

A New Approach to Multicultural Item Generation in the Development of Two Obesity-Specific Measures: The Obesity and Weight Loss Quality of Life (OWLQOL) Questionnaire and the Weight-Related Symptom Measure (WRSM)

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ABSTRACT

Background: Being overweight or obese has substantial effects on individuals' perceptions of their health and quality of life (QoL). Generic measures often miss important QoL information, and existing obesity-specific instruments have shortcomings with respect to cross-cultural input, application to differing levels of severity, conceptual clarity, and patient burden.

Objective: This study aimed to develop culturally sensitive measures of QoL and symptoms in overweight or obese persons, both those trying to lose weight and those not trying to lose weight.

Methods: Currently accepted criteria and guidelines for questionnaire development were streamlined and augmented to include cross-cultural input from 5 European countries and the United States. The preliminary pool of items was created based on qualitative interviews conducted in the United States, followed by an early check of item translatability and preharmonization across all languages. Ten additional qualitative in-country interviews were then conducted to produce further culture-specific items. This was followed by 2 forward and 1 backward translation, plus cognitive debriefing interviews in each country. Finally, an expanded international harmonization meeting was held to ensure inclusion of appropriate new items and their acceptability across all 6 cultures.

Results: The procedures described resulted in development of the 41-item Obesity and Weight Loss Quality of Life questionnaire and the 20-item Weight-Related Symptom Measure. These questionnaires are subject to further psychometric validation.

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Conclusions: Augmentation of the initial item-generation and international harmonization steps of questionnaire development through integration of cross-cultural input allowed greater validity of cross-cultural content while meeting time, budget, and resource constraints.

Key words: obesity, weight loss, quality of life, symptoms, OWLQOL, WRSM. (*Clin Ther.* 2002;24:690–700)

INTRODUCTION

In the United States alone, ~97 million adults are overweight or obese (body mass index [BMI] in kg/m²: 25–29.9 and ≥30, respectively) and are at risk for a variety of coexisting conditions.¹ Numerous large-scale epidemiologic studies have established obesity as a major risk factor for such chronic conditions as coronary heart disease, type 2 diabetes mellitus, hypertension, selected cancers, and musculoskeletal disorders.²

The prevalence of obesity is increasing worldwide. Data from various surveys and from the World Health Organization (WHO) MONICA (Monitoring of Trends and Determinants of Cardiovascular Disease) study suggest that the prevalence of obesity has been increasing during the past 15 years in some European countries, particularly among younger people.³ A similar trend has been observed in the United States.⁴ Data from studies conducted in various European nations suggest that the prevalence of obesity ranges from 10% to 20% in men and from 10% to 25% in women.⁵

Studies of the impact of obesity agree that increased BMI has a negative effect on many aspects of health-related quality of life (HRQoL).^{6–9} Obesity is associated with decreased psychological well-being,

poorer social integration, stigmatization, and low self-esteem. Additional effects are seen in the areas of functional status, work attendance, productivity, pain, and depression.^{10,11}

A study by Fontaine et al⁸ reported notable differences in functioning and distress levels (specifically in scores on the bodily pain, general health perception, vitality, physical functioning, and role-physical domains of the Medical Outcomes Study 36-item Short-Form Health Survey [SF-36]^{8,9}) between obese patients seeking treatment to help with weight loss and those not seeking such treatment. This suggests that treatment-seekers and non-treatment-seekers constitute 2 distinct populations when it comes to evaluation of condition-specific HRQoL.

Attempts have been made to measure HRQoL in overweight or obese patients using both generic and obesity-specific instruments. The SF-36 is the most widely used of the generic instruments. However, generic measures may not address domains crucial to obesity or may not detect minimally important changes with and without treatment.¹² Several obesity-specific measures have been developed, including the 140-item instrument constructed for the Swedish Obesity Study (SOS)^{10,13} from 6 separate psychosocial, health status, and behavioral scales, and the Impact of Weight on Quality of Life (IWQOL)¹¹ questionnaire, a 74-item instrument developed at Duke University, Durham, North Carolina. Existing obesity-specific measures either were developed for use in those with severe obesity or included no cross-cultural input in the item-generation process.^{9,13} Because there are differences in attitude toward obesity and the importance of attempting to lose weight across cultures, there is a need for

an HRQoL measure that not only can assess QoL in a broad range of overweight or obese persons, but also has been developed with item content derived from multiple cultures.

This article reports on the early qualitative and cross-cultural development of an obesity-specific HRQoL instrument and a symptom measure for use in the United States and 5 European countries (France, Germany, Italy, Spain, and the United Kingdom). These measures were developed to assess the impact of obesity on HRQoL in those who are mildly overweight (BMI 27–30) with comorbid conditions, those who are moderately obese (BMI >30–40) with and without comorbid conditions, and those trying and not trying to lose weight within these 2 BMI categories.

MODIFICATIONS TO THE DEVELOPMENT PROCESS

The design and data-collection processes used in development of the new measures were based on the recommendations of Patrick and Erickson,¹⁴ the Scientific Advisory Committee of the Medical Outcomes Trust,¹⁵ and Leidy et al.¹⁶ However, time constraints on the project called for a new approach allowing simultaneous incorporation of cross-cultural inputs from the relevant countries without compromising accepted practices of instrument development. Other attempts to incorporate greater cross-cultural input into the development of instruments have been described in the literature and have included consensus meetings,¹⁷ international diversity groups,¹⁸ and expert panels.¹⁹ The WHO Quality of Life measure employed a concurrent development process for the initial group of countries.^{20,21}

Whereas previous approaches have offered various benefits, the time and resources required were beyond the scope of the present project. Other published approaches to expediting the standard translation process in the face of short time lines and limited resources^{16,22} have not adequately met the need for simultaneous incorporation of culture-specific content during the development and translation phases. Therefore, an altered process was developed for use in this project that would incorporate cross-cultural content during the development phase and achieve full harmonization of the new items before the end of the translation phase.

The steps used in this project were as follows: (1) initial item development, involving creation of a preliminary item pool in the United States through a combination of in-depth interviews and focus groups including individuals who were either obese or overweight with comorbidities; (2) preharmonization of the initial item pool, in which an early check of item translatability into each language was performed; (3) translation and cognitive debriefing interviews, including 2 forward and 1 backward translation plus field-testing with in-depth commentary from persons in the 6 countries; (4) extended qualitative development, in which 10 additional qualitative in-country interviews were conducted to produce culture-specific items missing from the preliminary US pool; and (5) expanded international harmonization, ensuring the inclusion of contributions from each European country in the final measures. The figure depicts the overall process, and the components of each step are detailed in the following sections.

The innovative features in this process were integration of an assessment of item

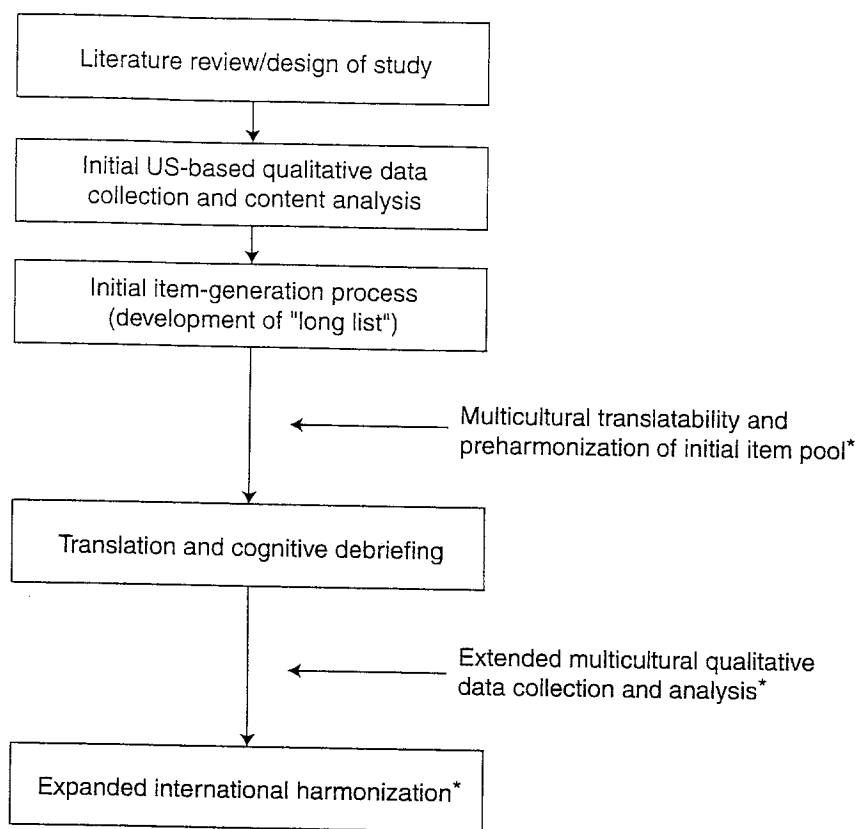


Figure. The augmented development process. *Expanded step.

translatability across cultures into the preharmonization phase and production of culture-specific items through extended qualitative data collection in each country. Multicultural input from the preharmonization step was used to modify the first draft of the items, with input from the qualitative in-country interviews added at the expanded international harmonization step. Thus, 2 obesity-specific measures were developed in a timely and resource-efficient manner with potentially greater applicability across cultures than would have been possible with US-based development alone.

Individuals' participation in the study was voluntary, and informed consent was obtained from each participant according

to current laws and institutional review requirements of the countries involved.

THE DEVELOPMENT MODEL

Initial Item Development

A demographically stratified sample of 68 overweight (with comorbid conditions) and obese individuals (BMI 27–40) was recruited in the United States. Individual interviews and focus groups were conducted in California, Florida, New Jersey, and Washington. The sample was divided equally between those trying and not trying to lose weight. Seventy-two percent had ≥ 1 of 3 targeted comorbid conditions (diabetes, dyslipidemia,

and hypertension). The mean age of the population was 52 years. Approximately 50% were male, 60% were white, and 69% were married or living as married (Table I).

The US-based qualitative research was followed by extensive analyses of the interviews to generate item content. A preliminary list of 55 items and 28 symptoms was created. Several existing obesity-specific measures were reviewed for usable concepts and descriptions, including the IWQOL,¹¹ the SOS intervention study battery,^{10,12} the Three-Factor Eating Questionnaire,²³ and the obesity-specific HRQoL measure developed by Mathias et al.⁹ To ensure drafting of the best possible items, a careful comparison was made between the content and wording of existing instruments, their precursor measures, and the actual words of individuals participating in the qualitative interviews. It was found that the intended item content was generally best conveyed by individuals' own words rather than by the wording used on existing measures (eg, "I don't feel attractive to others because of my weight" rather than "Have you ever been concerned or worried about your ability to attract members of the opposite sex?").

During this review, it became evident that some of the preliminary item content related to symptoms of obesity and attempts to lose weight. Therefore, several of these items (eg, "I feel physically uncomfortable" and "I feel depressed") were incorporated into the measure of symptom bothersomeness.

International Preharmonization of Initial Item Pool

Because some of the content of the new obesity-specific measures was likely to be

Table I. Demographic characteristics of the initial qualitative development sample.

Age, y	
Mean (SD)	52 (10.5)
Range	28–70
Sex, no. (%)	
Male	35 (51)
Female	33 (49)
Race, no. (%)	
White (non-Hispanic)	41 (60)
Black/African American	17 (25)
Hispanic/Latino	4 (6)
Asian/Pacific Islander	2 (3)
Other	4 (6)
Marital status, no. (%)	
Married/living as married	47 (69)
Divorced/separated	11 (16)
Never married	6 (9)
Widowed	4 (6)
Body mass index, kg/m ²	
Mean (SD)	33.4 (4.1)
Range	26–42
Education, no. (%)	
Some high school	1 (1)
High school graduate	11 (16)
Some college	30 (44)
College graduate	13 (19)
Postgraduate	13 (19)
Income, no. (%)	
<\$20,000	7 (10)
\$20,000–\$35,000	8 (12)
\$35,000–\$50,000	22 (32)
\$50,000–\$75,000	17 (25)
\$75,000–\$100,000	12 (18)
>\$100,000	2 (3)

culturally linked, it was deemed important to include international input at the stage of item development rather than at the usual stage of translation of the final instrument. The initial item pool of 55 items and 28 symptoms was refined at an international preharmonization meeting of the US team and 5 European cultural translation experts. The objective was to ensure that all retained items could be expressed in each of the languages and were relevant to each of the cultures. Responses to the HRQoL items and symptom-bothersomeness items were to use the same 7-point scale (not at all, hardly, somewhat, moderately, a good deal, a great deal, a very great deal).

Translation and Cognitive Debriefing

The preliminary version of each measure was translated into the target language using standard translation techniques.^{15,19,24} A reconciled forward translation was created from 2 independent forward translations. A backward translation of the reconciled forward translation was developed and evaluated for equivalence with the original draft measures. After agreement had been reached on the first version of each measure, in-depth cog-

nitive debriefing interviews were performed across all 6 cultures to ensure that the item content, response scales, and instructions were understood as intended. In addition, the clarity of the instructions and format, required reading level, and overall burden of self-administration were evaluated for potential problems.²⁵

The combined sample for the cognitive debriefing interviews, which differed from the sample involved in the initial phase, included 35 obese and overweight patients (10 from the United States and 5 from each of the European countries). Debriefing patients were required to have a BMI between 27 and 40, be approximately equally distributed between sexes, include both those trying to lose weight and those not trying, and be distributed across the targeted comorbidities (a subgroup with no comorbidities was also included).

Interviewees were asked to rank each of the items in the draft measures in terms of its importance to them. Results of the interviews and ranking exercise were compiled and brought to the expanded international harmonization meeting to guide final revisions to the measures. Table II lists interviewees' top 10 selections from the draft items, aggregated by country.

Table II. Top 10 items from cognitive debriefing interviews, ranked by importance.

1. I feel good about myself when I am losing weight.
 2. I get frustrated trying to find clothes I look good in.
 3. I worry about how much my weight affects my health.
 4. I am afraid that I will gain back any weight that I lose.
 5. I worry about the physical stress that my weight puts on my body.
 6. Because of my weight, I try to wear clothes that hide my shape.
 7. I am embarrassed to undress in front of others because of my weight.
 8. I get discouraged when I try to lose weight.
 9. My weight prevents me from doing what I want to do.
 10. My weight prevents me from enjoying life.
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Extended Qualitative Development

At the close of the international preharmonization meeting, each cultural translation expert was provided with an interview guide and short training in analyzing the content of qualitative interviews. During the extended qualitative development phase, these experts performed interviews with separate groups of 10 obese or overweight subjects per country, both with and without comorbid conditions. These interviews were shorter than those conducted at the outset of the project and focused only on those qualitative culturally linked items concerning the impact of obesity that had not been covered in the previous work. The list of additional items (Table III) was

brought to the expanded international harmonization meeting for consideration for inclusion in the final revised measures.

Expanded International Harmonization

As summarized in Table IV, the expanded international harmonization meeting carefully reviewed the results of the cognitive debriefing interviews, item rankings, and extended cross-cultural qualitative work to finalize the first drafts of the measures. Items were dropped if they were not both relevant to and acceptable in all 6 cultures. For example, on the HRQoL measure, the UK item "I stay at home because of my weight" was changed to "I avoid going out because of my weight" to

Table III. Additional obesity-related quality-of-life items and symptoms, by country.

Country/Suggested Item or Symptom

France

- I dread the future.
- My family is ashamed of me.
- I have a feeling of injustice because our metabolisms do not react the same way to food.
- Back pain

Germany

- Others think of me as undisciplined.
- I am not the person I see in the mirror.

Italy

- I envy people who are thin.
- I feel people are watching me.
- Increased hunger

Spain

- I feel discriminated against when I try to find clothes I look good in.
- I need help from my family to diet correctly.

United Kingdom

- I stay at home because of my weight.
 - I find it hard to motivate myself to lose weight.
-

Table IV. Steps in the expanded international harmonization process.

1. Review of all US and European debriefing results
2. Review of subject ranking exercises, by country and total
3. Revision/reduction of items to produce a second draft of cross-culturally relevant items for the health-related quality-of-life and symptom measures
4. Review of all suggested additional items from in-country qualitative work, with a focus on cross-cultural relevance and acceptability*
5. Translatability, importance, and nonduplication of concepts addressed in existing items*
6. Translation and backward translation of all newly added items or changes
7. Development of a third draft of the measures
8. International harmonization of the revised measures to ensure linguistic and content consistency across all 6 cultures

*Expanded step.

overcome cultural differences in the concept of “staying at home,” and the French item “I have a feeling of injustice because our metabolisms do not react the same way to food” was eventually dropped because no universally acceptable wording could be found. Revisions to the symptom measure included changing “intolerance to cold/heat” to “sensitivity to cold/heat” for better translatability, and changing “bodily pain” to “back pain” based on French interviewees’ perception that the latter was more condition specific. One new symptom, “increased hunger,” was added based on the Italian interviews. At the end of this process, 11 items were either revised or added based on suggestions from the European qualitative work.

Once agreed and finalized, the items and symptoms were harmonized to ensure content equivalency between the different language versions. This process resulted in 2 measures: a 41-item Obesity and Weight Loss Quality of Life (OWLQOL) questionnaire and a 20-item Weight-Related Symptom Measure (WRSM). These questionnaires are subject to further psychometric validation.

DISCUSSION

Several criticisms have been raised regarding the use of questionnaires translated into other languages after development in an English-speaking culture.¹⁷ First, cultural differences may make items that were appropriate to the original country of little relevance in other countries, and important culturally linked concepts may be missed. Some items in the initial measure may have no equivalents in another language. Even when an attempt has been made to do better than a simple translation of existing instruments, the cross-cultural comparability of items may still be limited.¹⁶

To avoid such pitfalls in the development of the OWLQOL questionnaire and WRSM, cross-cultural input was integrated at several stages before finalization of the content. First, a large amount of qualitative data collection was used to incorporate cross-cultural input from 6 countries simultaneously. One hundred fifty-three obese and overweight persons were interviewed (68 in the United States and 10 each from France, Germany, Italy,

Spain, and the United Kingdom), plus an additional 35 who participated in cognitive debriefing interviews across all countries. The collection of this additional qualitative data was considered crucial due to the wide range of culturally linked factors (including aspects of living, interactions with others, and health-related behaviors) affected by being either overweight with comorbid conditions or obese. Additional qualitative research was also necessary to gather adequate input from the wide range of obese and overweight persons with various related comorbid conditions, as well as those trying and not trying to lose weight.

Although the original pool of items was based on US qualitative research, qualitative work in the other countries allowed the addition of culture-specific concepts that had not been expressed prominently or at all in the original work. During the expanded international harmonization meeting, each country's cultural translation expert spoke the item first in his or her language and then as translated back into English. Hearing these translations into the target languages gave the bilingual or trilingual experts an opportunity to make further linguistic refinements to the sometimes difficult-to-express content. This addition to the harmonization process helped avoid the problem of overlapping concepts and reduced the bias often found in multiple-language versions as the result of independent translations. The final items in the new measures had the advantages of sounding natural, being easy to read, and having high face validity in their respective languages.

The modified development model described here helped avoid a common criticism of instrument development based on a single culture while achieving effi-

ciencies in budget, time, and human resources. Because of the large amount of qualitative work in the early stage of development, it is reasonable to expect these measures to have greater content validity and thus greater sensitivity to issues of importance to persons with obesity. Based on the authors' review of the literature, these are the first obesity-specific measures to be designed with culturally specific input from 6 major Western cultures. The inclusion of cross-cultural qualitative work during the item-generation process should allow more culturally sensitive assessment of the symptoms and impact on HRQoL of being overweight with comorbid conditions or obese and trying or not trying to lose weight.

A validation study has now been completed, resulting in further reduction of the OWLQOL to 33 items and development of a measurement model with 4 domains (self-image, trying to lose weight, social stigma, and physical health).²⁶ A written report is in preparation that presents a full evaluation of the psychometric properties of both the revised OWLQOL and the WRSM. Studies are under way in the United States and Europe to further evaluate the cross-cultural psychometric properties of both measures.

CONCLUSIONS

Use of the new methodology expedited the qualitative stage of development of 2 obesity-specific measures, the OWLQOL and the WRSM, for use in 6 countries. It is expected that integration of cross-cultural input at both the preharmonization and expanded international harmonization stages will achieve high content validity of both measures across all 6 cultures. Whereas the qualitative phase of new

instrument development traditionally takes ~9 months for development in 1 language, plus another 3 months for cross-cultural translation, the procedures described in this article required only 9 months to produce 2 new measures and prepare them for psychometric testing in 6 countries.

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