



## Editorial

### Patient Reported Outcome Measures: What Is Their Importance?☆

### Medidas de desenlace reportadas por el paciente: ¿cuál es su importancia?

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The broad concept of patient reported outcome measures (PROM) includes measurements reported by those who have a disease. These cover a spectrum that ranges from evaluating symptoms, adherence to treatment, functional capacity, health status and quality of life to quality of care aspects.<sup>1</sup>

In the mid 1970s a movement began to include the perspective of the patient as part of the necessary assessments to determine the health of people. In the beginning, this concern arose because of differences between administrators and those who made decisions regarding health.<sup>2</sup> The medical center was supposed to be a patient center environment, taking into account the family context. PROM is a journey from the administrative to the true essence of clinical work. It is also an ethical dimension that attempts to incorporate the patient's perspective in assessing health.<sup>3</sup> Therefore, at least two fundamental questions arise: who can better assess the patient health and disease status and the changes they both suffer, and in the end, who makes decisions about the patient's health?

#### Models of Patient Care

There are two models that have dominated health care in recent decades. On the one hand, the medical model, which is characterized by a paternalistic behavior, with the physician conceived as an expert, where obtaining patient information in conjunction with biomedical knowledge will lead to a correct diagnosis and appropriate treatment. On the other hand, the patient-centered model is presented as a dialogue between doctor and patient. The main objective of this model is to take into account the patient's experience to gain a better understanding of the fears, expectations, thoughts, beliefs and socio-cultural context in which the illness and decision-making by the patient and their families are carried out.<sup>4</sup> Listening to the patient's voice is useful to build outcome measures that integrate both models. These movements are reflected in the development of outcome measures as evidence in clinical practice, as well as the so-called evidence-based medicine. This movement is closer to the model focused on biomedicine, and a small part

includes measures from the patient's perspective, though with little representation has provoked fierce criticism.<sup>5,6</sup> There is also alternative and complementary medicine movement based on narratives, which raises and gets to know the patient's perspective from a more humanistic approach and a methodology that tends more toward quality than to quantification.<sup>7-9</sup>

These positions are not without problems and limitations, so several questions have been identified. The skepticism regarding the clinical use of PROM has led to criticism of the value of a standardized and written measurement and led to the direct question of how to make the patients assess their health status. It has objected to the comparison of the numerical scale selected by the patient to an evolution parameter (pain, for example), and the patient's narrative. The dilemma seems reasonable, but PROM possibly takes the results to a level that allows for comparison between patient groups regarding the benefits and risks of medical interventions. This information would be useful for the doctors, both in their daily practice in the evaluation of different interventions (whether routine or new) and in the daily exercise of their profession. The measurement does not replace or minimize the patient's narrative on their health; rather what occurs is an objectification of a subjective patient.<sup>2</sup>

There is another important issue. This is related to difficulties in performing these measurements in daily practice, given the time constraints determined by the health system for medical care. In addition, the problems with the use of patient time to complete the questionnaires related to PROM that this activity entails. It also involves the difficulty of filling, qualifying and managing the resulting information. The latter implies the need to acquaint both the clinician and the patient with the filling of the questionnaires.

Based on the above, we highlight the importance of PROM at different levels.

Clinically, including the patient in a drug PROM allows more participation by including all those affected in the clinical act, that is, the doctor, patient and family members. Medicine has probably forgotten its reason of existence, the patients and their well-being, focusing on objectifying clinical practice, that is, favoring the measurement, only considering the perspective of the physician as an "expert", and ignoring the patient. By involving the patient's perspective, as well as the measurement, we begin to be complementary, also promoting a more comprehensive evaluation of the clinical event. Thus, the information verbalized by the patient

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during the clinical consultation is complemented by the standardized measurement of outcomes from the perspective of patient and physician. Having these different measurements enables better decision-making by participants.<sup>10</sup>

There has been improvement from the level of clinical research, with improved PROM measuring the impact of the disease from the perspective of the sufferer. In this way it is possible to assess whether new health interventions are effective and efficient for the core of clinical care, the patient. This takes into account not only the evaluation by the physician. This comprehensive assessment measures, among other things, regional and ethnic differences of the different groups involved in clinical trials. Furthermore, the development of the PROM must follow a combined approach. That is, through qualitative studies and impact assessment of the disease it should begin with methods to get the concepts, ideas, values and/or beliefs of patients and families. In a next step, this information will allow the development of instruments that meet these criteria, and psychometric measures allowing accurate measurement (quantitative study) in different populations.<sup>10,11</sup>

These aspects have been considered in guidelines for the development of measures from the perspective of the patient for drug approval authorities (Food and Drug Administration).<sup>10</sup> This means that researchers from different disciplines (clinical researchers, statisticians and researchers in psychosocial areas) can collaborate for the development of these measurements. In addition to the above, it has been reported that PROM assessment may be influenced by the sociocultural context of the patient, the shape and location of the application of questionnaires, by the familiarity of patients in answering these questionnaires and by the relationship they may have with the clinician–researcher (unlike ethnic, socioeconomic, gender and other aspects).<sup>2,12</sup> Nothing is free from bias (measurement errors). However, the act of looking at different measures together would reduce biases inherent in each of them separately.

From an ethical perspective, PROM offer elements to reinforce the idea of patient autonomy and beneficence by the physician through improved communication and decision making. It also allows the opportunity to assess the welfare of the patient from his or her own perspective and from the doctors. It also supports the idea that by identifying improvements or opportunities for improvement of care, it is contributing to a better quality of care and comply with the fundamental ethical precept of “no harm”.<sup>2,4</sup>

At the decision-making and health policymaking levels, there are reports that indicate the efforts of governments of developed countries to have these patient derived outcome measures. It is important that these publications are available for the general population, as is the case of Patient Reported Outcomes Measurement Information System (PROMIS) (available at:

[www.nihpromis.org/default.aspx](http://www.nihpromis.org/default.aspx)). PROMIS is an effort by the National Institutes of Health of the United States of America. It aims to provide the clinician and the researcher with measures of health outcomes and well being from the perspective of patients. These measures should be valid, reproducible, flexible and inclusive. In the UK there is NICE (National Institute of Clinical Excellence). It is an independent institution that has among its objectives to provide the patient, health professionals and the general public a guide to the best available medical practice. The guides include quantitative information, which dominated its creation in 1999—but in recent years, these guidelines are recommendations based on both quantitative and qualitative studies. The latter aims to take into account at the same time the prospects of the patient and society.<sup>1</sup>

To summarize, we conclude that PROM are critical, relevant, and complementary in doctor–patient interaction. It is also important to highlight that it is fundamental to know the information that the patient expressed in clinical practice. This information is necessary for making decisions on their treatment and/or on new interventions that go beyond the clinical act, which implies integrating social and political decision making in relation to health.

### Conflict of Interest

The author declares no conflicts of interest.

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