



International Society for Quality of Life Research

Volume 11 Issue 2

Newsletter for ISOQOL Members

September 2006

PRESIDENT'S MESSAGE

Peter Fayers, PhD
Aberdeen, UK

The annual ISOQOL conferences usually identify a theme. This year's theme is *HRQOL Research: Making an Impact in the Real World*. The pre-conference declaration states that "The aims of the Conference are to encourage members to look at how HRQOL research has and can be used in practice to improve patient well-being." The conference committee has also brought together speakers from regulatory bodies (such as EMEA and FDA) to provide insight from their perspective. In addition, there will be a panel including the editors of the *Lancet* and *Quality of Life Research* to discuss the expectations of journals.

This made me wonder what the themes have been for the past few years – partly because I had faint recollections of similar themes in the past. Are we actually moving forward? Well, since 2000 the themes were:

2000: Vancouver
Interpretation of HRQOL Measures; and determination of a meaningful change in HRQOL

2001: Amsterdam
HRQL in daily clinical practice; health-related quality of life (HRQL) and mental health; psychosocial modeling of HRQL outcomes; and HRQL, happiness and social indicators research.

2002: Orlando
Theoretical models of QoL; methodological advances in QoL; and linking QoL and clinicians.

2003: Prague
It was decided not to declare a specific theme!

2004: Hong Kong
Harmonizing international health-related quality of life (HRQOL) research, with emphasis on cultural and linguistic issues, including the problems of defining and conceptualizing HRQOL.

2004: Boston symposium
The future of HRQL measurement: methods and applications (covering assessment, measurement theory, cognitive sciences in health outcomes assessment, statistical analysis, qualitative research, and outcomes research being applied).

2005: San Francisco
Building bridges to enhance quality of life (with sessions on policy applications, HRQOL assessment in clinical practice, and presentations by stakeholders including government, accreditation organizations, patient advocates, and clinical trialists).

Of course there are some common threads – such as "daily clinical practice" in 2000, "linking QoL and clinicians" in 2002, "HRQOL assessment in clinical practice" and our present theme of how has and can HRQOL research be used in practice to improve patient well-being. But, overall, the breadth of topics and lack of overlap rather surprised and reassured me. Furthermore it is surely appropriate that clinical practice and individual patients remain a major focus of our Society, as ultimately it is the individual patient that we are assessing, it is the individual patient whose opinion we are seeking, and the whole rationale for assessing HRQOL it is improve or maintain the "quality of life" of the present patient and future patients. On the other hand, I was surprised that "clinical trials" were never explicitly featured (although in 2005 "clinical trialists" were mentioned among the stakeholders).

The other thing that struck me is that many of these topics remain of major interest. For example, "interpretation of HRQOL and determination of a meaningful change" are still strongly debated, and there are sure to be presentations on these subjects in Lisbon.

Meanwhile, it certainly seems to me that the content of our programmes has changed over the years. This is very much endorsed by the number of people who have commented to me that recently the meetings have been more interesting than they used to be. (Although, as a statistician, I am aware that an alternative and more negative hypothesis could be that ISOQOL conferences are unwelcoming to newcomers, and that only those who have been to several previous meetings can start to appreciate the conferences! Fortunately that does not seem to be the case, and many new attendees also say how interesting the meetings are.) In particular, many of those to whom I have

President, continued on page 7

IN THIS ISSUE . . .

President's Message	Page 1
Let's Talk	Page 2
FDA/PROs Meeting	Page 3
PROs in Clinical Practice Meeting	Page 4
Website Report	Page 4
MAYO/FDA Meeting	Page 5
Election Results	Page 7
Member News	Page 8
New Members	Page 9
2007 Meeting Info	Page 10
Membership Info	Page 10

The ISOQOL Newsletter is published three times a year by the International Society for Quality of Life Research with the cooperation of Degnon Associates.

Newsletter Editor
Kathleen Wyrwich, PhD, USA

Deadline for articles
for our next issue is
November 1, 2006

Send articles and/or suggestions to:
info@isoqol.org

President
Peter Fayers, PhD, UK

President-Elect
Madeleine King, PhD, Australia

Secretary-Treasurer
Rick Berzon, DrPH, USA

Past-President
David Feeny, PhD, Canada

Editor of the Journal
Ron Hays, PhD, USA

Executive Director
Laura Degnon, CAE, USA

Board Members
Andrea Bezjak, MD, MSc, Canada
Andrew Bottomley, PhD, Belgium
John Brazier, PhD, UK
Cynthia Gross, PhD, USA
Graeme Hawthorne, PhD, Australia
Kwok-fai Leung, PdipOT, China
Elaine McColl, PhD, UK
Laura Schwartzmann, MD, Uruguay

ISOQOL Executive Office

6728 Old McLean Village Drive
McLean, VA 22101-3906 USA
PH: 703-556-9222
FAX: 703-556-8729
info@isoqol.org
www.isoqol.org

ISOQOL is managed by
Degnon Associates

LET'S TALK

Kathleen W. Wyrwich, PhD
St. Louis, MO, USA

In my last column on substantive issues in the measurement of health-related quality of life, I asked for your responses to two questions

Are we putting too much effort and publication space into the translation and validation of QOL measures for use in other nations and languages? And secondly, are there minimum criteria that this publications genre should report in the publication of results?

I solicited three ISOQOL members to weigh in on this question. First, Ron D. Hays, PhD, Editor-in-Chief of Quality of Life Research, submitted the journal's Policy on Cross-Cultural Evaluations of Existing HRQOL Measures. He states:

Several manuscripts reporting cross-cultural evaluations of existing HRQOL measures are submitted to *Quality of Life Research* and the journal has published a large number of them. For example, in 2005 we published the following articles:

- 1) "Reliability and construct validity of the SF-36 in Turkish cancer patients"
- 2) "Validity and reliability of the Chinese (Singapore) version of the Parkinson's Disease Questionnaire"
- 3) "Is the standard SF-12 Health Survey valid and equivalent for a Chinese population"
- 4) "Translation and psychometric testing of the Basque version of the SF-36 Health Survey"
- 5) "The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30): Validation of English version in Singapore"
- 6) "Validating and norming of the Greek SF-36 Health Survey"
- 7) "Development and psychometric tests of the Chinese-version Low Vision Quality of Life Questionnaire"
- 8) "Preliminary evidence of the measurement properties of the Chinese

version of the Child Health Questionnaire, parent form (CHQ-PF50) and child form (CHQ-CF87)"

- 9) "Validity and reliability of the Bangla version of WHOQOL-BREF on an adolescent population in Bangladesh"
- 10) "Psychometric evaluation of the Chinese version of the Pittsburgh Sleep Quality Index (CPSQI) in primary insomnia and control subjects"
- 11) "Construct validation of the Greek SF-36 Health Survey"
- 12) "Determining the basis psychometric properties of the Greek KDQOL-SF™"
- 13) "Validity and reliability of the Italian version of the Quality of Life, Enjoyment and Satisfaction Questionnaire" and
- 14) "Evaluation and discriminative properties of the Portuguese MacNew Heart Disease Health-related Quality of Life Questionnaire."

Because many of these papers are primarily of national or "local" rather than international interest, the journal policy is to ask that these manuscripts be submitted as brief communications. In addition, the bar we are setting for publishing these brief communications is higher now than it has been in the past. To be accepted for publication, these brief communications need to be evaluated positively by peer reviewers and make a noteworthy contribution to the existing literature.

A full length manuscript will be considered for publication in *Quality of Life Research* only if it provides substantially new methodological and/or substantive knowledge to the field (e.g., a superior method of cross-cultural adaptation, more thorough evaluation of the original instrument being adapted, multi-language or multi-country comparisons, etc.). Authors submitting full length manuscripts must provide an accompanying letter justifying the need for a full length report of their work.

We encourage each of you to submit your best work to *Quality of Life Research* and to review manuscripts whenever possible.

Let's Talk, continued on page 6

ISOQOL SATELLITE MEETING ON PATIENT REPORTED OUTCOMES AND REGULATORY ISSUES

*Dennis Revicki, PhD
Bethesda, MD, USA*

The draft FDA guidance on the methods and use of patient reported outcome instruments in pharmaceutical product development, evaluation and labeling has generated a considerable amount of commentary and activity in the health outcomes research community. ISOQOL sponsored a meeting which was organized by Bill Lenderking, Jeff Sloan and myself to further contribute to this discussion and to advance thinking on various measurement and methodological aspects of health outcomes research. The meeting was held in Washington, DC on June 29, 2006 at the Renaissance Mayflower Hotel. Meeting participants came from throughout the United States and from Europe, and included government, industry and academic researchers. The opening plenary session provided an overview of recent developments and thinking by the FDA related to patient reported outcomes and methods by Ed Rock, John Powers and Sahar Dawisha, all from the FDA. It was clear from the presentations that the FDA has evolved in their thinking and understanding about patient reported outcomes, but it is important to note that many of the FDA reviewers and staff are clinicians who have a narrow focus in ensuring that there is sufficient evidence of patient benefits, based on clinical efficacy and patient reported outcomes, and acceptable side effects of new therapy. Many FDA staff are new to health outcomes research and they appreciate these type discussions with ISOQOL members and others in the outcome community.

Next, the meeting consisted of a series of state-of-the-science presentations on conceptual frameworks and labeling statements, best practices on patient reported outcome instrument development, standards for and documentation of the psy-

chometric evaluation of measures, key statistical analysis issues and methods, and responsiveness and interpretation of patient reported outcome data. The content of these sessions were based on the joint contribution of a number of ISOQOL members, including Dennis Revicki, Bill Lenderking, Jeff Sloan, Diane Fairclough, Neil Aaronson, Dave Cella, Jakob Bjorner, and Peter Fayers.

First, Dennis Revicki and others provided an overview of the rationale and explication of endpoint and conceptual models for health outcomes research focused on needed information to support patient reported outcome instruments in pharmaceutical development and evaluation and for labeling claims. Articulating the rationale for measuring health outcome domains and providing the conceptual model demonstrating the mechanisms, links, and content of patient reported outcome measures demonstrates the importance of these outcomes for assessing product effectiveness. Next, Bill Lenderking and colleagues summarized several important issues associated with instrument development, including involvement of the patient in instrument development, appropriate recall periods, weighting of items in developing a summary score, and appropriate validation when items are used to measure a different concept or when the measure is to be used in a different patient population. Ron Hays then presented on proposed standards for evaluating and documenting the psychometric qualities of measures of use in medical product development and to support labeling claims. The presentation covered the kinds of evidence needed to indicate that a PRO measure has a sufficient level of reliability and validity, evaluation approaches that can be used when a measure is revised, and the types of reliability and validity evaluation that are appropriate during different phases of clinical trials.

The next two presentations, by Jeff Sloan and colleagues on statistical analysis issues and methods and Dave Cella and colleagues on interpreting the results of patient reported outcome studies, responsiveness and minimal important differences, completed the day's major ses-

sions. The data analysis presentation covered missing data, handling multiplicity of patient reported outcome endpoints and longitudinal data analysis. There are a number of imputation and statistical modeling approaches for dealing with missing data and multiplicity, but no one method is appropriate for all situations observed in clinical trials. Finally, Dave Cella covered the relevant methods for evaluating instrument responsiveness and presented on guidelines for determining minimal important differences for patient reported outcome measures. The presentation discussed several myths about minimal important differences, including that the MID is equivalent to 0.5 standard deviation units, MIDs represent stable characteristics of instruments, are symmetrical, and that all anchors are equally relevant. There are challenges associated with interpreting findings from clinical trials based on patient reported outcome measures but there is enough research to help determine a way forward.

The closing session involved commentary and discussion by Margaret Rothman, Nancy Santanello, Albert Wu and Donna Lamping and active questioning from the audience participants. In fact, throughout the day's meeting, there were a number of lively and informative discussions. We think that the meeting was a success and we look forward to your participation in the planned one-day session with representatives from the EMEA and FDA on Tuesday, October 10 in Lisbon. Please check out the ISOQOL website for further information.

SAVE THE DATE!!

Special Conference on PROs in Clinical Practice

June 24-26, 2007
Budapest, Hungary

Claire Snyder, PhD
Baltimore, MD, USA

We are pleased to announce that a special conference on the use of patient-reported outcomes (PROs) in clinical practice has been planned for June 24 through 26, 2007 in Budapest, Hungary. Daily clinical practice is a relatively new setting in which PROs are being applied. The primary goal of PRO assessment in clinical practice is to provide information important for monitoring and ultimately improving patients' physical and psychosocial functioning, and facilitating effective symptom management during and following treatment. PRO data may also be used in clinical practice to inform decision-making and, more generally, to improve communication.

This three-day ISOQOL conference is intended to:

- ◆ Summarize the state-of-the-art of PRO assessment in daily clinical practice
- ◆ Identify gaps in our knowledge base (theoretical, empirical, and experiential) with regard to using PROs in clinical practice
- ◆ Develop a research agenda for improving the science and practicality of PRO assessment in clinical practice
- ◆ Involve various stakeholders in the discussion of PROs in clinical practice

There will be a half-day of workshops on Sunday, June 24. This will be followed by two full days of conference plenary and poster sessions. A significant amount of time will be reserved for discussion between presenters and the participants.

The topics that will be addressed during the conference include:

- ◆ Theoretical Underpinnings for Using PROs in Clinical Practice
- ◆ Applications of PROs in Clinical Practice
- ◆ Content of PROs in Clinical Practice
- ◆ Logistics of Collecting PROs in Clinical Practice
- ◆ Training Health Care Professionals to Use and Interpret Data from PROs in Clinical Practice
- ◆ Evaluating the Effectiveness of Using PROs in Clinical Practice

The conference is being chaired by Neil Aaronson, PhD, and Claire Snyder, PhD, in cooperation with a planning committee composed of: Michael Brundage, MD, MSc; David Osoba, MD; Galina Velikova, MD; Albert Wu, MD, MPH; and Susan Yount, PhD. Please feel free to contact Neil Aaronson (n.aaronson@nki.nl) or Claire Snyder (csnyder@jhsphe.edu) for more information. If you have ideas regarding workshops, please contact Albert Wu (awu@jhsphe.edu). Last but not least, if your organization would like to sponsor the conference or you know of another organization that would like to sponsor the conference, please contact Neil or Claire.

We look forward to seeing you in Budapest next June!



ISOQOL WEBSITE REPORT

By Jordana Schmier
Alexandria, VA USA

Most of us use web search engines daily. They are incredible tools, but they can also make it challenging to interpret our web usage reports. Why is this? Well, web crawlers (aka spiders or bots) are constantly searching the web and indexing it so that searches find the best page matches. However, these web crawlers' hits to the ISOQOL web site don't look any different than a real, live person using the site. Our almost 70,000 visits over the past 8 months are influenced by these web crawlers, and it's hard to pull out usage information separate from these searches.

With this in mind, there are still a few interesting points to share from our web site usage statistics from January through August 2006:

- ◆ About 1/3 of the visits to the site are from outside the United States
- ◆ "Hits" from each of these countries were responsible for at least 1% of all the views: United States, Australia, UK, Netherlands, Canada, Germany, Japan, France, China, and Spain
- ◆ The longest average visit for a single page was over 3.5 minutes for the page about the June 2006 FDA Guidance Meeting.
- ◆ The heaviest usage was in May. In general, Tuesdays have had the heaviest usage and Saturdays the least.
- ◆ Over 70% of us are using Internet Explorer to view the site.

If you have questions, concerns or want to suggest complementary meetings or conferences to which we should provide links, please contact me at jschmier@exponent.com.



MAYO/FDA MEETING ON OPERATIONALIZING THE FDA GUIDANCE FOR PATIENT-REPORTED OUTCOMES (PRO'S): TRANSCRIPTS AND PRESENTATIONS

Jeff Sloan, PhD
Rochester, MN USA

A meeting was held February 22-24, 2006 in Chantilly, VA to discuss the FDA Guidance for Patient-Reported Outcomes, with over 400 attendees, and experts from around the world. FDA representatives answered over 300 questions over the three days of the meeting regarding the content of the guidance document and implications for discussion, dissemination, and operationalization. Presentations included:

- ◆ The FDA Perspective on the Guidance for Patient-Reported Outcomes
- ◆ Patient Reported Outcomes: Conceptual Issues
- ◆ PRO Instrument Selection: Designing a Measurement Strategy
- ◆ Patient Reported Outcomes: Instrument Selection Issues
- ◆ What is Sufficient Evidence for the Validity of Patient-Reported Outcomes?
- ◆ Analysis, Interpretation, and Reporting Results Based on Patient-Reported Outcomes
- ◆ Evaluating Health-Related Quality of Life in Cancer Clinical Trials: The National Cancer Institute of Canada Clinical Trials Group Experience
- ◆ CCOP Perspective on the FDA PRO Guidance: What does it mean for NCI-Sponsored Cancer Trials?
- ◆ Evaluating Health-Related Quality of Life in Cancer Clinical Trials: The European Experience
- ◆ Regulatory Issues: Perspectives from the ERIQA Group
- ◆ A Special Presentation

All presentations and discussions at the meeting were audio-taped. Mayo CME has put together a DVD which includes all the slide presentations with accompanying audio as well as audio of all the Q&A with the FDA representatives. If you would like to purchase a copy of the six-DVD set which covers the entire three-day event, please contact Martha Hoag (contact information below) or use the order form below.

Copies are now available at \$75 per set. Please complete the form below or contact Martha Hoag, Mayo Clinic College of Medicine, School of Continuing Medical Education, Plummer 2-60, Rochester, MN 55905, (507) 266-5045 or e-mail hoag.martha@mayo.edu.

Shipping Information (Please print or type all information)	
Name _____	
Address _____	
City _____ State _____ Zip _____	
Phone _____ Email _____	
Price	
FDA Guidance on Patient Reported Outcomes: <i>Discussion, Dissemination and Operationalization</i> 6-Audio DVD Set	\$75.00 ea
Total Payment Enclosed (U.S. Currency)	
*The price listed for this material is for individual use and includes shipping and handling. There is no CME credit available for this set. For additional questions contact Martha Hoag at (507) 266-5045 or email hoag.martha@mayo.edu .	
Payment Method	
<input type="checkbox"/> Check (payable to Mayo Foundation)	
<input type="checkbox"/> Credit Card: <input type="checkbox"/> Visa <input type="checkbox"/> MasterCard <input type="checkbox"/> Discover	
Card Number _____	
Signature _____	
Mail or Fax this complete order form and payment to: Mayo School of CME, 200 First Street SW, Plummer 2-60, Rochester, MN 55905 Website: www.mayo.edu/cme , E-mail: cme@mayo.edu	

Let's Talk, from page 2

Next, Sonya Eremenco, MA, and David Cella, PhD, on behalf of Center on Outcomes, Research and Education (CORE), Evanston Northwestern Healthcare, gave the following response.

Cultural and linguistic differences between people are fascinating. At the same time, these differences threaten our ability to indiscriminately pool health-related quality of life data in our international or multicultural studies. Translating questionnaires into different languages is not merely a redundant and pre-formulated exercise; each experience is a reach into another culture and its effect on the way a concept is expressed and understood. Rarely does this cease to be interesting or novel. Publication of these exercises can and should reflect the new lessons learned from each experience. At the same time, it is of immense practical value to illustrate in the published literature that a given questionnaire has been translated using state of the science techniques, and that the technique has preserved the essence of the source questionnaire. In short, we believe it is important and justifiable to have publication venues for QOL instrument translation work.

In our experience, it has been rather difficult to publish QOL instrument translation and validation articles, and to find relevant publications when needed. In fact, there is a recurrent question that arises whenever we talk about equivalence in translations and cross-cultural measurement which is whether it is indeed possible to equate patient reported outcomes results from different countries, where the impact of culture on symptom experience can mediate how the symptoms are actually reported. Without empirical evidence either to support or refute these issues, we will continue to question whether cross-cultural data pooling is justifiable. As the practical world of clinical research grows smaller, the demand for cross-cultural measurement and aggregation of data from multinational studies will only increase and will require further evidence of the suitability of translations methods as well as validation methods.

There are minimum criteria that should be applied to this genre of publication. These criteria should include both qualitative research methods and results as well as quantitative methods and results. It is often only in the examination of qualitative data that conceptual equivalence between the translation and its source version can be assessed and confirmed. It is quite possible to find measurement equivalence between items that actually do not mean the same thing, just because the two patient groups happened to answer them consistently. We do encourage the use of analytical models such as Item Response Theory and Differential Item Functioning as a way to quantitatively test for equivalent item performance. While DIF methods can detect items which seem to perform differently between two groups, they do not provide any information on the reasons for this differential performance. This step requires investigator thoughtfulness. Using these methods, researchers can detect items which seem to lack measurement equivalence, but then must return to qualitative methods to investigate the reasons for this type of performance. That said, we do not advocate requiring IRT or DIF methods as a minimum criteria. These studies require large samples sizes for robust results and it has not been shown that this activity, while informative and very interesting, is essential to ensure a quality translation. Practical considerations of time and cost come into play here. The data reported in such publications should meet acceptable scientific standards with regard to appropriate data collection, recognized analytical methods, and meeting standards for interpretation, whether quantitative or qualitative. Sample size should not be the sole criterion upon which to decide whether a publication is suitable or not, but rather whether the findings shed important light on issues that are in need of further investigation.

In conclusion, we do not wish to discourage research in the adaptation of measures for different languages and cultures because this information is beneficial to the further development and validation of each measure. Validation is never full or final; it is an ongoing endeavor with re-

gard to the properties and usefulness of the instrument in question, and the data provided by publications of translations and adaptations of this measure is vital to its continued validation. Moreover, these data help everyone in the scientific community to better understand and appreciate how the same disease may manifest itself differently in disparate cultures. This can lead to improvements in health care delivery as well as global quality of life.

Many thanks to Ron, Sonya, and David for their well-crafted responses. The new question that I would like to toss around considers our Mission Statement. It reads:

The scientific study of Quality of Life relevant to health and healthcare is the mission of the International Society for Quality of Life Research (ISOQOL). The Society promotes the rigorous investigation of health-related quality of life measurement from conceptualization to application and practice. ISOQOL fosters the worldwide exchange of information through:

- * Scientific Publications,
- * International Conferences,
- * Educational Outreach, and Collaborative Support for HRQOL Initiatives.

My question for your thought in this issue is:

Does this mission statement encompass and reflect who and what the organization is? Do we need a tune-up or are we focused and working together as a Society towards this mission?

What do you think? Please reply to wyrwichk@slu.edu with your thumbs up or down, as well as your reasons, before November 1, 2006. I look forward to reading and relaying your responses.



ISOQOL 2006 ELECTION RESULTS

ISOQOL would like to thank the following for their service:

Peter Fayers, President
Oct. 2004 - Oct. 2005
Andrea Bezzak, Board Member
Oct. 2003 - Oct. 2006
Andrew Bottomley, Board Member
Oct. 2003 - Oct. 2006
Kwok-fai Leung, Board Member
Oct. 2003 - Oct. 2006
Laura Schwartzmann, Board Member
Oct. 2003 - Oct. 2006

... and welcome the following to the ISOQOL Board of Directors:

Donna Lamping, President-Elect
(Oct. 2006 - Oct. 2007)
Nancy Mayo, Board Member
(Oct. 2006 - Oct. 2009)
Carol Moinpour, Board Member
(Oct. 2006 - Oct. 2009)
Lena Ring, Board Member
(Oct. 2006 - Oct. 2009)

The fourth board position will be determined by a run-off election between Jeff Sloan and Bryce Reeve, who had received the same number of votes at the conclusion of the regular election.



MEMBER NEWS

In May, George Torrance received the 2006 Avedis Donabedian Outcomes Research Lifetime Achievement Award from the International Society of Pharmacoeconomics and Outcomes Research. This award was his third lifetime achievement award; in 2001 he received the Award for Career Achievement from the Society for Medical Decision Making, and in 2002 he won the President's Award from ISOQOL. Our congrats, George!



Deborah Watkins Bruner, RN, PhD has recently moved from Fox Chase Cancer Center to the University of Pennsylvania as Independence Professor of Nursing. Dr. Bruner is directing a new Core Facility in the Abramson Cancer Center for Recruitment, Retention and Outreach.



Dr. Jolie Ringash, BSc, MD, MSc, FRCP(C) was recently appointed as Co-Chair of the Quality of Life Committee at the National Cancer Institute of Canada Clinical Trials Group (NCIC-CTG) along with Dr. Michael Brundage. The committee is grateful for the ongoing contributions of former Chair Dr. Andrea Bezzak.



President, from page 1

spoken point out specific changes – for example, that now there are fewer presentations of routine development of yet another instrument for disease areas that are already well covered. Instead, there is greater focus on general methodology, coupled with increasing number of papers presenting results in various disease areas. I shall find it most interesting to hear what the journal editors perceive as interesting and relevant research in HRQOL, as editors should be finely tuned into what their readers want to read about – one implication being that possibly similar issues will be of greatest interest to our participants, too.

Another point that I notice about the themes is that although the society is called ISOQOL, we consistently refer to HRQOL (when we occasionally lapse into QoL, as in 2002, it is presumably because we rely on context to make it clear that for us by QoL we mean HRQOL). Not surprisingly, the name ISOQOL continues to confuse people. I have had considerable debate with a couple of members of the International Society for Quality-of-Life Studies (ISQOLS), who protest that our instruments do not assess quality of life – yet they are happy to admit the term health-related quality of life. However, I would counter that the title of

their society is equally misleading, and that this is partially acknowledged by those of their members who are working with measures of “subjective well-being” in preference to using the term QoL. We have been discussing with ISQOLS the possibility of having a joint session at one of our future conferences, maybe next year.

Meanwhile, we still debate the distinctions between measures of health status versus quality of life instruments. And now the FDA draft guidelines have clearly staked a preference for Patient Reported Outcomes (PROs) as the relevant concept and term. Furthermore, as reported in the previous newsletter (page 3), FDA representatives have repeatedly clarified that PRO, quality of life and HRQOL are *not* interchangeable terms or concepts, and that “quality of life as a general concept has never been approved in a labeling claim.” That statement certainly appears to fly in the face of what many of us are doing. Many disease-specific instruments assess a number of “PROs” in the form of symptoms, side effects, limitations of functioning, etc., but a number of us also commonly use questions about “your overall quality of life” as convenient summary measures providing an overall assessment of whether interventions are worthwhile. Hopefully the conference speakers representing the regulatory bodies will provide some insight into their reasoning for being so deprecatory about HRQOL – we can be sure that interesting ideas will emerge!

All of which makes me muse over just what it is that we want to be measuring. I wonder whether a good starting point might be to ask the patients themselves: “What is the best way to assess your treatments? Should we focus entirely on things such as your symptoms, or would you prefer us in addition to ask about your overall quality of life (or health status etc.)?” Perhaps a future theme for a conference might take us back to basics!



ISOQOL 13th Annual Conference
October 10 - 14, 2006 ~ Corinthia Alfa Hotel, Lisbon Portugal
HRQOL Research: Making an Impact in the Real World

Tuesday, October 10, 2006

8:30 am - 4:45 pm

Patient Reported Outcomes and the Global Regulatory Environment: The ISOQOL Workshop on Measures and Methods

Wednesday, October 11, 2006

9:30 am – 4:30 pm

Workshops

Thursday, October 12, 2006

8:00 – 9:00 am

Special Interest Group meetings

KIDS: QoL Assessment in Children & Adolescence
 HIV/AIDS
 New Investigators

8:00 am – 12:30 pm

Poster Session 1 on display

9:00–10:30 am

Plenary 1

10:30 –11:15 am

Break and Meet the Authors Poster Session

11:15 am – 12:45 pm

Concurrent sessions

Symposium and Oral Sessions

12:50 – 2:00 pm

Lunch panel session:

“What the Editors Say!”

David McNamee (Lancet), Ron Hays and Neil Aaronson (QLR)

2:00 – 3:30 pm

Concurrent sessions

Symposium and Oral Sessions

2:00 – 6:15 pm

Poster Session 2 on Display

3:30 – 4:00 pm

Break

4:00 – 5:30 pm

Concurrent sessions

Symposium and Oral Sessions

5:30 – 6:15 pm

Meet the authors poster session

6:00 – 7:00 pm

Mentor/Mentee session

Friday, October 13, 2006

8:00 – 9:00 am

Special Interest Group meetings

Response Shift
 Mental Health
 Translation and Cultural Adaptation
 Translation Research

8:00 am – 12:30 pm

Poster Session 3 on display

9:00 – 10:30 am

Plenary 2 “QOL and the policy makers”

10:30 –11:15 am

Break and meet the authors poster session

11:15 am – 12 :45 pm

Concurrent sessions

Symposium and Oral Sessions

12:45 – 2:00 pm

ISOQOL Business Meeting Lunch

2:00 – 3:30 pm

Concurrent sessions

Symposium and Oral Sessions

2:00 – 6:15 pm

Poster Session 4 on display

3:30 – 4:00 pm

Break

4:00 – 5:30 pm

Concurrent sessions

Symposium and Oral Sessions

5:30 – 6:15 pm

Meet the authors poster session

6:00 – 7:00 pm

Special Interest Group meetings

Quality of Life Research in Ibero America
 QoL in Clinical Practice

Saturday, October 14, 2006

8:00 am – 12:30 pm

Poster Session 5 on display

9:00 – 10:30 am

Plenary 3

10:30 – 11:15 am

Break and meet the authors poster session

11:15 am – 12 :45 pm

Concurrent Sessions

Symposium and Oral Sessions

12:45 – 2:00 pm

Lunch on your own

2:00 – 3:30 pm

Concurrent sessions

Symposium and Oral Sessions

2:00 – 6:15 pm

Poster Session 6 on display

3:30 – 4:00 pm

Break

4:00 – 5:30 pm

Concurrent sessions

Symposium and Oral Sessions

5:30 – 6:15 pm

Meet the authors poster session

7:30 pm

Gala Dinner



ISOQOL WELCOMES NEW MEMBERS

Angels Pont Acuna

Barcelona, Spain

Debra Adamson, M.S.

Newbergh, In USA

Kingsley Akhigbe, MB, BS, FWACP

Benin city, EDO Nigeria

Kerry Avery, BSc, PhD

Bristol, United Kingdom

Amy M. Barrett, MSPH

Chapel Hill, NC USA

Antonia Bennett, MA

Seattle, WA USA

Elsbeth Bloem, MSC

Amsterdam, The Netherlands

John Browne, PhD

London, United Kingdom

Stefan Cano, BSc, PhD

London, United Kingdom

Paulo Carita

Barneux, France

Eduardo Chachamovich, MD

Porto Alegre, RS Brazil

Peter Chin, MD, MSHS

San Francisco, CA USA

Nadine Connor, PhD

Madison, WI USA

Christine De La Loge

Braine-P' Aend, Belgium

Maria C. De Leon, BA

Chicago, IL USA

Yeda Aparecida De Oliveira Duarte, PhD

Sao Paulo, Brazil

Henrica C.W. de Vet, PhD

Amsterdam, The Netherlands

Maartje de Wit, MSc

Amsterdam, The Netherlands

Haryana Dhillon, BSc, MA

Sydney, NSW Australia

Christina Donatti, PhD

Oxford, United Kingdom

Rodney Dunn

Ann Arbor, MI USA

Susanne Ebrahim, MSc

Cologne, German

Jan-Hendrik Egberts, MD

Kiel, SH Germany

Claire Evvin, MPH

RTP, NC USA

Nunit Gu-Yarsh, PhD

Haifa, Israel

Marlene Gyldmark

Basel, Switzerland

Amin Haiderali, MBA

Mississauga, ON Canada

Paul Han, MD

Bethesda, MD USA

Kristin Harris, BSc(C)

Toronto, ON Canada

Richard Hector, MPH

Los Angeles, CA USA

Cheryl Hill, PhD

Research Triangle Park, NC USA

William Hogoboom, DA

Madison, WI USA

Susan Horsman, BA

Edmonton, AB Canada

Caroline Houchin, MA, BA

Oxford, United Kingdom

Wen-wei Huang, MA

Shantou City, Guangdong, China

Shih-Ying (Audrey) Hung, MS

Madison, WI USA

Joanne Jordan, MPH, BA, BSc

Parkville, Vic Australia

Elizabeth Jurd, BSocSc, Mlitt, MMedSc

King Cross, NSW Australia

Scott Kabo

Willow Grave, PA USA

Svetlana Kalyadina, MD, PhD

Saint Petersburg, Russia

Agnes Sofia Kavacs, MA

Budapest, Hungary

Dorothy Keininger

Braine-l'Alleud, Belgium

Dinesh Khanna, MD, MS

Cincinnati, OH USA

Tomoaki Kimura, MS

Hiroshima, Japan

Winslow Klaskala, MS, PhD

Bridgewater, NJ USA

Taavi Lai, MD

Tartu, Estonia

Maaikje Langelaan, MSc

Amsterdam, The Netherlands

Lauren Ji-Young Lee, Pharm D

Irvine, CA USA

Yuelin Li, PhD

New York, NY USA

Leticia Lopez Sanchez, MA, PhD

Buenos Aires, CF Argentina

Ramona Lucas, PhD, MD, MPH

Barcelona, Spain

Lene Lunde, MA

Bergen, Norway

Richard Mena, MD

Crystal Lake, IL USA

Sara Miri, MD

Seattle, WA USA

Miklos Zsolt Molnar, MD, PhD

Budapest, Hungary

Ricky Mullis, MSc

Keele, Staffordshire, United Kingdom

Marko Mychaskiw, BS, MS, PhD

New York, NY USA

Cindy Nowinski, MD, PhD

Evanston, IL USA

Gary Okano, PhD

Thousand Oaks, CA USA

Jorge Palacio-Vieira, MA

Barcelona, Spain

Shreekant Parasuraman, PhD

Collegeville, PA USA

Guenter Rapatz, MSc

Switzerland

Judith M. Scott, MPH

Bethesda, MD USA

Severine Seemann, PhD

Lyon, France

Sona Lee Shah, PhD

West Haven, CT USA

Abdul Hannn Shaikh, MS

Dhaka, Bangladesh

Deepika Shaligram, MBBS, MD

Chennai, TN India

Claire Shenton, BSc

Cardiff, Wales, United Kingdom

Ashley Smith, PhD

Bethesda, MD USA

Bhaskar Somani, MRLS

Aberden, United Kingdom

Marinda Spies-Dorgelo, MSc

Amsterdam, The Netherlands

Selwyn Stanley, PhD

Tiruchirappalli, Tamilnadu, INDIA

Aimee Swartz, MPH

Northhampton, MA USA

Theron Taber

Scottsdale, AZ USA

Steve Tally, PhD

San Diego, CA USA

Michelle Thompson, BA

Raleigh, NC USA

Gabriel Vest

Scottsdale, AZ USA

Pernilla Viklund, PhD, RN

Bristol, United Kingdom

Ester Villalonga Olives

Barcelona, Spain

Robyn von Maltzahn, MSc

Oxford, Oxfordshire, United Kingdom

Barbara Nyanzi Wakholi, BA

Entebbe, Uganda

Chonghua Wan, PhD

Rochester, NY USA

Keith Wenzel, BA

Oregon, WI USA

Richard E. White, PhD, Mbc

Chadds Ford, PA USA

David Whitehurst, MSc, LLB

Stoke-on-Trent, Staffordshire, England

Kathryn Winter, MS

Philadelphia, PA USA

Wendy Wong, Chinese

Hong Kong, SAR

Chia-Huei Wu, MA

Taipei City, Taiwan, ROC

Beatrice Yamada, PhD, MS

Sao Paulo, Brasil

Melissa Yeager, JD

Seattle, WA USA

Ina Zschocke

Hamburg, Germany



ADVERTISEMENTS

Assistant Professor/Instructor, Division of Health Policy, Weill Medical College of Cornell University, New York City. The Division of Health Policy in the Department of Public Health at Weill Medical College of Cornell University is seeking a faculty member at the Assistant Professor (tenure-track) or Instructor level to join our growing academic research group in New York City. The Division's mission is to conduct research on policy issues relevant to the local, national, and global delivery of health care. These include the allocation of scarce resources, financing and reimbursement, health care technology assessment, program evaluation, and organization of the health care delivery system. We are seeking faculty members who plan on careers in externally-funded, clinically-oriented health policy research in an academic medical center environment. Successful candidates will have a doctorate in health services research, economics, decision science, public health, or a related field by July 1, 2007. Candidates must have a demonstrated record of successful quantitative research related to health policy and strong potential for obtaining external funding. We are especially interested in candidates with interests in urban health and health disparities, global health, and medical technology assessment (including information technology), but all fields will be considered. Interested candidates should send a letter of application including a statement of research and policy interests, a CV, and contact information for three professional references to: Bruce R. Schackman, PhD, Chief, Division of Health Policy, Department of Public Health, Weill Medical College of Cornell University, 411 East 69th Street, New York, NY 10021, brs2006@med.cornell.edu. Applications will be accepted until the position is filled, with review of applications beginning immediately.

Global Health Outcomes Scientist - The purpose of the Global Health Outcomes Scientist position is to provide scientific and technical expertise to ensure that the Health Outcomes research conducted

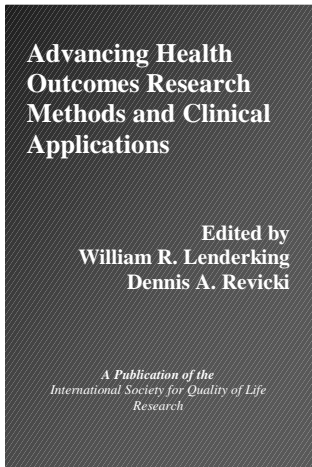
provides the necessary and needed information that informs the development of program phase molecules. The position will initially be focused in Diabetes. The Scientist oversees and ensures health economics/outcomes research strategies and programs to support Pricing, Reimbursement and Access activities for Lilly products. The Scientist demonstrates and applies in-depth knowledge, understanding, and evaluation of clinical, economic, and/or patient reported outcomes methodologies. The Scientist effectively communicates complex concepts to internal and external business partners, along with scientific communities, in support of health outcomes research. Moreover, the Scientist provides technical and scientific leadership to influence cross-functional initiatives. A graduate degree in a field relevant to HO or significant previous training and experience in designing and conducting research and disseminating the results in the areas of health economics, health outcomes, disease management, and/or population health may be sufficient in lieu of a graduate degree. Strong communication and interpersonal skills and the ability to work successfully in a team/cross-functional environment. The ability to think and act globally with a customer focus and a solution orientation. Technical and analytic capabilities in the areas of economic modeling, economic evaluation, cost-effectiveness evaluation, burden of disease, epidemiology, statistics, and health care policy etc. The ability to influence individuals strong project management skills. ELI LILLY AND COMPANY IS AN EQUAL OPPORTUNITY EMPLOYER. To apply, please click on the link below or go to <http://www.lilly.com/careers> and reference Job ID 50270979.

Faculty Position – Psychometrician - The Cleveland Clinic is seeking an additional faculty member to join its multidisciplinary group in quantitative health sciences. The current group has 24 faculty and over 90 total members and is expected to grow substantially over the next several years. Areas of research application include biostatistics, clinical trials, statistical genetics and

bioinformatics, statistical computing, predictive modeling, quality of life assessment, and cost-effectiveness analysis. Successful candidates must have excellent written and verbal skills with the ability and desire to conduct both collaborative and methodologic research. A doctoral degree with expertise in quality of life instrument development and validation is required. The level of appointment will be based on the experience of the candidate and may be at the full, associate, or assistant level. The Cleveland Clinic is a top-ranked medical center and has been the leading heart care center for over a decade. The Clinic has a strong academic mission with its medical school and world-renown Lerner Research Institute. The metropolitan and suburban areas of Cleveland comprise a population of over 3 million, rich in cultural diversity. The city itself is centrally located to several other large cities yet enjoys a low cost of living index. Interested candidates should e-mail curriculum vitae, the names of at least three references, and a letter summarizing experience and research interests to QHSjobsearch@ccf.org. These and other current openings may be found at <http://www.ccf.org/qhs>.



ORDER YOURS TODAY...



Advancing Health Outcomes Research Methods and Clinical Applications

Edited by
**William R. Lenderking
and Dennis A. Revicki**

386 pages; ISBN 0-9656837-4-5

Topics Include:

- A Broad Look at Outcomes Research
- Item Response Theory
- Computerized Approaches to Qualitative Text Analysis
- Longitudinal Data Analysis
- Outcomes Research Applied
- Theoretical Issues in Research on Health Status, Quality of Life
- Bayesian Methodology
- Theoretical and Applied Aspects of Utility Measurement
- Looking to the Future of Outcomes Research

\$80/ISOQOL members and \$95/non-members

Bulk discounts are available for orders of 100 copies or more. **All orders must be prepaid.**

My check for \$ _____ is enclosed. Please make checks payable to "ISOQOL."

Please bill my credit card MasterCard Visa

Card # _____ Exp Date _____

Name _____ Signature _____

Address _____

City _____ State/Province _____ Country _____

Zip/Postal Code _____ Telephone _____

Fax _____ Email _____

Return completed form and payment to:

ISOQOL

6728 Old McLean Village Drive ~ McLean, VA 22101 USA

703-556-9222 ~ Fax 703-556-8729 ~ Email: info@isoqol.org ~ www.isoqol.org

V11-12

Mark your Calendar. . .

ISOQOL 14th Annual Conference
October 10 - 13, 2007
Toronto, Ontario Canada



Toronto's Old City Hall officially opened on September 18, 1899. Photo Credit: Tourism Toronto

**ISOQOL invites you to join us
for an educational experience
in the City of Imagination**

**Symposium, Paper and
Poster Abstract submissions
will begin February 2007**

Visit www.ISOQOL.org for the
latest information.

ISOQOL MEMBERSHIP BENEFITS

Know someone who might benefit from ISOQOL membership? Share these benefits with them and encourage them to join today!

- * Online Membership Directory
- * Participation in a variety of Special Interest Groups
- * Reduced subscription rate for the *Quality of Life Research Journal*
- * Reduced conference registration rates
- * Annual meetings of the International Society for Quality of Life
- * Opportunity to present and hear cutting edge research presentations and posters
- * Opportunity to have special interest group meetings at the annual meeting
- * Access to the "Members Only" section of the ISOQOL website – an invaluable resource tool!
- * Participation in a variety of committees
- * Participation in the ISOQOL listserv - email communication with other QOL experts
- * Exposure to and participation with other professionals involved in quality of life research activities
- * Discount on annual subscriptions to the Quality of Life Instruments Database, offered by MAPI Research Institute
- * Complimentary receipt of newsletters published 3-times/year
- * While supplies last: Quality Metric's 9-CD set "Understanding Health Outcomes: An Accredited Educational Series on CD-ROM. Series One: Health Status: Concepts, Measures, and Applications"

ADVERTISING RATES

ISOQOL Members:

1st 10 lines - no charge
11 or more lines - \$10/line

Non-Members:

1st 10 lines - \$150.00
11 or more lines - \$10/line

Each line contains approximately 36 characters and spaces; this figure is an estimate only; advertisers will be charged based on the actual number of lines printed in the newsletter. If you have any questions, or if you wish to advertise a position opening, please contact the ISOQOL Executive Office.