more technical and long-term view. This is the only way to achieve a rational use of the available therapies. In fact, given that the major cause of drug failure in the cardiovascular setting is not a lack of safety or efficacy, but of commercial viability,³ an agreement could be reached with the administration regarding a more cost-effective penetration, but in exchange for an extension of the patent to make it easier for the manufacturer to make a profit. In cardiology, we should learn the recent lesson concerning the new antiplatelet agents, in which there are wide differences among the Spanish autonomous communities in terms of the indications and funding, because history could repeat itself with the arrival of PCSK9 and LCZ696 for heart failure.

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Sustainability of the Health System: Beyond Cost-effectiveness Analyses. Response



Sostenibilidad del sistema sanitario: más allá de los análisis de coste-efectividad. Respuesta

To the Editor,

We appreciate and agree with the letter of Lozano et al, and take advantage of their use of zoom to join them in their insistence on the sustainability of the Spanish health system beyond cost-effectiveness analysis, one of the tools that have been shown to help preserve it. Let's forget for the moment that Spain is the only important European country that does not use economic evaluation, even for large investments, and let's think in terms of "continuous evaluation". This would involve a system of benchmarking, with price regulation, and public funding that would gradually stimulate those centers with better results. It would be a way to integrate evaluation into the public management circuit: budgeting, implementation, evaluation...

An agreement among health professionals, industry, and administrators is unquestionably necessary. The professionals have a duty to their patients; administrators have to answer to everyone. Thus, given their preeminence, they must ensure that industry's innovation (there are many other types of innovation—including nonscientific, like the Spanish multinational Inditex or the Swedish Ikea—in processes and organization) occurs where the benefit in terms of quantity and quality of life will be greatest. For this purpose, mechanisms like value-based pricing seem to be adequate.

The maximization of social welfare requires prioritization, because the demand exceeds the resources in all sectors. Economic evaluation is useful in prioritization and has dispelled doubts concerning the well-being derived from social investment in education and training. It helps to indicate and finance innovations selectively and conditionally, and extend or restrict them on the basis of trials. There are a number of alternatives that can reinforce, and also replace, the current patent system.¹

For guidelines to be viable and for them to *really* be used, they should be adapted to local determinants, including the costs of their recommendations. A translation along these lines is provided by a number of sources, for example, the fundamentals of InnovaSEC^{2,3} or a recent and irrefutable editorial of the European Society of Medical Oncology (ESMO): "Leaving the pricing-efficacy

of cancer drugs out of the equation (the ESMO clinical benefit scale) is no longer an option".⁴ The unaffordable is not done or undertaken if it reduces the well-being of the general public.

More technical and longer-term criteria are also necessary. It suffices to mention any structural change: even the apparently slightest interventions (surgical checklist, hand hygiene) require an institutional change (in rules of the game and values).

To increase the quality of the public administration (health care included) in Spain demands an improvement in our politics, starting, for example, with a new law regarding political parties. Meanwhile, we should prepare to weather the storm.

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