OPINION ARTICLE

Should efficacy be the prevailing criterion to create clinical practice guidelines?

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Undoubtedly, the appearance of practice guidelines for the management of several diseases has been one of the greatest advances in current medicine. In this sense, vascular medicine has been a pioneer. The advent of the evidence-based medicine paradigm has provided us a scientific basis to define the robustness of various diagnostic and therapeutic procedures and has made it possible to determine objective levels of recommendations. Up to the present, efficacy and safety have been the principal criteria used to classify a procedure, al least at our environment. Let us take the example of a pharmaceutical product X for the treatment of hypertension. Firstly, we would like to know if X really reduces blood pressure and to what extension; this defines the efficacy of X. Secondly, we would be like to recognize the impacts of X in terms of clinical endpoints (death, prevention of major cardiovascular events, etc.). In this sense we shall assess the type and amount of articles published about X and its outcomes. Then we shall deal with X's safety, adverse events and drug interactions. Once all this information is available, we shall finally propose if the use of the drug X for the treatment of hypertension has a grade of recommendation I, II or III with a level of evidence a, b or c.

Up to now we have made a brief description of the process of weighting the scientific evidence necessary to make a recommendation. Curiously, costs and preferences are not taken into account during the process of assessing the evidence, although they are two fundamental aspects at the moment of putting in practice a diagnostic or therapeutic procedure. Therefore, the question of the title of the present article arises: should efficacy be the prevailing criterion to create clinical practice guidelines? According to what has been previously mentioned, the answer should be affirmative. The statement "as physicians, we should only take care of the effects of the drug; anything else is a problem of those who pay for it", has been invariably invocated. Nevertheless, a superficial analysis of this issue might lead us to another answer. Most governments are worried about the number and the preference of use of health resources. Yet, many forums and scientific societies, responsible of making practice guidelines, do not seem to consider the impact in health costs their proposals imply. Can the real possibilities to clear the expenses related to a certain treatment or practice be ignored? Let us suppose that X has a recommendation level Ia for the treatment of hypertension. Would it be justifiable to recommend X if its cost was high? Is X better tolerated or preferred by hypertensive populations? Does X have any influence in patients' quality of life? If a physician or a health system do not prescribe X to their patients, are they committing some degree of malpractice?

These questions may only be answered with certain previous information, such as the costs of X, patients' preference among antihypertensive drugs and how quality of life is modified. Two sources of information are potentially useful. Firstly, data on pharmacological and economical studies, and studies on quality of life (cost-effectiveness and cost-benefit analysis) published in the international literature will enable us to reach an approach. Nevertheless, the most relevant information comes from our population. In this case, bibliographic research will result almost null.

In Scotland, Glasgow's Health System is an example of the importance of these aspects. In 2004, experts from the National Health System Great Glasgow established drug recommendations for different conditions based on "clinical effectiveness, cost-effectiveness, safety and patients' acceptance". Based on these criteria, Glasgow's Health System recommended primary prevention with statins in patients with an estimated 10 year-absolute risk of 30% or greater. (2) By the same time, the recommendation of the Adult Treatment Panel III of the National Cholesterol Education Programme, USA, for primary prevention, was therapy with statins in subjects with an estimated risk of 20% or greater, taking into consideration the same aspects related to clinical efficacy and effectiveness, safety and cost-effectiveness. (3) Is there any valid explanation for such a discrepancy? Initially, it is possible to think that each health administration adopted a cut-point according to their clinical and financial needs. Each country defined the amount of resources that could be assigned for the treatment of dyslipemia, based on their priorities.

Many members of the medical community consider that the introduction of economical variables and patients' preferences in the process of guidelines or consensus making is a taboo. Nevertheless, as and old aphorism used by the economists states "society has unlimited wants and needs, but limited resources". This represents a challenge for the experts invited by our Society to write a Consensus. The regulations of the Committee on Standardization and Consensus establish that the objectives of the Consensus are "…to support the rationale use of diagnostic and

therapeutic resources, optimizing the quality of health care…", "…to develop guidelines and establish the standards for clinical follow-up, prognosis assessment and the choice of the appropriate treatment…"and finally "…as these guidelines will not be dogmatic, but rather flexible and directed towards the argentine cardiology community, *they should adjust to the current conditions of planning, availability and use of diagnostic and therapeutic resources in our country"*. This last issue should probably be taken into account more extensively in a near future. Recommendation guidelines based on clinical effectiveness do not explain how to assign resources in health. (4) That is why it would be appropriate to include this analysis in the consensus. International information will initially prevail until national data are more developed. In this sense it would be important if our Society, a pioneer in several aspects, starts searching for information related to cost-effectiveness and, most of all, to cost-benefit, including quality of life as a central element in decision-making.

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