Available online at www.sciencedirect.com

SciVerse ScienceDirect

journal homepage: www.elsevier.com/locate/jval

Health-Related Quality of Life Measurement in Children and Adolescents in Ibero-American Countries, 2000 to 2010

Luis Rajmil, MD, PhD[1,2,3,], Mariana Roizen, MD[4], Alfonso Urzúa, Psy, PhD[5], Carlos Hidalgo-Rasmussen, Psy, PhD[6], Gabriela Fernández, Psy[7], Juan José Dapueto, MD, PhD[7], and the Working Group on HRQOL in Children in Ibero-American Countries*

[1]*URSS, IMIM-Institut de Recerca Hospital del Mar, Barcelona, Spain;* [2]*Catalan Agency for Health Information, Assessment and Quality, Barcelona, Spain;* [3]*CIBER de Epidemiología y Salud Pública, Madrid, Spain;* [4]*Committee of Quality of Life, Bone Marrow Transplant, Hospital Garrahan, Buenos Aires, Argentina;* [5]*Psychology, Universidad Católica del Norte, Antofagasta, Chile;* [6]*South Universitary Center (CUsur), University of Guadalajara, Jalisco, Mexico;* [7]*Departamento de Psicología Médica de la Facultad de Medicina, Universidad de la República, Montevideo, Uruguay.*

A B S T R A C T

Objectives: To analyze the characteristics of instruments designed to assess the health-related quality of life (HRQOL) in children, developed or adapted from 2000 to 2010 in Argentina, Chile, Mexico, Spain, and Uruguay. **Methods:** The protocol-led literature review included database searching (e.g., Medline, ISI Science Citation Index) and manual searching to retrieve studies focused on measures of HRQOL, health status, or well-being addressed to children and adolescents. Country-specific filters were applied to identify studies carried out in the participating countries. The characteristics of the instruments and type of studies were analyzed. Descriptive characteristics and psychometric properties were analyzed following the guidelines of the Scientific Advisory Committee of the Medical Outcomes Trust. **Results:** Ninety-nine documents were included. Thirty-one questionnaires were identified, 24 instruments were adapted, and the psychometric properties of 20 HRQOL instruments were reported in the study period. There was substantial variability in the number and characteristics of the dimensions included. Reliability was generally acceptable, and the majority of instruments provided data on internal consistency (n = 18) and, to a lesser extent, on test-retest reliability (n = 12). Nearly all studies reported construct validity, but only four analyzed sensitivity to change. **Conclusions:** There is a scarcity of instruments to measure HRQOL of children and adolescents in the countries analyzed. Certain psychometric characteristics have been reasonably well tested, but others, most notably sensitivity to change, have not been tested in most instruments. Extension of this study to other Latin American countries would help to further identify gaps in this area and promote the use of HRQOL measurement in children and adolescents in Spanish-speaking cultures.

Keywords: adolescents, children, health-related quality of life, psychometric properties.

Introduction

There is a growing interest in assessing the health-related quality of life (HRQOL) in children and adolescents [1]1. Currently, there is no consensus regarding the theoretical framework and concepts to be measured for this purpose [2], which may include children's health status, QOL, HRQOL, satisfaction, and well-being. Nevertheless, a recent systematic review has identified nearly 100 generic and disease-specific instruments addressed to children and adolescents [3]. Most of these instruments have been developed in English-speaking cultures, whereas less attention has been paid to this area in Spanish-speaking countries and cultures. A previous systematic review of HRQOL instruments targeting children and adolescents published up to the year 2000 in Spain identified 15 generic and disease-specific instruments [4]. More than half the currently available instruments, however, were published after 2001 [3].

The advances in health care and health technology and rapid developments in the field of patient-reported outcome (PRO) measures imply a need to update and refine reviews of HRQOL instruments and their psychometric characteristics. These reviews would help researchers seeking to choose the best instrument for their needs and would serve as a means to promote the use of PRO instruments, especially in Spanish-speaking countries where their use is relatively recent. Moreover, cross-cultural issues should be taken into account when conducting multicenter and international studies using PRO instruments. Spanish-speaking countries include a population of approximately 450 hundred million individuals, with a high proportion of children and adolescents; hence, there is a clear need to determine the current status of available resources enabling HRQOL measurement in children living in these countries.

The objectives of this study were to analyze the characteristics of instruments designed to assess HRQOL in children, developed or adapted from 2000 to 2010 in Argentina, Chile, Mexico, Spain, and Uruguay; to describe the studies reporting HRQOL measures in children in the countries analyzed; and to propose recommenda-

* *Address correspondence to:* Luis Rajmil, Health Services Research Unit, IMIM-Institut de Recerca Hospital del Mar, Parc de Salut Mar, Barcelona Biomedical Research Park (Office 138.03), Doctor Aiguader, 88, E-08003 Barcelona, Spain.

E-mail: lrajmil@imim.es; lrajmil@aatrm.catsalut.cat.

1098-3015/$36.00 – see front matter

doi:10.1016/j.jval.2011.11.028

tions that will help improve the use and interpretation of HRQOL measures for children in Ibero-American countries.

Methods

The literature review included PubMed, ISI web of knowledge, specific Ibero-American databases such as Scielo or Bireme, abstracts from local congresses in the participating countries, manual searching of previously identified manuscripts, and previous reviews. The literature review was carried out according to a common protocol and central coordination process in Spain (L.R.). A database (Biblio-PRO, available at: http://bibliopro.imim.es/BiblioPRO.asp) containing a virtual library of outcome measures reported by Spanish patients was included for Spain.

To identify HRQOL instruments developed and/or published between January 2000 and July 2010, an original database search was carried out by using combinations of keywords such as "child" [MeSH] OR "adolescent" [MeSH] OR adolescent* OR child* OR teenage* [ti] OR kid* [ti] OR pediatr* OR pediatr* AND "questionnaires" [mh] NOT adult [mh] OR "health surveys" OR "quality of life" [majr] OR "quality of life" [ti] OR "health status" [majr] OR "health status" [ti] OR "functional status" [ti] OR "well being" [ti] OR "perceived health status." Age limits (0–18 years), language (Spanish, French, English, German), and filters for each country were also applied. The literature review strategy is available from the authors on request.

Inclusion and exclusion criteria

For a specific country to be included in the study, at least one researcher from the Ibero-American International Network on HRQOL in Children from the country in question had to be participating in the study. The dates to review were limited taking into account the previous Spanish review [4].

Documents were included if they reported on subjective measures intended to collect data on QOL, health status, well-being, or functional status in samples of children from the participating countries. Documents reporting the use of symptom checklists (e.g., regarding diet and nutrition, physical activity, psychiatric symptoms), editorials, and opinion articles were excluded, as well as those using instruments developed for the adult population, except when it was possible to analyze the children sample separately. Three researchers (M.R., A.U., and L.R.) conducted a pilot test analyzing the first 70 documents from PubMed. The number of documents included ranged from 5 to 7; 10 to 12 documents were classified as uncertain; and agreement (Kappa Index) was 0.45 to 0.71. A consensus process involving conference calls among the participating researchers was carried out to decide on inclusion/exclusion of each document.

Variables and analysis

Documents included were stratified according to the type of study in terms of its purpose regarding HRQOL measurement: initial development or adaptation of an instrument (forward and back translation followed by qualitative techniques such as cognitive interviews.), analysis of psychometric properties of a previously developed or adapted instrument, observational study using a previously validated instrument or a nonstandardized HRQOL measure, and interventional or experimental study.

Cultural and language adaptations and translations and the methods used to achieve conceptual equivalence were assessed. We recorded whether at least one forward and back translation had been performed and how differences between the original and translated versions were resolved. The extent of participation by the target population (cognitive debriefings) and differences and similarities relative to the population involved in the original development process were also assessed. Cross-cultural equivalence was scored as follows: 0, nonstandardized or incomplete process; 1, at least one forward and back translation and reconciliation; 2, previous process plus cognitive debriefing with target population; 3, full process including detailed explanations about differences relative to the original version and solutions given; 4, original version; and NA, not enough available information.

The following characteristics were analyzed from studies assessing an instrument's psychometric properties: country of origin, age range, type of respondent (child/adolescent self-report, parent/proxy, both), number of dimensions and items, psychometric properties (ceiling and floor effects, reliability, validity, sensitivity to change), and country in which the instrument was adapted or validated. Generic and disease-specific instruments are presented separately in the "Results" section. Different versions of the same instrument (e.g., versions for different age groups, short versions) were also considered, and their psychometric properties are summarized in the "Results" section. For each instrument included in this analysis, the psychometric properties of reliability, validity, and sensitivity to change were evaluated in accordance with recommendations in the scientific literature on the desirable characteristics of HRQOL instruments [5,6].

Reliability refers to the extent to which the instrument is free from random error, and it is usually assessed by measuring the scale's internal consistency and test-retest reliability [7]. *Internal consistency* refers to the fact that all items are homogeneous and measures specific aspects of a scale, while *test-retest reliability* refers to the reproducibility or stability over time of domain and overall scores when the conditions of measurement do not change [8,9]. Range on the reliability coefficient was collected when it was available.

Validity is the extent to which an instrument measures what it intends to measure [5,10]. *Content validity* refers to the evidence that the content domain of an instrument is appropriate for its intended use. In the present study, content validity was assessed by analyzing participation of the target population (and the age range when available) in the process of item development, and by looking at the available information on the use of expert panel judgment for assessing the clarity, comprehensiveness, and redundancy of the instrument's items and scales. Content validity was classified according to whether expert opinion was the main source of information or the target population (children or parents) was the main source. Construct validity measures the extent to which the questionnaire confirms a priori hypotheses, including its capacity to detect expected differences between groups of subjects (known groups validity) or associations with other instruments measuring constructs expected to be directly correlated (convergent and discriminant validity). *Criterion validity* refers to the degree to which scores on the instrument being validated correlate with scores on an external marker, which can be accepted as the reference standard, for example, when scores on a dimension measuring academic achievement are compared with results on school reports. Exploratory factor analysis and confirmatory factor analysis were also used as indicators of the structural validity of the instruments analyzed. Exploratory factor analysis and confirmatory factor analysis in particular reflect a priori expectations of a theoretical-conceptual model based on clinical and biopsychosocial models. *Sensitivity to change* refers to the ability of the questionnaire to detect clinically important changes in health status or HRQOL over time [5]. This factor can be measured in various ways, such as the standardized response mean and measurement error, but in the great majority of cases, it was assessed by calculating the effect size. Reporting on the type of validity assessed and sensitivity to change (yes/no) was also analyzed in the present study. A comparison on the extent to which the validated instruments included similar domain and item content was carried out by examining the name and content of domains and items from generic instruments.