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INSTRUMENTS

A System for Integrating Generic and Disease-Specific Patient-Reported Outcome (PRO) Measures

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KEYWORDS
GENERIC PRO MEASURES, DISEASE-SPECIFIC PRO MEASURES, COMPUTER ADAPTIVE TESTS (CAT), ITEM RESPONSE THEORY (IRT), ADAPTIVE SURVEY LOGIC (ASLX®), COMORBIDITY IMPACT INDEX™

After three years of NIH-sponsored research and development, the Quality of Life Information System (QOLIX®) is being made available for independent evaluation. QOLIX is a web-based Patient-Reported Outcome (PRO) monitoring system that integrates newly-developed generic and condition-specific PRO measures to increase their comprehensiveness in comparison with familiar legacy PROs. QOLIX measures a profile of ten generic domains and includes disease-specific impact measures of ten domains but with specific disease attributions. For all outcomes, QOLIX improves measurement efficiency using a new Adaptive Survey Logic (ASLX®) that proved in preliminary studies to be faster than routine computer adaptive tests (CAT) for most respondents and to better adapt measurement to the purpose of each PRO application. To make interpretation easier, the system uses standardized scales and norm-based scoring for both generic and disease-specific outcomes. In a nutshell, QOLIX attempts to do for both generic *and* disease-specific tools what the Medical Outcomes Study (MOS) profiles and summary measures did for generic health PROs decades ago.[1] We briefly describe here the content of the system, some of its features, identify sources of more technical system information, and share some preliminary findings.

Core Modules

QOLIX consists of five core modules that were developed specifically to complement each other and, when administered in stepwise fashion, achieve a more efficient approach to comprehensive assessments of PROs. The system is self-administered and scored in real time on the Internet. It includes the following modules, presented in the order of administration: (1) demographics (administered only at baseline); (2) self-evaluated transition (SET) measures of health outcomes (e.g., better, same, and worse categories) that enable direct estimates of changes over time (administered only at follow-ups); (3) Generic Health Assessment profile, including Physical and Emotional Health Summary Measures (PHGS® and EHGS®); (4) Chronic Condition Checklist (QCCC™) for 35 or more chronic conditions (administered only at baseline); and (5) Quality of Life Disease Impact Scale (QDIS®) that is standardized in terms of content and scoring for each disease reported and is aggregated across diseases. The core modules are programmed to be very brief for most respondents to allow time for system customization (e.g., supplemental legacy modules) to meet the needs of specific research applications. QOLIX system features are summarized briefly below.

QOLIX Generic Health Assessment (QGEN®). Planning for this development project began with re-analyses of the generic and disease-specific measures and large database from the Medical Outcomes Study.[1] Conceptually, MOS measures are the ancestors of the MOS short-forms in widespread use today. It is noteworthy that they were developed using "classical" as opposed to modern psychometric methods, e.g., item response theory (IRT).[2] Some MOS measures were so lengthy that they might be considered "item banks" by today's standards.

After re-analyzing MOS data using contemporary methods, measures worthy of further study were selected and new generic measures were developed for testing during the NIH-funded Computerized Adaptive Testing of Disease Impact (DICAT) Project[3] (described briefly below). Data were analyzed to evaluate practical issues such as respondent burden as well as psychometric standards. Priority was placed on determining whether improvements in item content were worthwhile and whether measures could be improved while also maintaining comparability with the familiar metrics underlying legacy generic tools.

Although legacy MOS (e.g., SF-36, SF-12, SF-6) and PROMIS[4] short-forms have generally been used in either-or fashion, the DICAT Project studied them in combination with each other for the domains they have in common (listed below). For each of these domains, priority was placed on developing the best possible global item in comparison with the corresponding item bank because the first item administered may be the only one for that domain and, if not, its response may determine the selection of additional items.[5] The result was a comprehensive item bank for each of ten generic domains with cross-calibrated global screening items and alternate forms of measures including (for common domains and available items): legacy MOS, contemporary PROMIS, and new QOLIX items. The ten domains include (those bolded are common to MOS, PROMIS, and QOLIX): **physical functioning**, role limitations attributed to general health, role limitations due to physical health, role limitations due to emotional problems, **pain**, general health (GH), vitality (including energy and **fatigue**), **social functioning**, mental health (including **depression**, **anxiety**), and health distress. In terms of item content and format, noteworthy QOLIX improvements include better face validity, broader content validity (e.g., generic and disease-specific items that explicitly ask respondents to evaluate "quality of life"), item response categories (Very easy-Unable to do) shown to measure over a wider range for role and social functioning domains, and standardized (Very often-Never) response categories for all pain, mental health, and vitality item banks. Head-to-head comparisons are underway and are encouraged for those with permissions to use aforementioned and other legacy surveys.

In addition to the profile of ten generic domains, QGEN scales enable estimation of Physical and Emotional Health Summary Measures (PHGS and EHGS, respectively), which are analogous to the original MOS physical and mental component summary measures. Like the MOS summaries and PROMIS measures,[6] PHGS and EHGS are scored using a T-score transformation to have a mean of 50 and SD of 10 in the general US population.

Quality of Life Disease Impact Scales (QDIS®). The primary focus of the DICAT Project was on developing an improved approach to the self-assessment of disease-specific PROs for those with multiple chronic conditions. To fill the content gaps in widely used disease-specific measures, unrepresented domains that have been shown to vary across chronic diseases and their treatments were added systematically. As recommended decades ago,[7] our primary source for improving disease-specific item banks was the content of

IN THIS ISSUE

widely used *generic* measures. However, QDIS went even further by attempting to standardize the item calibrations used to score impact metrics across diseases; as judged using accepted psychometric standards, that attempt appears to have been successful.[8] The resulting QDIS measures provide: (1) a more comprehensive disease-specific impact score for each disease (e.g., QDIS-OA for osteoarthritis [OA]) and (2) a Comorbidity Impact Index™ designed to help distinguish between the impact of a primary disease (e.g., OA) and the impact of comorbid conditions when interpreting generic health outcomes. QDIS banks are standardized to represent ten generic domains (physical, role and social function, general health, health distress, vitality, mental/emotional health, cognitive function, sleep, and quality of life) across all diseases. After the global impact measures, all items use the same five-choice categorical rating scale (Very often-Never) and have attribution to a specific disease. The important assumptions underlying this application of modern item response theory (IRT)[2] were tested and confirmed in analyses of DICAT data (n=5,347), enabling standardized metrics across diseases. As explained elsewhere,[8] QDIS estimates are scored unfavorably (higher is greater disease impact) using a norm-based T-score linear transformation to achieve a mean of 50 and SD of 10 in the US population.

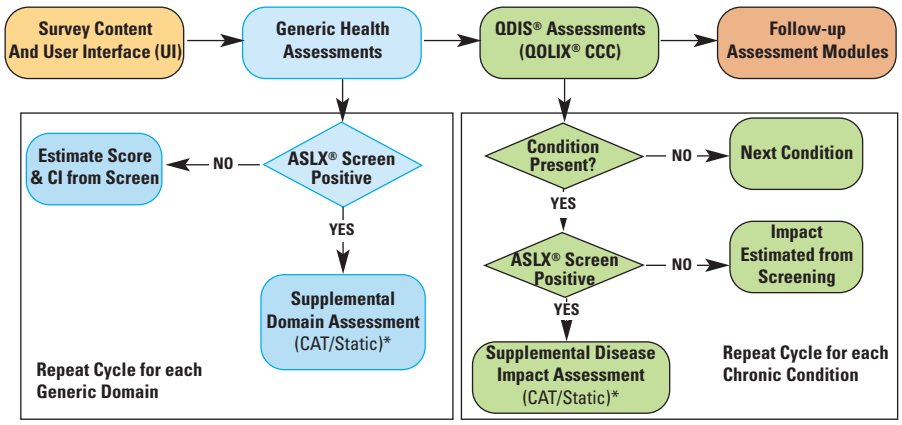
Adaptive Survey Logic (ASLX)

At the heart of the QOLIX system is a new measurement management methodology called adaptive survey logic (ASLX). *ASLX maximizes the efficiency of generic and disease-specific PRO assessments in an iterative fashion by reducing respondent burden and matching the precision of score estimates to meet the specific needs of each PRO application.* For example, ASLX better matches measurement (including whether to measure and how much to measure) to its specific purpose and the score range observed in the population. CAT is proving to be very useful in selecting, administering, and scoring the most informative survey items.[9] *However, CAT is not useful in deciding whether a PRO domain warrants CAT measurement in the first place.* ASLX was conceived to make such decisions in real time using the adequacy of domain score estimates and other considerations to achieve the best possible measurement management logic for each PRO application.

Briefly, as shown in the Generic Health Assessments column of Figure 1, generic screens and further assessments (if warranted) are completed first.

Figure 1.

ASLX® (Adaptive Survey Logic) Flow Chart



Abbreviations: Quality of Life Information System (QOLIX®), Disease Impact Scale (QDIS®), Adaptive Survey Logic System (ASLX®), Chronic Condition Checklist (CCC), Computer Adaptive Test (CAT), User Interface (UI)

A global generic item is administered to provide an initial score estimate for a given domain and as a basis for managing any additional measurement required. For example, for some purposes those with more impairment may be more likely to be administered a multi-item (static or CAT) scale to more precisely estimate a domain score. For the remaining respondents, an unbiased but relatively "noisy" estimate of that domain score may be sufficient for that domain if it is sufficient for summary score estimation. Regardless of how items are selected, responses are scored on the same underlying metric so that results can be compared and meaningfully interpreted for each domain. These alternate form estimates differ only in terms of their precision, which is usually greater using CAT. Second, as shown in the column headed QDIS in Figure 1, for each condition reported on a 35-item Chronic Condition Checklist, a global QDIS impact item (calibrated to enable comparisons across diseases) is administered. Those attributing noteworthy impact to a condition are administered (static or CAT) QDIS items sufficient for precise estimation of that burden. This cycle is repeated for each chronic disease. In DICAT Project evaluations to date,[8] administration of the entire QDIS module took an average of one minute and 18 seconds for those with one chronic condition, and an additional 18 seconds for each comorbid condition. ASLX reduces survey length beyond reductions with CAT without substantial loss of information, and reduces respondent burden by an average of one-half to two-thirds in comparison with legacy measures.

In support of multi-stage approaches like the QOLIX system summarized above, it is noteworthy and encouraging that a

forthcoming article about "Universal Measures" written by a NIH/NIA-sponsored working group on health outcomes for older persons with multiple chronic conditions has recently recommended that a combination of brief initial measures (e.g., pain, fatigue, physical and mental health, and social-role function) be administered and that initial responses should determine whether and what follow-on measures are administered.[10]

Integrating Generic and Disease-specific Outcomes

QOLIX is an innovative integration of generic and disease-specific measures developed and evaluated together to be less redundant and more complementary. Both use norm-based scoring and the same T-score transformation. As a result, both generic and disease-specific measures have a mean of 50 (SD = 10). For QDIS, for all conditions, the reference population is the US chronically ill population in 2011/2012. For QGEN, the reference population in studies to date was the total US general population in 2011/2012.[8,11] QGEN generic norms for the chronically ill population are being evaluated. QDIS is scored negatively – higher is greater impact; QGEN is scored positively – *higher* is better health and quality of life.

Use of a common metric for both measures facilitates the integration and interpretation of disease-specific and generic PROs at both group and individual patient levels. To evaluate this integration, cross-sectional household surveys and longitudinal panels were fielded in 2011-2012 (total N=10,624). All surveys included representative US population samples and over-sampled the chronically ill. These studies evaluated QOLIX alternate form measures to determine how well they performed in comparison with legacy tools in applications that closely approximate their intended use in measuring PROs. Clinical and predictive validity was evaluated to determine whether improvements in item content were worthwhile and whether measurement efficiency could be improved while also maintaining comparability with the familiar metrics underlying legacy tools. This is analogous to how Fahrenheit and Centigrade thermometers were cross-calibrated hundreds of years ago and are routinely reported in parallel, regardless of which is used to estimate temperature. QOLIX generic and disease-specific preliminary findings have been reported.[8,11,12]

Summary and Next Steps

Our approach to improving and integrating generic and disease-specific measures builds on: (1) published studies of objective clinical markers and specific symptoms and their impact on both condition-specific and generic PROs; (2) measurement models improved using item response theory (IRT) methodology; as well as, (3) predictive studies of the clinical, economic, and social consequences of PROs across multiple disease areas. The reports of preliminary findings for QDIS, in comparison with legacy disease-specific measures, have been presented at scientific conferences[8,11,12] and results are encouraging. For example, in the first Internet-based pilot study of 228 patients with chronic kidney disease (CKD), a 2-6 item QDIS for CKD score achieved a relative validity of 96.1% in comparison with the 25-item QDIS bank total score in a validity test comparing different CKD severity groups. This result compares favorably with the relative validity of 54.2%, observed for the legacy 23-item KDQOL Total Score in the same test of discriminant validity.[12] The development of QDIS and information about its use and interpretation is summarized in QDIS Primers now being evaluated by early adopters of QDIS.

In summary, preliminary findings suggest that the new condition-specific (QDIS) and generic (QGEN) measures are (in comparisons with legacy measures): (a) psychometrically sound; (b) achieve substantial reductions in respondent burden; (c) estimate scores reliably (> 0.90) for equal or greater percentages of those who are well and for those who are chronically ill; (d) reduce the percentages of well and chronically ill scoring at the ceiling and floor; and (e) show equivalent or better responsiveness across groups reporting better or worse PRO outcomes. After three years of NIH-sponsored research and development, QOLIX is now available for independent evaluation in scholarly research studies in the U.S. and available for all purposes elsewhere.

For further information, visit www.jwrginc.com or www.qolix.com.

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Readability Assessment of Information and Consent Forms for Cancer Clinical Trials in Italy

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KEYWORDS

CONSENT FORMS, READABILITY, GULPEASE INDEX, CLINICAL TRIAL, STUDY PARTICIPANT, ETHICAL COMMITTEE

Introduction

The signed informed consent form represents an absolute requirement for voluntary consent to participate in clinical trials as a pre-requisite key for the ethical conduct of research and evidence of the subject's consent to participation. How much patients really understand and comprehend these Information and Consent Forms (ICFs) has often been debated and readability standards have been suggested to improve their comprehensibility.

Methods

A sample of 114 ICFs administered to Italian cancer patients for phase II-IV trials from 2007 to 2012 were examined (see Figure 1). ICFs for which only a paper format was available were excluded from the analysis, as well as those that were unavailable or incomplete. All the 114 ICFs had been approved by the referring Ethical Committee. To determine their readability scoring, the Gulpease Index was used.[1] Developed in 1988 and validated for Italian, the scale is automated in Microsoft Word and is based upon two linguistic variables, the length of the word and of the sentence (mean number of words per phrase), as per the following formula:

89-LP/10+FR*3, with LP=letters*100/total words, and FR=sentences*100/total words.

Results range from 0 to 100, where "100" indicates the highest readability and "0" the lowest (see Figure 2).

In detail, documents:

- Below 80 are difficult for a 5th-grade reading level (elementary level),
- Below 60 are difficult to read for 8th grade,
- Below 40 are difficult to read for 13th grade (high-school diploma).

The advisable reading score for most documents should be in the 60-70 range. The National Cancer Institute recommendations for the simplification of Informed Consent documents suggest the reading level should be 8th grade or lower.[2]

Results

Mean number of pages of the 114 assessable ICFs was 10.3 (2.5÷27.5); those for industry-funded trials (n. 47, 41.2%) were significantly longer than those for investigator-initiated trials (n. 67, 58.8%) with mean number of pages of 15.4 and 6.7 respectively (p<0.0005). Significantly higher was also the number of pages of the ICF when comparing international (n. 50, 43.9%) to national trials (n. 64, 56.1%) with mean number of pages of 15.1 vs. 6.5. The mean Gulpease Index readability score of the 114 ICFs was 41 (30÷67) irrespective of valuable variables. Only one ICF (0.87%) met the >60 desirable readability value.

Conclusion

ICFs for cancer trials have poor readability scores, seem far too complex, and are too long to be read and understood by an average study participant. This may result in the signing of a document which has not been fully grasped, with poor understanding of the implications of trial/research participation. Moreover, information sheets and consent forms for international research are translated into Italian – mostly from English – and in the attempt to adhere to the original text and keeping the translation literal, they often lack fluency and readability. If a document is long and hard to read – 50% of the ICFs for

Figure 1.

Cancer sites of the 114 studies for which the ICFs were analyzed

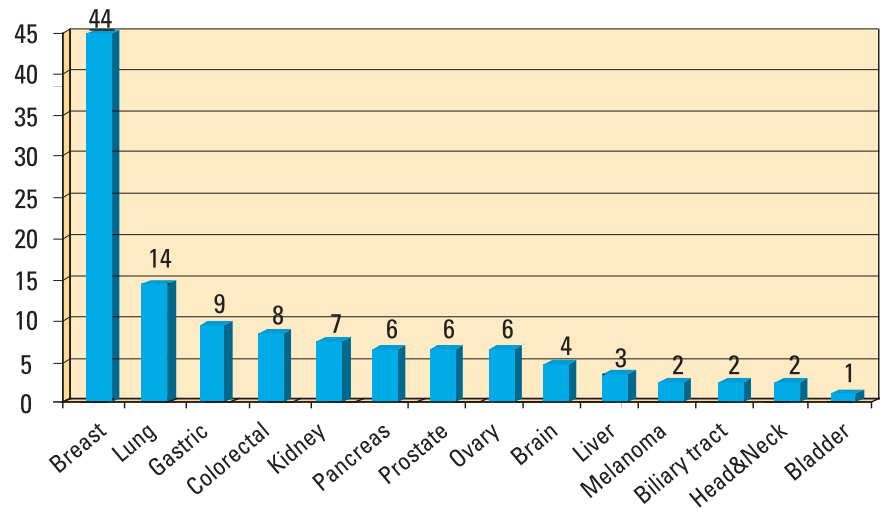
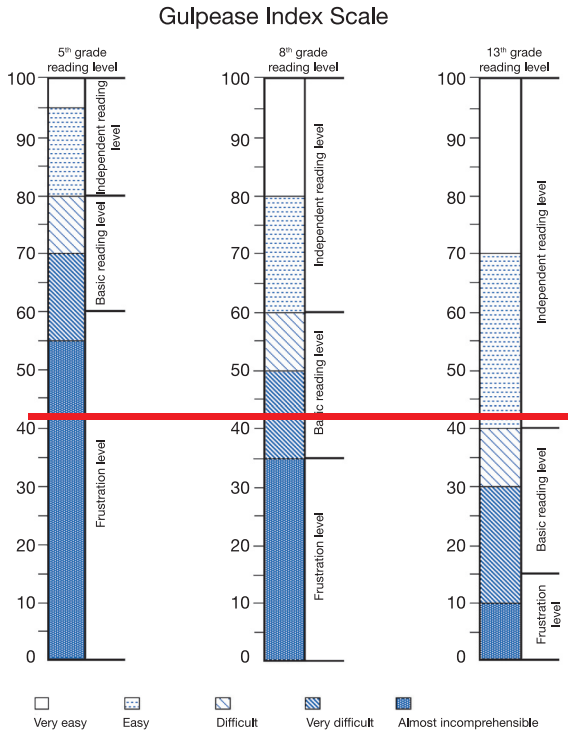


Figure 2.

The Gulpease Readability Index



international trials have more than 16 pages – some patients may not read it at all, and those who do, might not understand everything but dare not say so, leading to a hasty and perfunctory acceptance. This represents a major ethical concern within clinical trials, especially for research subjects with low literacy, as consent ought to be given when the participant is genuinely informed and not frustrated by comprehension issues. Every effort should be made to obtain a truly informed consent assessing the ICF readability prior to study activation.

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TRIBUTE...

2012 International Avedis Donabedian Outcomes Research Lifetime Achievement Award

Donald L. Patrick, a member of the MAPI Research Trust Scientific Advisory Committee, was awarded the prestigious 2012 International Avedis Donabedian Outcomes Research Lifetime Achievement Award by the International Society for Pharmacoeconomics and Outcomes Research in Washington, DC this past June.

This award was established in honor of the late Avedis Donabedian to acknowledge those individuals who have made a major contribution to the improvement of health outcomes. Dr. Donabedian was a renowned faculty member of the University of Michigan School of Public Health and dedicated his life to improving the quality of health care and healthcare systems, and directed such research towards health outcomes as the measure of quality.

Dr. Patrick spent a sabbatical year with the MAPI Group in Lyon during 1994. As part of that year, he studied with Dr. Catherine Acquadro and Katrin Conway in learning about cross-cultural adaptation of outcome measures. He also helped in the establishment of the Institute and contributed to the development of PROQOLID and other information services provided by MAPI. Dr. Patrick notes, "It was my year at MAPI that created my interest in the international development and dissemination of quality-of-life measures and other patient-reported outcomes. I developed an appreciation of the fascinating and deeply complex cultural issues surrounding linguistic validation and how people think, feel, and report about their health and illness."

Dr. Patrick was the inaugural President of the International Society for Quality of Life Research and currently serves on the Board of Directors of ISPOR. Dr. Patrick has been a member of the MAPI Scientific Advisory Committee since its establishment. Under the auspices of MAPI, he co-chairs the Translation and Cultural Adaptation Special Interest Group of the International Society for Quality of Life Research with Katrin Conway and co-convenes the Cochrane Collaboration Patient-Reported Outcomes Methods Group with Gordon Guyatt

BiblioPRO: Online Library of Patient-Reported Outcomes in Spanish

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

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-centered 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.[1] 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[2] and many others were originally developed internationally.[3]

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)[4] and its publication was continued 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/).[5]

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).[6] 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 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.[7] 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 of the entire list of PRO instruments to find potential candidates for the repository; the classification system used; and the model for evaluating the performance of the instruments.

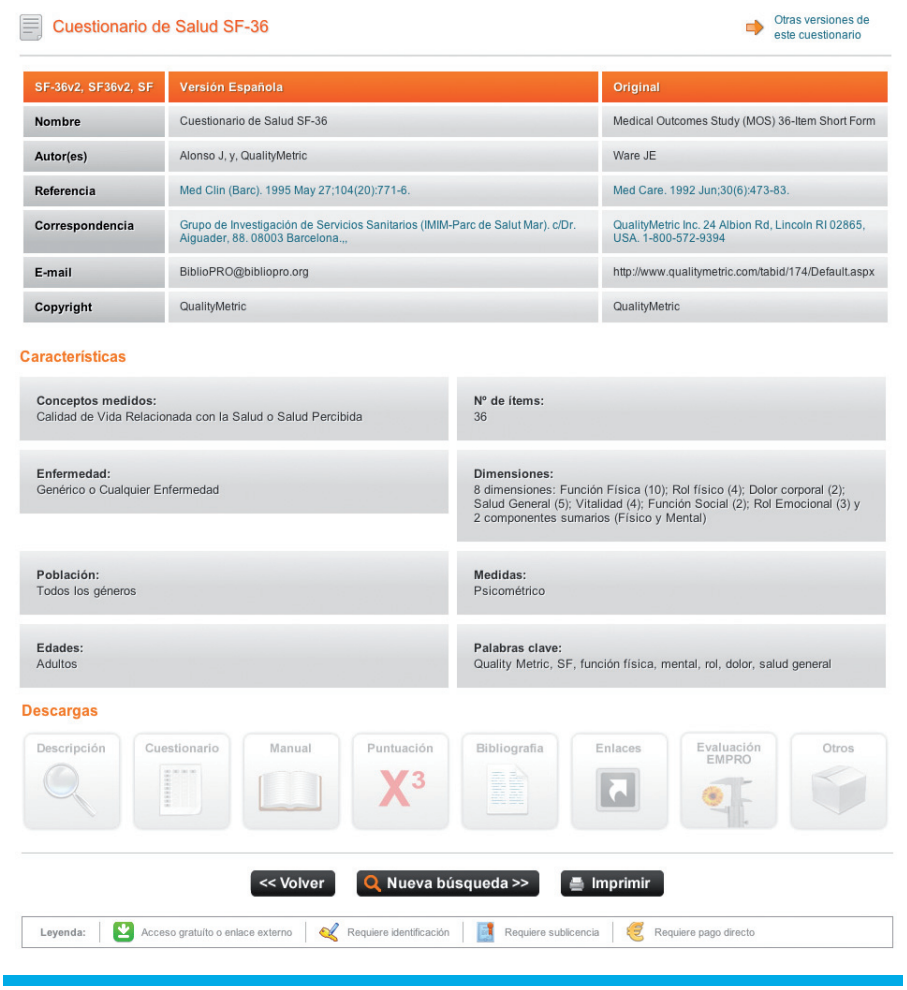
Identification of candidate instruments (systematic search)

With the aim to identify all the existing Spanish PRO instruments, peer-reviewed systematic reviews are periodically performed using a sensitive search in PubMed.[8] 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

Figure 1.

BiblioPRO: example of a technical sheet for an instrument



contact information, are described. As 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[9] and the International Classification of Functioning (ICF).[10] *BiblioPRO*'s classification system of PROs considers three major domains: the concepts/constructs measured, the target population, and the measurement model.[11] 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).[12] 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 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, *BilbioPRO* 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.[13] 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.[14] 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-centered health services.

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ACKNOWLEDGEMENTS

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NEWS FROM...

Clinical Trials: India Calling

Thangaraj Nagasamy

India, with its billion-plus population offering vast genetic diversity and a large pool of patients, holds great promise for much-needed clinical trials. While drug development costs have gone up by leaps and bounds in the past decade, the competition for the limited availability of potential trial participants has been astounding. In their pursuit for cost-effective clinical research, biotech and pharmaceutical companies have begun outsourcing clinical trials to developing countries. Though a newly industrialized country, India provides a huge market for new therapeutics and healthcare has been receiving increased attention from the federal and provincial governments. This apart, India has a large number of qualified patient volunteers and the cost of doing clinical research is far cheaper here.

India is turning into a clinical research hub due to a number of factors. India has been attracting pharma giants because the country offers nearly 900,000 specialty hospital beds, over 600,000 clinicians, about 250 medical colleges and a large pool of skilled English-speaking medical personnel. Government-funded medical and pharmaceutical institutions with state-of-the-art facilities have been on the rise in recent times and they serve as ideal centers for multi-centered clinical trials. Though the number of clinical trials happening globally is reported to have come down due to steep rise in trial cost, India can boast that it can provide research and the development process at a competitive price; this has been proved by the fact that the clinical trial outsourced market in India has grown by 30% from 2010 to 2012. India has over 150 contract research organizations that are involved in carrying out clinical trials of outsourced clinical development activities.

The launch of the Clinical Trials Registry in India in 2007 marked a new chapter in the clinical-trial registration process in India. Concerted efforts have been taken to encourage voluntary registration by conducting Clinical Trials Registry workshops with the participation of people likely to be involved in clinical trials. The Clinical Trials Registry of India is in conformity with WHO norms and has all the 20 items of the WHO Clinical Trials Registry Platform.

Clinical trials have entered a crucial phase and more dependence has been placed on them in improving therapeutic regimens and ensuring advancement in medical practice. Since clinical trials have enormous potential for benefiting patients, it has become necessary to have transparency, accountability, and accessibility with a view to establish public trust in clinical-trial data. From the traditional production of generic medicines, the Indian pharmaceutical industry has also begun its work in original drug research. With a large skilled pool of medical professionals in an IT-enabled environment, India serves as an enviable knowledge hub that is capable of providing statistical support in the clinical-trial domain.

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Tips and Tricks for Using Direct-to-Patient Contacts in Pharmacoepidemiological Studies

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KEYWORDS
DIRECT-TO-PATIENT CONTACT, TELEPHONE INTERVIEW, PHARMACOEPIDEMIOLOGICAL STUDY, LOST-TO-FOLLOW-UP MINIMIZATION, PROTOCOL COMPLIANCE, PHARMACOVIGILANCE SYSTEMS

Direct-To-Patient Contact (DTPC) has been commonly used for decades in epidemiology. It has played a major role in the strategies used to maximize subject retention and to minimize non-response throughout the course of longitudinal cohort studies.[1] As the natural historian of his/her own illness, the patient has become a sought-after reliable and irreplaceable source of information in studies using Patient-Reported Outcomes (PRO).[2]

Despite increasing recognition of the interest of using DTPCs in pharmacoepidemiological studies, several concerns have been and are still regularly expressed (see Table 1).

Some of them are completely justified. Others are based on misunderstandings or misinterpretations of the complicated and evolving regulations and systems of reference present in such studies, contextual pressure (compliance with post-marketing adverse drug experience reporting requirements to health authorities or intra-company functioning rules), lack of experience in late-phase studies and epidemiological methods (for example, studies conducted by teams specialized in preapproval clinical trials) and sometimes stereotypes.

In order to take advantage of the benefits of using DTPCs (see Table 2), concerns should be taken into account and mastered.

Based on more than eleven years of experience and feedback, here are some "tips and tricks" that can be used to overcome potential concerns when using DTPCs. These not-exhaustive rules are of particular importance when managing contacts by telephone or e-mail.

1. Anticipate ethical and regulatory concerns by reinsurance: win everybody's trust

- **Show independence vs. pharmaceutical companies, monitors, and data managers:** from a data privacy perspective, the structure in charge of DTCPs should be an "airlock" between the subject and the sponsor, the monitor, and the data-manager. Ensure that patients' contact details will never be provided to them. Data privacy protection authorities and subjects are worried about the potential use of patient's contact details for other purposes than the study. A commitment to delete patients' contact details at the end of the study from all data-support systems (computer and paper) is reassuring.
- **Clearly separate contact details management from clinical data collection:**
  - Check carefully all documents sent to or returned by patients by this principle: no medical information should be included in a document having patient contact details. Pay careful attention to the study title: it can clearly reveal a disease.
  - Set up two independent databases: one for managing the contacts (CRM orientated) and one for collecting the clinical data (eCRF/ePRO). Do not link or store the patients' health data and their contact details on the same application.
- **Show professionalism in DTPC management:**
  Reinsure on skills and management of personnel involved in contacts, including training, supervision, quality controls, medical back-up, and individual professional secrecy commitments.
- **Explain what personnel involved in contacts will manage and what they will not manage.** Ensure that the DTPC Unit personnel will never interfere with the usual relationship between patients and healthcare professionals (HCPs); they should not be considered as a substitute for the patient medical follow-up. Patients or their legal representatives should be systematically reminded to contact their HCP for any medical question or problem.
- **Justify the scientific need for using DTCP** in the study, considering that what is not scientific is not ethical. The need for using DTCP should be obvious for the subject, the HCP and the protocol's reviewers.
- **Keep the information given to subjects and HCPs simple.** Do not unnecessarily amplify ethical and regulatory concerns: too many warnings and legal clauses can generate suspicion in some cultures.

2. Master methodological biases

- **Standardize and harmonize the data collection process:**
  - Minimize the number of plate-forms to be involved in case of telephone assessments.
  - Use as many Computer-Assisted Telephone Interview Systems as possible (combining call scripts and questionnaires).
- **Induction and interpretation biases should be controlled** by training the interviewers to respect the call script, the exact wording of questions and answers for validated questionnaires, and to be neutral during the call. In this respect, the involvement of a HCP as an interviewer should be cautiously considered. Regular quality controls of interviewers should be performed regarding technical and communication skills, compliance to the contact quality plan, and good reporting.
- Organize strategies and escalation plans to **reduce lost-to-follow-up** rates.

Table 1.

Main concerns about DTPCs and their confrontation with experience

Concerns about DTPCs	Experience
Only a Health Care Professional (HCP) can provide accurate and reliable data.	False. When questionnaires are properly designed, validated, and administered, patients provide reliable perceptual and factual data. Depending on the nature of the study, some factual clinical data should be medically confirmed by an HCP. Therefore, each study using DTPC should be designed to document clinical data appropriately. In some patient assessments, HCPs may actually introduce bias, through induction of responses, interpretation, and reformulation. Using appropriately trained, non-HCP interviewers helps to avoid these problems.
Direct contact to patient by a third party will interfere in the relationship between patients and HCPs.	False. Patients and their treating HCPs are very sensitive about this question. Systems for DTPC should be conscientiously designed to promote the patient-HCP relationship, rather than interfere with it. DTPCs are not to be used for providing medical advice. However, to ensure that any emergent safety information is appropriately managed, procedures for safety reporting must be included in each DTPC system (see below).
Patients will be reluctant to be contacted by someone other than his/her treating HCP.	False. Patients, particularly the elderly, are often happy to talk about their health. Direct-to-patient contact, when properly implemented, can achieve a desirable level of confidence, particularly when the treating HCP has encouraged the contact process.
HCP will be reluctant to accept a third party contacting their patients.	Not necessarily. Late-phase research differs significantly from the preapproval, randomized clinical trial setting. Investigators in late-phase research may not be experienced in study management, and HCPs generally welcome the direct-to-patient principle, when provided with sufficient information and assurance about the system to be implemented. Furthermore, acceptance by HCPs is enhanced through positive feedbacks from their patients after the initial DTPCs are performed.
Pharmaceutical companies may have direct contact with patients in a study.	False. Except for a few countries and/or in some limited specific circumstances (e.g., health-product safety-management duty), direct contacts between pharmaceutical companies and patients are commonly either prohibited or at least very strongly supervised/regulated. When not performed by investigator sites, all DTPCs should be managed through an independent, trustworthy, third-party organization, with mandated procedures to guarantee consistent, impartial collection and confidentiality protection for all patient data.
DTPCs are less efficient when managed by a third party.	False. Unlike HCPs, professional interviewers have no day-to-day medical practice to combine with their activities in a study: it is more efficient for them to perform all necessary attempts to contact and obtain information from the patient. Available technology offers a variety of approaches for DTPC, so that the most appropriate method(s) for the individual study design and requirements may be selected, e.g., telephone, Smartphone, postal mail, e-mail, and/or Internet.
Ethics committees, Institutional Review Boards (IRBs), and other competent authorities will reject a protocol that includes direct-to-patient contact.	Unlikely, especially if appropriate information has been provided and the study design clearly justifies DTPC. In the process of protocol development, ethical and regulatory concerns should be anticipated, and every effort made to satisfy them proactively, by furnishing thorough documentation of processes, training, and safeguards. With this approach, questions are more likely than outright refusals which, in our experience, are infrequent. However, some health authorities ultimately may require the re-classification of a non-interventional study design as "interventional" on the grounds that a continuing DTPC process cannot be considered as normal clinical practice.
Adverse drug reactions (ADRs) or medical device adverse events (AEs)/adverse device effects (ADEs) may be revealed during a direct-to-patient contact.	True. These concerns regarding pharmacovigilance and medical-device vigilance must be addressed proactively in the design of any study using DTPC. Study-specific safety-management plans must be developed to include procedures for reporting of suspected adverse drug reactions or medical device adverse events/adverse device effects in accordance with appropriate regulations and as required by health authorities, in addition to mandating appropriate training and continued supervision of personnel involved in DTPC.

Table 2.

Benefits of Direct-to-Patient Contact

- Robust study results, including improvement in response rate, retention/withdrawals, and loss to follow-up
- Increased study acceptance by patients and HCPs
- Investigators save time and have reduced study burden
- Patients gain a sense of increased assistance, with more comfortable interactions and proactive assessments of their condition
- Improved compliance with the protocol, study methodology, and scheduled processes
- More reliable PRO data, including control over confusion bias and patient selection bias, and fewer missing and/or inconsistent data
- Original, simplified, efficient, and cost-effective study design, particularly useful for proactive pharmacovigilance systems
- Secured study organization and follow-up

- Be sure that the questionnaires to be used have been **validated** for the medium of assessment. If not, at a minimum, test it through a pilot study.
- Take advantage of the possibility to **avoid confusion bias** by a PRO data collection outside of a doctor's appointment.
- Combine data-collection modes to be in line with each patient's lifestyle even if this may generate some data-management burden. This will better **control selection bias** and **improve response rates**: the patient sample and study results will be more robust.

3. Keep it simple: be reasonable and in phase with patient lifestyle in the real world

- Useless burden for patients is the enemy of a study, particularly for prospective long-term registry/cohort studies and studies requiring frequent assessments. **Limit the assessment to the essential information you should collect.** Avoid the "nice-to-have" approach leading to a long and complicated assessment for the patient, or sort out questions in order of priority: filter questions (should have) followed by optional questions (nice to have).
- Should a questionnaire be specifically developed for a study, **use comprehensible questions and answers** to allow the patient to answer. Test your questionnaire on patients using the future medium for assessment (cognitive interviews). This is of major importance if the questionnaire is assessed over the phone.
- **Use a dedicated version for each medium used for assessment.**
- **Combine several methods to communicate with the subject.** Consider that the investigator as an HCP is not the best profile for training a subject for the use of a new technology: prefer well-tried, easy-to-use, and widely used technologies to the latest communication medium. Bear in mind for long-term studies that technologies and subject customs will change quickly over time.
- **Respect subject privacy concerns:** some patients do not wish to share with their relatives their participation in a study—particularly when the disease is a sensitive one—or the physicians they have visited. Communication with relatives should be neutral and cautious in order to protect the subject's privacy.

4. Do not mistake medical-regulation service or study-monitoring service for patient's assessment

- **Do not involve HCPs when not strictly necessary** for the purpose of the assessment. Do not require a Clinical Research Associate (CRA) background to perform assessments. Such skills are not relevant for the majority of pharmacoepidemiological studies.
- **Master the level of competencies.** Avoid asking non-HCP personnel to act and react as physicians or nurses. On the contrary, clearly limit their activity to the process they are in charge of. Return calls to a patient by a physician can be performed when needed.
- **Set up an easy-to-understand process** in order to manage reporting of adverse drug reactions during a contact (using a short safety-management plan and an easy-to-complete event report form).

5. Rely on robust processes and sound organization for contacts rather than on individual skills

- **Write a "contact-management plan."**
- **Anticipate as many as possible situations** in call scripts.
- **Perform appropriate training of interviewers,** including study objectives, disease, pharmaco-vigilance and data privacy protection concerns, tools to be used, call scripts, escalation process, a to-do or not-to-do list and expectations, of all stakeholders in the study. But do not train an interviewer as an investigator or a monitor: limit the training to what they may encounter during their contacts with patients.

Conclusion

These tips and tricks may contribute to the development of a consensual guidance on "Good Patient Contact Management Practices in Studies". Such guidance would be beneficial to ensure a safe and efficient use of this valuable tool in pharmacoepidemiological studies.

For more information, please contact: Sandra Wiederkehr, PhD, Project Director, Direct-to-Patient Contact Department (PROCLINICA™), swiederkehr@registratmapi.com

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Clinical Data Interchange Standards Consortium (CDISC)

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KEYWORDS
STANDARD CONTROLLED TERMINOLOGY, QUESTIONNAIRES, CLINICAL TRIAL, STANDARDIZATION

The Clinical Data Interchange Standards Consortium (CDISC), a global, non-profit standards development organization, works with the FDA, US National Institutes of Health (NIH), and global organizations conducting clinical research to represent data collected in clinical trials in a standardized format that can be more consistently analyzed and reviewed.

One of our initiatives is to define standard controlled terminology for questions included on questionnaires.

The first step is to get permission from intellectual property owners to represent an instrument in an industry-standard metadata format that has been defined by CDISC. Participation in this process will ensure that when incorporated in future clinical trials, the instrument is accurately and efficiently represented in a CDISC-standard format.

CDISC standards for an instrument will include standardized variable names and controlled terminology for database values. We would also like to include an annotated Case Report Form version of the instrument that shows how each question is represented using standard CDISC variable names. This information will be maintained on the CDISC website where it can be accessed directly by clinical researchers.

Please note that all instrument owners will maintain full copyright status when granting this permission to CDISC. In fact, we expect that making the instrument compatible with our standards could increase its use, especially for clinical trials that are being submitted to the FDA and conducted by research institutions. See Table 1 for examples of questionnaires for which the terminology has been developed or is in development.

For more information, please visit www.cdisc.org or contact Bernice Yost at byost@cdisc.org

Table 1.

CDISC Questionnaire Controlled Terminology (extract)

OID	Name DataType (CDISC Submission Value)	DataType Extensible	NCI Code	CDISC Synonym	
	CDISC Submission Value [ODM:CodedValue]				
CL.C100129.QSCAT	Questionnaire Category (QSCAT)	Text Extensible: Yes	C100129	Questionnaire Category	
	BPI		C100759	BPI1	
	BPI SHORT FORM		C100760	BPI2	
	BPRS-A		C100761	BPR01	
	CGI		C100763	CGI01	
	C-SSRS BASELINE		C100765	CSS01	
	COMM		C100764	COMM01	
	EQ-5D-3L		C66957	EQ5D01	
	FPSR		C100766	FPSR1	
	HAMD 17		C100767	HAMD1	
	KPS SCALE		C100768	KPSS	
	MNSI		C100771	MNSI1	
	MMSE		C100770	MMS1	

PUBLICATIONS...

New Methods Can Extend the Use of Minimal Important Difference Units in Meta-analyses of Continuous Outcome Measures.

Johnston BC, Thorlund K, da Costa BR, Furukawa TA, Guyatt GH.
J Clin Epidemiol. 2012 Aug;65(8):817-26.

Systematic reviews of clinical trials that include measurements of continuous outcomes such as health-related quality of life potentially provide critical information for patients and clinicians facing challenging healthcare decisions. When, as is most often the case, individual clinical trials use different measurement instruments for the same construct (such as physical or emotional function), authors typically report differences between intervention and control in standard deviation units (so-called "standardized mean difference" or "effect size"). This approach has statistical limitations (it is influenced by the heterogeneity of the population) and is non-intuitive for decision makers. The Hospital for Sick Children's Dr. Bradley Johnston and colleagues have recently developed an alternative approach: reporting results in minimal important difference units (the smallest difference patients experience as important), a method that has been used at the clinical-trial level but not yet at the meta-analysis level. This approach provides a potential solution to both the statistical and interpretational problems of existing methods.

CDISC Definition	Preferred Term
A grouping of observations within the Questionnaire domain.	CDISC Questionnaire Category Terminology
Brief Pain Inventory (BPI) (copyright 1991 Charles S. Cleeland, PhD, Pain Research Group, All rights reserved).	Brief Pain Inventory Questionnaire
Brief Pain Inventory Short Form (BPI2) (copyright 1991 Charles S. Cleeland, PhD, Pain Research Group, All rights reserved).	Brief Pain Inventory Short Form Questionnaire
Brief Psychiatric Rating Scale (BPRS-A) (Overall JE, Gorham DR (1962). The brief psychiatric rating scale. Psychological Reports 1962 vol. 10, pp799-812).	Brief Psychiatric Rating Scale A Questionnaire
Clinical Global Impression (CGI) (Guy W: ECDEU Assessment Manual for Psychopharmacology. Rockville, MD: U.S. Department of Health, Education, and Welfare; 1976).	Clinical Global Impression Questionnaire
Columbia-Suicidality Severity Rating Scale (C-SSRS) Baseline Version 2009-01-14 (Posner, K.; Brent, D.; Lucas, C.; Gould, M.; Stanley, B.; Brown, G.; Fisher, P.; Zelazny, J.; Burke, A.; Oquendo, M.; Mann, J.; copyright 2008 The Research Foundation for Mental Hygiene, Inc.).	Columbia-Suicidality Severity Rating Scale Questionnaire
Current Opioid Misuse Measure (COMM) (copyright 2010 Inflexxion, Inc., All rights reserved).	Current Opioid Misuse Measure Questionnaire
The EuroQol (European Quality of Life) Five Dimension Three Level Scale (EQ-5D-3L) (copyright 1990 EuroQol Group EQ-5D. All rights reserved).	EuroQOL Three Dimension Five Level Questionnaire
Faces Pain Scale - Revised (FPS-R) (Hicks CL, von Baeyer CL, van Korlaar I, Goodenough B. Faces Pain Scale-Revised: Toward a Common Metric in Pediatric Pain Measurement. Pain 2001; 93:173-183).	Faces Pain Scale Revised Questionnaire
The Hamilton Depression Rating Scale 17-Item (HAMD 17) (Hamilton M. Development of a rating scale for primary depressive illness. Br J Soc Clin Psychol 1967; 6(4):278-96).	Hamilton Depression Rating Scale 17 Item Questionnaire
The Karnofsky Performance Status Scale (KPSS) (Karnofsky DA, Burchenal JH. (1949). "The Clinical Evaluation of Chemotherapeutic Agents in Cancer." In: MacLeod CM (Ed), Evaluation of Chemotherapeutic Agents. Columbia Univ Press. Page 196).	Karnofsky Performance Status Scale Questionnaire
Michigan Neuropathy Screening Instrument (MNSI) (copyright University of Michigan, 2000, All rights reserved).	Michigan Neuropathy Screening Instrument Questionnaire
The Mini-Mental State Examination (MMSE) (Folstein MF, Folstein SE, McHugh PR. "Mini-Mental State": A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res. 1975; 12(3):189-98).	Mini-Mental State Examination Questionnaire

New Questionnaires Distributed by MAPI Research Trust

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KEYWORDS
QUESTIONNAIRES, DISTRIBUTION, COPYRIGHT, LICENSING

MAPI Research Trust is a not-for-profit organization that aims to facilitate access to PRO questionnaires. Our services include the management of a PRO Questionnaires Distribution Center that acts as a facilitator between the authors and the users of questionnaires by centralizing the licensing process as well as gathering all available translations and updated and accurate information on the instruments. These services are very valuable to the authors as well as to the questionnaires' users.

Acting on behalf of the authors, MAPI Research Trust is today the official distributor of more than 115 PRO questionnaires.
In 2012, MAPI Research Trust has enriched its catalog with the following eight new instruments:

BI - Barthel Index

➤*Developed by:* Florence I Mahoney; Dorothea W Barthel (USA)

➤*Objective:* To measure a person's daily functioning, specifically the activities of daily living (ADL) and mobility.

➤*Copyright:* © The Maryland State Medical Society

➤*Reference publication:*
Mahoney FI, Barthel DW. Functional evaluation: The Barthel Index. Md State Med J. 1965 Feb;14:56-61.

ESS - Epworth Sleepiness Scale

➤*Developed by:* Murray Johns (Australia)

➤*Objective:* To measure a subject's usual level of daytime sleepiness or average sleep propensity.

➤*Copyright:* © M.W. Johns 1990-1997

➤*Reference publications:*

- Johns MW. The clinical assessment of daytime sleepiness in patients with obstructive sleep apnea. In: Surgery for snoring and obstructive sleep apnea syndrome, ed. Fabiani M. Kugler publications, The Hague, 2003: 283-295.
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- Johns MW. Reliability and factor analysis of the Epworth Sleepiness Scale. Sleep. 1992 Aug;15(4):376-81.
- Johns MW. A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. Sleep. 1991 Dec;14(6):540-5

MAF - Multidimensional Assessment of Fatigue

➤*Developed by:* Basia Belza (USA)

➤*Objective:* To measure self-reported fatigue in adults with chronic illness.

➤*Copyright:* © Basia Belza

➤*Reference publication:*
Belza BL, Henke CJ, Yelin EH, Epstein WV, Gilliss CL. Correlates of fatigue in older adults with rheumatoid arthritis. Nurs Res. 1993 Mar-Apr;42(2):93-9.

PACD - Pediatric Asthma Caregiver Diary

➤*Developed by:* Merck Sharp & Dohme Corp. (USA)

➤*Objective:* To assess asthma symptoms, medication, and impact on asthma on usual activities in children with asthma.

➤*Copyright:* © Merck & Co., Inc. Whitehouse Station, N.J., U.S.A. All rights reserved.

➤*Reference publication:*
Santanello NC, Demuro-Mercon C, Davies G, Validation of a pediatric asthma caregiver diary. J Allergy Clin Immunol. 2000 Nov;106(5):861-6.

QBPDS - Quebec Back Pain Disability Scale

➤*Developed by:* Jacek A. Kopec (Canada)

➤*Objective:* To measure functional disability for patients with back pain.

➤*Copyright:* QBPDS © Jacek A. Kopec, 1995, All rights reserved.

➤*Reference publications:*

- Kopec JA, Esdaile JM, Abrahamowicz M, Abenhaim L, Wood-Dauphinee S, Lamping DL, Williams JI. The Quebec Back Pain Disability Scale: conceptualization and development. J ClinEpidemiol. 1996 Feb;49(2):151-61.
- Kopec JA, Esdaile JM, Abrahamowicz M, Abenhaim L, Wood-Dauphinee S, Lamping DL, Williams JI. The Quebec Back Pain Disability Scale. Measurement properties. Spine (Phila Pa 1976). 1995 Feb 1;20(3):341-52.

TBQ - Burden of Treatment Questionnaire

➤*Developed by:* Philippe Ravaud and Viet-Thi Tran (France)

➤*Objective:* To measure Treatment Burden, that is the impact of the workload of healthcare on a patient's well-being and functioning, among patients with multiple chronic conditions.

➤*Copyright:* TBQ © Ravaud et al, 2012. All rights reserved

➤*Reference publication:*
Tran VT, Montori VM, Eton DT, Baruch D, Falissard B, Ravaud P. Development and description of measurement properties of an instrument to assess Treatment Burden among patients with multiple chronic conditions. BMC Med. 2012 Jul 4;10(1):68.

New Questionnaires Distributed by MAPI Research Trust pp. 16-17

TRIM-D - Treatment Related Impact Measure for Diabetes

TRIM-D Device - Treatment Related Impact Measure for Diabetes - Device

➤*Developed by:* Novo Nordisk (Denmark)

➤*Objective:* The aim of this bi-modular instrument is to measure treatment related impact on subjects of diabetes medication and diabetes devices.

➤*Copyright:* © Novo Nordisk, August 2008.

➤*Reference publications:*

- Brod, M, Christensen, T, Bushnell, D. Maximising the Value of Validation Findings to Better Understand Treatment Satisfaction Issues for Diabetes. Quality of Life Research 2007; 16:1053-1063.
- Brod M, Christensen T, Hammer M, Busk AK, Bushnell D. Examining the ability to detect change using the TRIM-Diabetes and TRIM-Diabetes Device measures. Quality of Life Research 2011; DOI 10.1007/s11136-011-9886-7.

For detailed information on the conditions to access the questionnaires and to consult our entire catalog, please visit MAPI Research Trust's website: www.mapi-trust.org, section Services, Questionnaire Licensing, Our catalog, and then click on the appropriate link to find specific information about each questionnaire.

For any specific questions, please contact: PROinformation@mapi-trust.org

If you have developed a health outcomes questionnaire and if you are interested in MAPI Research Trust's distribution services, please contact Marie Dulac Trimoreau at mdulac@mapigroup.com

CATHERINE POUGET AWARD

Catherine Pouget

How to Apply

CRB Joyce, Member of the Scientific Advisory Committee of MAPI Research Trust

In 2001, the MAPI Research Institute created this award in memory of a young colleague and friend who had died of cancer after receiving disappointingly insensitive and insufficient support during her illness.

The award is intended to improve the care of patients in terminal illness, including the education of those who care for them. It is not limited to projects with a scientific basis; even if you have not received formal scientific training, you may also make good use of your experience and ideas, and put forward relevant proposals. Whether scientific or not, your proposal may focus upon patients' families, medical and other caregivers, or patients themselves, but your objective will always be to *improve the quality of care* received by patients with terminal illness. Younger investigators and others are especially encouraged to apply.

Your application will be evaluated by senior staff members of MAPI Research Trust and its Advisory Committee. One award of up to a maximum of $10,000 will be made each year. The proposed work should be completed in not more than two years.

Criteria

The criteria for evaluation of your application for the award are: (a) appropriateness (relevance to the purpose stated above); (b) imaginativeness (originality of the concept and/or method of execution and evaluation); (c) realism (likelihood that the defined objective and its evaluation will be achieved within the intended period); and (d) generalizability (usefulness/transferability to other people or institutions in the field).

An account of the background to your proposal is not required unless you consider that it is especially relevant. However, you should clearly answer the following questions:

(a) What is the specific problem that you intend to explore?
(b) What method(s) will you choose in order to solve this problem?
(c) What methods do you propose to show that your work was successful?
(d) What does each major item in your proposal cost (the total to be $10,000 or less)?
(e) How do you intend to use the results?

You should briefly describe the people you intend to study, and how you will find and recruit them. Also remember ethical issues, such as institutional review.

Applications that facilitate additions to existing projects may be submitted. Your budget justification should address any overlaps with such funding.

Application Form

On a separate, initial sheet, give your date of birth; highest general and/or professional qualification; current professional position (academic, research, or neither) or other information relevant to your proposed research; and *up to but not more than three* of your OWN publications or presentations, if available. The main text should consist of *not more than 1500 words* or six double-spaced pages in 14-point type, in English.

The successful candidate is required to submit a brief (300 to 500 words) description of the project, an interim summary of 300 words within three months of ending the first year of work, and a full report within six months of ending the final (first or second) year. These narratives will be published in the *Patient-Reported Outcomes Newsletter*.

Three copies of the completed form should be submitted, preferably in PDF format, by e-mail, to Ms.Tatiana Gauchon: tgauchon@mapigroup.com

The winner of the Catherine Pouget Award for 2010 was Koen Pardon. The following is a brief report on his study.

Development of an Intervention to Improve Physician-Patient Communication in Patients with Advanced Cancer

A focus group study of the End-of-Life Care Research Group of Ghent University and the Vrije Universiteit Brussel, Belgium

Koen Pardon, PhD
Ghent University & Vrije Universiteit Brussel, Belgium

Abstract

Information provision and shared medical decision-making are hampered in the context of advanced lung cancer. Three focus group discussions with oncologists and pulmonologists were held to identify barriers and list suggestions for improvement. On the basis of the results, eight practice recommendations and a model of intervention for physicians (a communication-skills training program) and for patients (a question-prompt list) were proposed. Recommendations and interventions were evaluated as clear, useful and attainable, but have to be further tested on their effect on information provision and shared decision-making and patient-reported outcomes such as patient satisfaction and quality of life.

Background

Between 2007 and 2010, the End-of-Life Care Research Group of Ghent University and the Vrije Universiteit Brussel in Belgium conducted a large study on preferences for information and participation in medical decision-making of advanced lung cancer patients in Flanders, the Dutch-speaking part of Belgium. We found that a lot of recently diagnosed patients who wanted to be informed about prognosis, palliative care, and end-of-life decisions with possible life-shortening effects (ELDs) were not optimally informed. Patients who wanted to share the medical decisions with their physician often did not achieve this degree of involvement and were less involved than they preferred.

Objectives and methods

The first goal of this follow-up study was to discuss these problems with pulmonologists and oncologists of hospitals that have a full oncology program to identify barriers to information provision and shared decision-making and to list suggestions for improvement. The methodology of focus groups was used. A focus-group is a qualitative research method that consists of a group discussion and is oriented at gaining more insights. The discussions were audio-taped and analyzed. The second goal was to develop recommendations and a model of intervention to improve the communication, and to present these to oncologists and pulmonologists for evaluation using a self-developed questionnaire.

Results

Three 120-minute focus-group discussions, with a total of eight oncologists and five pulmonologists, took place. The mean age of the oncologists and pulmonologists was 45 years (30-70) and 62% of them were males. The questionnaire for evaluation of the proposed recommendations and model of intervention was sent to the participating physicians in June 2012 and the response rate by July 1, 2012 was 54%.

The main identified barriers to information provision about prognosis, palliative care, and ELDs were the fear of destroying hope in the patient, uncertainty of the disease trajectory, and the attitude of physicians to cure and prolong life rather than to offer palliative

care options. Barriers for shared medical decision-making were the physician's belief that shared decision-making was not possible, the complexity of medical decision-making, the perceived lack of training, and the perceived lack of interesting contributions to the medical decision-making process by the patient.

The physicians suggested several interventions to improve the information provision and decision-making. The interventions could be categorized in structural, patient-related, and physician-related interventions. The most discussed structural intervention concerned the installment of regular interdisciplinary meetings to discuss the patients' psychosocial issues. The suggested interventions that were related to the patient aimed to make the patient more responsible for the communication process. An example of such an intervention was the advice to the patient to write down all the questions for the physician between consultations. A method related to the physician that was seen as extremely useful to improve communication concerned regular communication training with videotaped role play involving simulated patients. This training was seen as effective when tailored to the specific needs of the physician and when containing follow-up sessions.

On the basis of the suggestions for improvement that were made, we proposed eight recommendations for physicians and a model of intervention. The recommendations concerned:

(1) structurally discussing the patient's psychosocial issues with other healthcare professionals to get greater insight into the patient and his or her information and participation preferences;
(2) preparing the consultation and prioritizing the issues that have to be discussed in the consultation, and delegating communication tasks regarding routine technical issues to the nursing staff;
(3) ensuring continuity in communication by being the key physician who follows the patient throughout his or her disease trajectory;
(4) referring the patient to professional help when he or she experiences difficulties in coping with the information and medical decision-making process;
(5) discussing palliative care and end-of-life care by default, early on in the disease course;
(6) discussing the specific information and participation preferences explicitly with the patient;
(7) making the patients more responsible for the communication process by instructing them to prepare a list of questions; and
(8) taking a short but intensive communication-skills training program. The proposed model of intervention was an evidenced-based communication-skills training program with role play for physicians and the use of a prompt list of questions for patients.

Oncologists and pulmonologists evaluated the recommendations and intervention as clear, useful, and attainable with mean scores between 6 and 9 on a scale from 1 being "not at all" to 10 being "very clear/useful/attainable." The willingness to implement the recommendations and intervention was also high (from 7 to 9). The recommendation that received the highest score overall was the recommendation to "instruct the patient to prepare a list of questions between consultations."

Conclusion

This study suggested a set of promising recommendations and a model of intervention to improve information provision and shared decision-making in the context of advanced (lung) cancer. In future research the recommendations and model have to be thoroughly compared with those that are described in the medical literature and have to be further tested on their effect on communication.

For more information, please contact Koen Pardon at koen.pardon@vub.ac.be.

NEWS FROM...

An important Initiative on Quality of Life (QOL) and Palliative Care in Nephrology in Latin America

Dr. Juan J. Dapueto, Professor, Director of the Departamento de Psicología Médica, Facultad de Medicina, Universidad de la República, Montevideo, Uruguay
jdapueto@hc.edu.uy

The Latin-American Society of Nephrology and Hypertension (SLANH) has recently instituted the Quality of Life and Palliative Care Committee. This group is formed by health professionals of the various disciplines involved in the care of patients with end-stage renal diseases, nephrologists, nurses, social workers, nutritionists, mental health professionals, and palliative care specialists from Argentina, Chile, Colombia, Cuba, the Dominican Republic, and Uruguay. The Committee is led by the Chilean nephrologist and president elect of the Chilean Society of Nephrology, Dr. Carlos Zúñiga San Martín.

The Committee is the product of a long process that started in 2004 when a workshop on health-related quality of life was held by SLANH in the context of the 12th Latin-American Congress of Nephrology, in Punta del Este, Uruguay. From then on, committees on QOL, palliative care, and ethics were organized by the national societies of Chile, Uruguay, and Argentina. Other countries are following the same model. Last July, the 2nd Workshop on Quality of Life and Palliative Care took place in Santiago, Chile.

Is a palliative-care approach suitable for renal patients?

Dialysis as a replacement treatment for the end-stage renal disease (ESRD) relieves the symptoms of uremia and prolongs life but it is not in itself curative and, as any other form of treatment, it carries a certain amount of associated morbidity that impacts on the quality of life (QOL) of the patients. Once in dialysis, patients are confronted to the paradox of enjoying the extraordinary benefits of technology and modern medicine, and the challenge of living with limitations. While dialysis allows patients to build a full life, the underlying systemic disease that caused the renal failure, surreptitiously progresses, affecting other organs and functions that, in turn, impact functional status and QOL. The case of diabetes is paradigmatic with its sequelae of blindness, amputations, painful neuropathies, and cerebral vascular damage, among others. Focusing on the symptom burden and the level of disability, the emotional, social/familial, and spiritual well-being of patients is now a major objective of renal replacement treatments.

A palliative-care approach ***aimed at improving the QOL of patients and families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification, assessment, and treatment of pain and other physical, psychosocial and spiritual problems[1],*** as defined by the World Health Organization (WHO), is not only suitable but also mandatory in the case of ESRD patients.

The SLANH initiative, by creating a committee devoted to the consideration of these aspects of patient care, will contribute to promote the implementation and development of this model of care throughout the continent, providing scientific support for researchers, and developing continuing medical education programs and training courses to Latin American nephrologists, with a special emphasis in including QOL and palliative-care issues in residency programs.

Quality of life, palliative care, and ethical issues involved in the management of ESRD patients

There are many aspects that have to be taken into consideration when dealing with ESRD patients in order to reduce suffering, improve QOL, and help patients and their families in the decision-making process. Some of them are included in the list below:

- Pain management
- Sleep disorders
- Sexual dysfunction
- Depression and other psychological and psychiatric syndromes
- Physical rehabilitation and the implementation of exercise protocols in the dialysis settings
- Nutritional therapy and its impact on QOL
- Inclusion of QOL assessment in daily clinical practice
- The adaptation of the patient-centered medicine approach to practice in nephrology
- Communication on advance directives and patient preferences
- QOL and ethical issues referring to the withholding and withdrawal of patients from dialysis
- Adherence and QOL
- The care of the dying patients and the design of end-of-life protocols
- Psychosocial and spiritual support to patients and families
- Programs aimed to reduce family burden
- The bereavement process of the family
- The "empty seat syndrome," the mourning process of the team members and fellow patients

An important Initiative on Quality of Life (QOL) and Palliative Care in Nephrology in Latin America (cont'd)

The aims of the committee

The committee aims to:

- Contribute to the study and dissemination of information related to QOL and palliative care in ESRD patients
- Promote the inclusion of these issues in national as well as regional conferences
- Contribute to a more comprehensive training of residents and other professionals in the field
- Develop continuing medical-education courses
- Design treatment guidelines and protocols
- Build a network between the national societies of nephrology and local groups throughout Latin America

In summary

A therapeutic approach based on the patients' assessments of QOL and their perceptions and preferences with regard to their needs for medical care demands a change of mentality and in behavioral patterns of the nephrology teams. Education and training are essential in promoting and sustaining these changes. We truly hope that the work of this new committee will bring together a critical mass of professionals interested in these issues and will contribute to set the basis of a more comprehensive and humanistic approach to ESRD patients and their families.

References

1. World Health Organization. *National cancer control programs: policies and managerial guidelines*, 2nd ed. Geneva, World Health Organization, 2002.

Other references of interest:

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Critical Path Institute's Patient-Reported Outcome Consortium

Stephen Joel Coons, PhD, Executive Director, PRO Consortium,
Critical Path Institute, Tucson, Arizona, USA

Critical Path Institute (C-Path) is a private, non-profit organization created in 2005 by the University of Arizona and the US Food and Drug Administration (FDA) to support the FDA's Critical Path Initiative, which is a strategy for transforming the way FDA-regulated medical products are developed, evaluated, manufactured, and used. The Patient-Reported Outcome (PRO) Consortium was established in late 2008 by C-Path, in cooperation with the FDA and the medical products industry, to collect the necessary evidence to support FDA "qualification" of new or existing PRO instruments for use in clinical trials where PRO endpoints can be used to support product-labeling claims.[1]

PRO instrument qualification, via the FDA's drug development tool qualification process, is a formal conclusion by the FDA that the results obtained from the PRO instrument within a stated context of use can be relied upon to measure important aspects of clinical benefit and can be used as the basis of medical product approval and labeling claims.[2] Qualification has the potential to: increase the number of accepted PRO measures used to support claims in product labeling; enhance comparability/consistency of endpoints across clinical trials; improve efficiency for sponsors in endpoint selection; and facilitate the FDA's review of medical products by standardizing PRO endpoints.

The PRO Consortium has 25 member firms (http://www.c-path.org/PRO.cfm). Its goals include enabling pre-competitive collaboration that includes FDA input and expertise, avoiding development of multiple PRO instruments for the same purpose, sharing costs of qualifying new or existing PRO instruments, and advancing the science of PRO measurement. The PRO Consortium has working groups in the following therapeutic areas: asthma, depression, functional dyspepsia, irritable bowel syndrome, mild cognitive impairment, non-small-cell lung cancer, and rheumatoid arthritis. The working groups are at different points on the path to PRO instrument qualification. The PRO Consortium is committed to sharing the procedural and scientific insights that emerge along the way.

1. Coons SJ, Kothari S, Monz BU, Burke LB. The Patient-Reported Outcome (PRO) Consortium: filling measurement gaps for PRO end points to support labeling claims. *Clinical Pharmacology and Therapeutics* 2011;90(5):743-8.
2. US Food and Drug Administration. Guidance for Industry: Qualification Process for Drug Development Tools (Draft). 2010; http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM230597.pdf. Accessed August 3, 2012.

ANNOUNCEMENTS

2012 ISOQOL Annual Conference
Budapest, Hungary
October 24-27, 2012

Registration now open

With Budapest's striking landscape, relaxing river, and beautiful architecture you will be pushed towards new discoveries both during the conference sessions and beyond. Join fellow health-related quality-of-life researchers, clinicians, and industry professionals and in sharing research through workshops, symposia, and engaging poster presentations. A host of networking receptions and breaks will allow you plenty of time to catch up with old friends and to make new connections. We welcome anyone engaged in quality-of-life research to join us at this meeting.

SIG Meetings

Each Special Interest Group (SIG) will be holding its annual meeting in Budapest. All ISOQOL members are invited to join a SIG and engage with activities throughout the year. Please see our online schedule of events for a full listing of dates and times these SIGs will be meeting. If you are not an ISOQOL member, participation in one of these SIGs is a great reason to join.

Plenary Sessions

Comparative Effectiveness Research and Patient-Centered Outcomes Research will be presented by Ethan Basch, MD MSc, Memorial Sloan-Kettering Cancer Center, Chair, Patient-Centeredness Workgroup, Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI); Andrew Vallance-Owen MBA FRCS Ed, Chairman, UK Department of Health's PROMs Stakeholder Group, and Albert W. Wu, MD MPH, Johns Hopkins Bloomberg School of Public Health. The session will be chaired by Neil K. Aaronson, PhD.

From Clinical Trials to Clinical Practice: Towards Bridging the Gap will be presented by Michael Brundage, MD, Cancer Research Institute at Queen's University, Ontario, Canada and Chair of the CONSORT PRO 2012 Executive and ISOQOL Reporting Guidelines Task Force; Paul Jacobsen, PhD H. Lee Moffitt Cancer Center & Research Institute and the University of South Florida, Tampa, FL, USA, and Holger J. Schünemann, MD, PhD, MSc, FRCP(C) McMaster University Health Sciences Centre, Hamilton, ON, Canada. The session will be chaired by Melanie Calvert, PhD and Fabio Efficace, PhD.

Innovations in eHealth will be presented by Paul Wicks, PhD, Patients Like Me, and Martha Grootenhuis, PhD, Emma Children's Hospital, Academic Medical Center, Amsterdam, The Netherlands. The session will be chaired by Sara Ahmed, PhD and Bernhard Holzner, PhD BE.

Paving the Path Towards Personalized Medicine will be presented by Per Hall, Karolinska Institute, Stockholm, Sweden; Donald E. Morisky, ScD ScM MPH, UCLA School of Public Health, Los Angeles, CA, USA and William E. Narrow, MD MPH, DSM-5 Task Force, American Psychiatric Association. The session will be chaired by Juan J. Dapueto, MD, PhD and Mirjam AG Sprangers, PhD.

To read additional information about our speakers, please visit http://www.isoqol.org/2012conference/schedule.php

Workshops and Luncheon Roundtables

Thirteen different workshops will offer attendees an opportunity to dive deep into a topic meeting specific educational needs. Titles of workshops include *Interpreting Utility (Preference-Based) Measures of Health-Related Quality of Life; Assessing Health Outcomes in a Global Clinical Research Setting: Challenges and Solutions to Manage Cultural Variability*; and *Improving the Reporting of Patient-Reported Outcomes in Clinical Trials*. Luncheon roundtable discussions will allow attendees time to discuss an area of mutual interest with a veteran in the field. Pre-registration is required for all workshops and for luncheon roundtables. Topics include *Cancer Survivorship, Innovations in Modern Psychometrics*, and a roundtable focused on the needs of students and new investigators: *CVs, Resumes, and Cover Letters, Oh My*!

Host Hotel

All of the scientific content for the conference will be held at the Budapest Marriott Hotel. All guest rooms have a view of the Danube River and the hotel is located in the city center, near Parliament, Buda Castle, restaurants and shopping. The views at night of the Royal Palace from the hotel are particularly breathtaking!

Closing Dinner on Saturday

Our closing dinner celebration will take place during a dinner cruise along the Danube River. Enjoy delightful entertainment and a delicious dinner with your colleagues and friends. Tickets for the event may be purchased through your registration.

The ISOQOL Translation and Cultural Adaptation Special Interest Group (TCA-SIG)

The ISOQOL Translation and Cultural Adaptation Special Interest Group (TCA-SIG) is delighted to announce that its annual meeting will take place on Thursday, October 25th from 6:00 pm to 7:30 pm during the ISOQOL 19th Annual Conference in Budapest, Hungary, October 24-27, 2012, at the Marriot Hotel.

The highlight of our annual meeting will be the following two presentations which, we are sure, will lead to stimulating discussions:

Conferences Congresses Workshops Meetings

ANNOUNCEMENTS

1. **"One Language: Benefits of a Universal Translation Approach,"** Helena Correia, Department of Medical Social Sciences, Northwestern University, Chicago, IL, USA

2. **"Impact of culture in PRO data,"** Ari Gnanasakthy, Head, Patient-Reported Outcomes, Novartis Pharmaceuticals Corporation

The TCA-SIG will also host a panel discussion about the usefulness and approach to "translatability assessment" of PRO measures. The session will take place on Friday, October 26, from 6:15 pm to 7:45 pm.

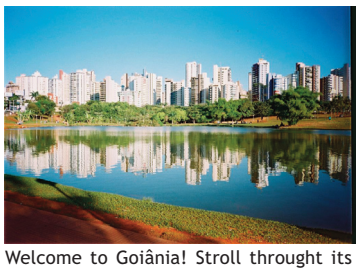
We hope you will join us in Budapest. Please contact Tatiana Gauchon at tgauchon@mapigroup.com for more information prior to the meeting or consult the ISOQOL website: www.isoqol.org

6th Ibero-American Meeting on Quality of Life Research

Goiânia - Goiás - Brazil - 11/29 to 12/01/2012 - San Marino Suite Hotel

We are celebrating the **6th Ibero-American Meeting on Quality of Life Research**, with the theme **"Measuring Quality of Life: Applications in Clinical Practice,"** from November 29 to December 1, 2012, in the Federal University of Goias, located in west-central Brazil. We invite all professionals interested in studies on health-related quality of life to participate.

The event will include conferences, round tables, and pre-congress courses. We have confirmed the participation of Drs. Claire Snyder from the USA, and Sara Ahmed from Canada, as well as renowned several Ibero-American colleagues.



Welcome to Goiânia! Stroll throught its beautiful woods and wie avenues and try not to fall in love...

Goiânia

It is the capital of the state of Goias, located in the central plateau of Brazil, 209 km (about 130 miles) from Brasilia, the country's capital. With a population of 1,318,148, Goiânia is among the seven Brazilian cities with the best quality of life; it takes pride in charming its denizens and visitors.

SPONSORS/COORDINATION:

- International Society for Quality of Life Research (ISOQOL) Ibero-American Section.
- Federal University of Goias (UFG).
- Multidisciplinary Group in Quality-of-Life Studies / UFG (GMPQV/UFG).
- Center for Research on Paradigm Care and Quality of Life (NEPAQ) of the Federal University of Goias.

ORGANIZATION: *International Society for Quality of Life Research (ISOQOL) - Ibero-American Section.*

REALIZATION: *Universidade Federal de Goiás (UFG) - Grupo Multiprofissional de Estudos em Qualidade de Vida (GMPQV) e Núcleo de Estudos em Paradigmas Assistenciais e Qualidade de Vida da Faculdade de Enfermagem (NEPAQ).*

CONTACT: *Equippe Eventos.* Rua 06, 370- sala 206.
Setor Oeste - Goiânia/ Goiás. Brazil CEP: 74.115-070
Phone: 55(62)3945-1374.
www.equippeeventos.net/isoqol

Call for Articles

PRO Newsletter 49

Any news and information on Patient-Reported Outcomes are welcome (e.g., short articles on on-going Quality of Life research, announcements of publications, meetings, websites, etc.)

Deadline for submission: **March 1, 2013**

Please send your article by e-mail to Mathilde Charnay at mcharnay@mapigroup.com

More information on www.pro-newsletter.com/submission.html

Conferences Congresses Workshops Meetings

CALENDAR

October 24-27, 2012

ISOQOL 19th Annual Conference

Budapest, Hungary
Marriott Hotel
www.isoqol.org

November 3-7, 2012

ISPOR 15th Annual European Congress

Berlin, Germany
ICC Berlin
www.ispor.org

November 20-21, 2012

DIA's training course on Health Technology Assessment (HTA)

Zürich, Switzerland
Mercure Zürich Stoller
www.diahome.org

Nov. 30 - Dec. 4, 2012

Annual Meeting of the American Epilepsy Society

San Diego, CA, USA
www.aesnet.org

March 4-6, 2013

DIA's 25th Annual EuroMeeting

Amsterdam, The Netherlands
RAI
www.diahome.org

March 26 – 28, 2013

PRO & eCOA Congress

Baltimore, MD, USA
Hotel Monaco
http://programs.phtcorp.com/2013_PRO_ePRO_Congress_Baltimore.html

May 7-8, 2013

CBI's 10th Forum on Patient-Reported Outcomes (PRO)

Philadelphia, PA, USA
www.cbinet.com

May 18-22, 2013

ISPOR 18th Annual International Meeting

New Orleans, LA, USA
Sheraton New Orleans
www.ispor.org

May 28-30, 2013

PRO & eCOA Congress 2013 Europe

Evian, France
Hotel Ermitage
http://programs.phtcorp.com/2013-PRO-ePRO-Congress-Evian-France.html

June 23-27, 2013

DIA's 49th Annual Meeting

Boston, MA, USA
Boston Convention and Exhibition Center
www.diahome.org

KEYWORDS

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Patient Reported Outcomes (PRO) NEWSLETTER

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