

# BiblioPRO: Online Library of Patient-Reported Outcomes in Spanish

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## Abstract

Patient-Reported Outcomes (PRO) have become important indicators in clinical and public health research. Most instruments had been developed in English-speaking countries. Cultural adaptations and new instruments are now available. *BiblioPRO* is an online repository of PRO measures in Spanish; its main goal is to promote an adequate use of these instruments in research and practice. It provides exhaustive online information, evidence-based evaluations, and educational training. This paper presents a description of *BiblioPRO* activities and the scientific bases supporting them. The importance of respect due to intellectual property and the opportunities of initiatives like *BiblioPRO* for patient-centred health services are discussed.

Health-related quality of life (HRQL) measurement was introduced in clinical research in the late 1940s. By the mid-1970s a number of major instruments were already developed and tested, some of which are still in use. Their use was on the rise and it extended to public health and policy research. With the flourishing of health outcomes research in the 1990s, the number of instruments exploded.<sup>1</sup> While most HRQL instruments had initially been developed in the US, Great Britain, or Canada, internationalization soon arrived and many instruments were then adapted for use in many different countries<sup>2</sup> and

many others were originally developed internationally.<sup>3</sup>

The early vision that a continuously updated repository of HRQL instruments was necessary originated in the US National Center for Health Statistics, where Pennifer Erickson led the Clearinghouse on Health Indexes. An initial publication of "Cumulated Annotations, October 1973-December 1974" was published in January 1976 (<http://www.cdc.gov/nchs/products/clearinghouse.htm>)<sup>4</sup> and it was continued to be published until the mid-1990s. At that time, an important but transient initiative for promoting the use of PROs was carried out by the Medical Outcomes Trust (MOT) in the US (<http://www.outcomes-trust.org/>).<sup>5</sup>

More recently, a major database "Patient-Reported Outcome and Quality of life Instruments Database" (PROQOLID), was jointly developed in 2005 by Marcello Tamburini (National Cancer Institute, Milan, Italy) and MAPI Research Trust ([http://www.proqolid.org/about\\_proqolid](http://www.proqolid.org/about_proqolid)).<sup>6</sup> Their objectives of providing an overview and relevant and updated information of existing PRO instruments, as well as to facilitate access to the instruments and their developers, have been clearly achieved.

The progressive incorporation of Spanish-speaking researchers to the field of HRQL, initially more evident in Spain but soon after in all of Latin America, has stimulated the interest

## KEYWORDS

PATIENT-REPORTED OUTCOMES, HEALTH-RELATED QUALITY OF LIFE, SPANISH, ONLINE ACCESS, INTELLECTUAL PROPERTY, TERMS OF USE

about PROs in Spanish. The increasing number of translations of instruments originally developed in other languages for use in Spanish-speaking societies prompted the need for a repository of instruments in Spanish.

## Objectives and services of BiblioPRO

*BiblioPRO* is an online library of Patient-Reported Outcome (PRO) measures in Spanish with the goal of promoting its adequate use in clinical research and practice by providing exhaustive information online, evidence-based evaluations, and offering specific educational training in this area. It was initially designed by investigators at the IMIM-Hospital del Mar Research Institute as a facility for responding to the increased demand for information about questionnaires that the research group had adapted or developed. It was in 2007 when the library was established for the first time in the context of a research network in public health (CIBERESP). In late 2011, *BiblioPRO* has launched a totally revised website (<http://www.bibliopro.org>).

The specific objectives of the library are: to identify all the currently available PRO measures in Spanish; to gather the maximum number of questionnaires together and make them available to the public in a free-access virtual library, allowing for the selection of the most appropriate instrument; and to facilitate respect to copyrights and all other legal requirements for the correct access and use of PRO instruments in Spanish. A multidisciplinary team of investigators in different Spanish institutions have formed a Scientific Committee that is in charge of making all relevant scientific decisions, while a technical project

manager and a scientific project manager run the day-to-day operation of the repository.

In order to achieve its objectives, the *BiblioPRO* website, whose language is exclusively Spanish, provides as much information about all Spanish PROs identified as possible: from basic information about the developers (both original and adaptation), to details and documents about the questionnaires, and, whenever possible, access to questionnaires, manuals and scoring and interpretation aids. For copyright holders, we offer the possibility of downloading their instrument without the users having to leave the website or to redirect users to a specific website in which to continue their transaction. The *BiblioPRO* website is prepared to handle payments as required by the copyright holder. The revised website has made every effort to make it very easy for users to navigate. Just clicking on the “questionnaire” icon starts the downloading process, which takes no more than two minutes to complete.

A crucial feature of *BiblioPRO* is an effective respect for copyright, a concept that is legally complex and differently understood in different settings.<sup>7</sup> Thus *BiblioPRO* is encouraging developers to allow their instruments to be distributed through the new website, without losing their copyright.

No registration is needed to access to *BiblioPRO*, except for the minority of instruments for which the copyright holders make registration mandatory. Registered users have access to an added functionality, "*My BiblioPRO*," from which they can keep track of their permissions of use, among other things. The Frequently Asked Questions section helps solving doubts related to the library and services. A Newsletter has been recently launched.

## Scientific bases of *BiblioPRO*

A number of scientific considerations make *BiblioPRO* a scientific-based resource. These include an exhaustive literature search to identify the entire list of instruments candidate for the repository; the classification system used; and the model for evaluating the performance of the instruments.

## Identification of candidate instruments (systematic search)

With the aim to identify all the existing Spanish PRO instruments, peer-reviewed systematic reviews are periodically performed using a sensitive search in PubMed.<sup>8</sup> A specific geographic filter search strategy is applied, as described elsewhere. Scientific documents about

the development of original PRO instruments in the Spanish language and Spanish versions of instruments originally developed in other languages are systematically searched for in three phases: (1) All titles are screened by at least two reviewers, with inconsistencies resolved by a third reviewer; (2) Review of abstracts and the entire document of all selected publications; and (3) Data extraction by experts in the development, assessment, and use of PRO measures.

Once identified and additional information and permissions are obtained from the authors and/or copyright holders, the new PRO instruments are included in the repository. For all of them, standardized technical specifications on eight key characteristics, together with contact information, are described. As

Figure 1.

*BiblioPRO*: example of a technical sheet for an instrument

SF-36v2, SF36v2, SF	Versión Española	Original
<b>Nombre</b>	Cuestionario de Salud SF-36	Medical Outcomes Study (MOS) 36-item Short Form
<b>Autor(es)</b>	Alonso J. y. QualityMetric	Ware JE
<b>Referencia</b>	Med Clin (Barc). 1995 May 27;104(20):771-6.	Med Care. 1992 Jun;30(6):473-83.
<b>Correspondencia</b>	Grupo de Investigación de Servicios Sanitarios (IMIM-Parc de Salut Mar). c/Dr. Aiguader, 88. 08003 Barcelona...	QualityMetric Inc. 24 Alblon Rd, Lincoln RI 02865, USA. 1-800-572-9394
<b>E-mail</b>	BiblioPRO@bibliopro.org	http://www.qualitymetric.com/tabid/174/Default.aspx
<b>Copyright</b>	QualityMetric	QualityMetric

  

### Características

<b>Conceptos medidos:</b> Calidad de Vida Relacionada con la Salud o Salud Percibida	<b>Nº de ítems:</b> 36
<b>Enfermedad:</b> Genérico o Cualquier Enfermedad	<b>Dimensiones:</b> 8 dimensiones: Función Física (10); Rol físico (4); Dolor corporal (2); Salud General (5); Vitalidad (4); Función Social (2); Rol Emocional (3) y 2 componentes sumarios (Físico y Mental)
<b>Población:</b> Todos los géneros	<b>Medidas:</b> Psicométrico
<b>Edades:</b> Adultos	<b>Palabras clave:</b> Quality Metric, SF, función física, mental, rol, dolor, salud general

  

### Descargas

Descripción	Cuestionario	Manual	Puntuación X <sup>3</sup>	Bibliografía	Enlaces	Evaluación EMPRO	Otros
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much as possible, additional downloadable documentation is also included: extended description, relevant bibliography, scoring description and calculation system, instrument's manual and/or population norms, and the questionnaire or the address for obtaining it. The layout of all this information appears in Figure 1, for the Health Survey Short Form (SF) as an example.

### A model-based classification system

Being the product of a research effort, *BiblioPRO* had to engage in the discussion and improvement of the conceptual basis and existing taxonomies for PROs. As a result, the platform developed a new, comprehensive classification system for PROs which is deeply rooted in two major contributions to this field, the Wilson and Cleary model for Quality of Life<sup>9</sup> and the International Classification of Functioning (ICF).<sup>10</sup> *BiblioPRO*'s classification system of PROs considers three major domains: the concepts/constructs measured, the target population, and the measurement model.<sup>11</sup> For the classification of concepts and constructs, the International Classification of Diseases (ICD-10) grouping is used (<http://apps.who.int/classifications/icd10/browse/2010>).<sup>12</sup> For the type of population, gender, age group, and culture are considered. And for measurement model, four categories are used: psychometric, econometric, clinimetric, and other types of instruments. This classification system is relatively simple as well as robust and useful. A user-friendly search engine was developed based on these classification specifications and it is incorporated into the procedure for locating the instruments.

As a result of both periodic systematic reviews and subsequent tasks that led to the final available content in the repository, *BiblioPRO* now includes

information on 524 Spanish PRO instruments. The last systematic review (covering the period of 2008-2010) has identified about 300 new instruments, for which we are actively collecting all the information and producing the final documents to be eventually available on the website.

Out of the 524 Spanish PRO instruments included in *BiblioPRO*, the most frequent one is health-related quality of life (52.1%), followed by symptoms (9.2%) and other health-related constructs (30.2%). It is interesting to point out that a large majority are disease-specific instruments (88.2%). Mental/behavioral health is the most frequent group of disorders (29.8%) followed by neoplasms (6.5%).

### Evaluation of PROs

Consistent with the objective of promoting an adequate use of instruments, the Scientific Committee of *BiblioPRO* addressed the issue of developing an evaluative framework for PROs. The starting point was the landmark summary recommendations made by the Scientific Advisory Committee of the Medical Outcomes Trust.<sup>13</sup> According to that recommendation, eight attributes should be reviewed: conceptual and measurement model, reliability, validity, sensibility to change, interpretability, burden of disease, administration mode, and cross-cultural and linguistic adaptations. In the case of Spanish PROs, the latter has particular importance.

From those principles, researchers engaged with *BiblioPRO* developed the Evaluating the Measurement of Patient-Reported Outcomes (EMPRO) tool, that allows applying the best-available evidence gained from the scientific method to clinical decision-making. The preliminary instrument was circulated to other researchers on the clarity of its content, comprehensiveness, and ease of use. Then, a final version, composed of 39 items, and a user's manual was

obtained.<sup>14</sup> The new EMPRO tool has shown good reliability and validity results.

For its application, a panel of two to four experts are asked to review all the documentation available for a given PRO, to minimize all possible bias. Disagreements are solved by consensus. Recently, an online application of the EMPRO has been developed. Reviewers are also asked to provide an overall recommendation of the assessed instrument. Clinicians and researchers may find such information useful when choosing among different instruments available for a specific application.

### Other scientific activities

As part of the scientific program of *BiblioPRO*, educational courses and specific training workshops for the use of EMPRO are held by its scientific committee members. Training workshops have provided a great opportunity to train evaluators who, when accredited, will be eligible to collaborate with the evaluations performed in *BiblioPRO*.

Finally, an important activity of this program is the *BiblioPRO* Scientific Meeting, which will be held on February 21, 2013 in Barcelona. We have invited all the Spanish authors, institutional and industry representatives of research services and research in this field. At this event, *BiblioPRO* will promote the possibilities of this new resource and the scientific discussion behind its development, adaptation, evaluation, and good practices in the use of PROs.

### Concluding remark

In this paper we have described *BiblioPRO*, an online repository of PRO measures in Spanish. The description of its objectives, services, and scientific activities should make clear the great opportunity that it represents for technological transfer in an era of patient-centred health services.

**For more information, please contact:**

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