

Quality of Life

QUARTERLY

IN THIS ISSUE...

- PAGE 1** President's Message
PAGE 3 From the Editor's Desk
PAGE 4 Research Organization Corner: EORTC
PAGE 6 News From The Chalkboard
PAGE 7 Calendar of Events
PAGE 9 Quality of Life Research Journal – Awards
PAGE 10 Patient-Centered Outcomes Research: Defining Standards
PAGE 11 Ivan Barofsky — An Enriching Learning Experience
PAGE 12 Publications
PAGE 14 ISOQOL Global News: New Chapter Structure

VOLUME 18 ISSUE 1
*Newsletter for
ISOQOL Members*
WINTER 2012

ADVERTISING INFORMATION

Contact Marketing Director,
Jean Wenzel
jwenzel@isoqol.org



PRESIDENT'S MESSAGE

Bryce B. Reeve, PhD



Happy New Year!!!! 2012 will be an exciting and active year for ISOQOL and for me. As the first official year of my 2-year

presidential term starts, my New Year's resolution is to enhance the level of communication among ISOQOL members, including the Board of Directors, committees, special interest groups (SIGs), and chapters. Unlike my yearly resolutions to eat healthy and exercise more that I will abandon by the time you read this letter, I promise to stick with this resolution to keep you better informed about all the activities going on within and outside the organization. My hope is that you will have a number of opportunities to play a significant role in ISOQOL's mission to advance the scientific field of HRQOL research.

It is an exciting time to work in this field as patient-centered outcomes

research (PCOR) becomes more and more of a priority; PCOR focuses on the patient as a whole by integrating patients' experiences, perspectives, and values as they relate to measuring the impact of disease and treatment on patients' lives. The extent to which we can successfully integrate patient-reported data with clinical data to identify safe and effective medical, technological, behavioral, or psychological interventions, the better we can improve the quality of care and outcomes for pediatric and adult patients.

ISOQOL provides the platform for us to share our experiences and perspectives in a multidisciplinary and collaborative environment. We have a number of SIGs focused on different topics (Child Health, QOL in Clinical Practice, Psychometrics, Response Shift, Translation and Cultural Adaptation, New Investigators), which are active throughout the year. At our 2012 ISOQOL Conference in Budapest, Hungary (Oct. 24-27), we will learn

Continued on page 2.



The ISOQOL Newsletter is published four times a year by the International Society of Quality of Life Research.

Newsletter Editor

Ana Popielnicki, BA, USA

Send articles with subject line addressed "Newsletter Submission" to:
info@isoqol.org

President

Bryce B. Reeve, PhD, USA

Secretary-Treasurer

William Lenderking, PhD, USA

Past-President

Carol M. Moinpour, PhD, USA

Executive Director

Rebecca Brandt, CAE, USA

Board Members

Ethan Basch, MD, MSc, USA

Michael Brundage, MD, Canada

Stefan Cano, BSc, PhD, UK

Henrica C.W. de Vet, PhD, The Netherlands

Fabio Efficace, PhD, Italy

Joanne Greenhalgh, PhD, UK

Cindy L.K. Lam, MD, Hong Kong

Maria-Jose Santana, PhD, Canada

Kathleen Wyrwich, PhD, USA

ISOQOL Executive Office

555 E. Wells Street, Suite 1100

Milwaukee, WI USA, 53202

Telephone: +1 (414) 918-9797

Fax: +1 (414) 276-3349

info@isoqol.org

www.isoqol.org

President's Message, Continued from page 1.

about many of these exciting initiatives from you and other experts.

In addition, ISOQOL plans to keep its members apprised of significant events as they relate to PCOR and plans to involve your expert opinion to shape the research field. For example, ISOQOL will seek your recommendations through a survey for minimal standards for the design or selection of PRO measures in PCOR (see page 10 in this newsletter). This is just the first of many opportunities for you to be involved in 2012.

ISOQOL cannot continue to serve as a leader in the field without your support and guidance. You are an important member of the ISOQOL family and we enjoy hearing from you. Please, feel free to contact me (bbreeve@email.unc.edu), Becky Brandt (rbrandt@isoqol.org) or any

of our ISOQOL Board members with questions or suggestions.

Finally, if I may suggest a New Year's resolution for you...Since "quality of life" is what we research, we can only understand and measure it if we experience it for ourselves. Thus, please set some time aside this year to improve your quality of life. Do something special for yourself and something special for a family member, friend, colleague, or someone you don't know.

May 2012 be a fruitful, healthy year for you and yours. I look forward to working with you and sharing some wonderful "quality of life" experiences.

Sincerely,

Bryce



RENEW YOUR ISOQOL MEMBERSHIP FOR 2012

Membership renewal for 2012 is available online through the ISOQOL Membership Central page, <http://www.isoqol.org/membershipcentral.htm>.

RENEW YOUR ISOQOL DUES TODAY!

FROM THE EDITOR'S DESK

By: Ana Popielnicki

I am very pleased to welcome you to the “new and improved”* Quality of Life Quarterly e-newsletter! (* Can anything be “new” and “improved” simultaneously? As a lifelong student of linguistics, I wonder about this widely-used marketing expression. Seems to me that “improved” implies a previous existence – albeit a less quality one – and that “new” by its definition means something that wasn’t and now is. Would love to hear your thoughts!).

But I digress. In this first issue of the year, we have our traditional President’s Message, with the first official address from Dr. Bryce Reeve to our members. We also have several exciting new sections and news to share with you. I’d like to take the opportunity to introduce you to these new sections and ask for your feedback and suggestions for future issues.

You will see an interesting article by Andrew Bottomley and Galina Velikova on Health-Related Quality of Life and EORTC. This is the first

of what we hope will be a series of featured organizations under our “Research Organizations Corner”. In “News from the Chalkboard”, EDI’s Director of Education Sharon Chaplock brings us her expertise and talks about Subject Matter Experts – look for future articles from Dr. Chaplock in each issue of QoL Quarterly.

This issue also brings you news on members’ publications, educational activities, and awards. Our indefatigable Marketing Director, Jean Wenzel, has gathered a listing of pertinent events for this first quarter of 2012 – please send us information of any upcoming events for the rest of the year that you think would be of interest to our members.

As to our global community, Board member and Chapters’ liaison Riekke De Vet presents the new global structure of organizations affiliated or linked to our Society. In this section, “ISOQOL Global News”, we would like to encourage all our members outside

of the US to contact us and submit their contributions and industry news.

I would like to invite your comments, suggestions, and questions for a new section we are planning to launch (hopefully!) starting next issue, in April (Letters to the Editor). Please send your e-mails directly to me at aap@tls-translations.com or to the office, at info@isoqol.org – do remember to write “ISOQOL Newsletter” in your subject line.

From our editorial and marketing staff, our very best wishes for a happy and healthy 2012! And to our members in China, who will be welcoming the Year of the Dragon this coming January 23, please receive our wishes for a healthy and auspicious new year!

Warm regards,



RESEARCH ORGANIZATION CORNER

HEALTH-RELATED QUALITY OF LIFE IN EORTC

50 YEARS OF PROGRESS FROM METHODOLOGICAL DEVELOPMENTS TO MAKING A REAL IMPACT ON ONCOLOGY PRACTICE AND RCTs

A. Bottomley, PhD and G. Velikova, MD, on behalf of the EORTC

EORTC (European Organisation for Research and Treatment of Cancer) is an international non-profit organization with a scientific goal created in 1962 by European cancer specialists. The organization's headquarters are located in Brussels. HRQOL outcome measures have been an integral part of EORTC Clinical Trials, being implemented for over 30 years. The EORTC created the Quality of Life Group (QLG) in 1981 with the mission to develop measures of patient-reported outcomes in cancer, including HRQOL, and to promote and coordinate clinical studies concerning the quality of life of cancer patients. The EORTC Quality of Life Department (QL Department) -- based in the EORTC Headquarters -- was established to provide management, administrative, practical and scientific support to all EORTC Clinical Trials co-operative groups, conducting clinical trials that implement HRQOL measures and collaborate with the QLG on major scientific issues. In 2012, the QLD will celebrate its 20th year with a major conference funded via a peer-reviewed grant from the European Union (EU). This will be the 3rd EORTC Conference to be held at the European Parliament.

Development and validation of a modular system for HRQOL measurement: EORTC QLQ-C30, a core cancer quality of life questionnaire and supplementary questionnaire modules

In the 1990s the EORTC QL Group introduced the concept of *modular HRQOL measurement* in oncology,

based on a core cancer questionnaire and cancer site-specific modules covering specific symptoms, treatment side effects and functional problems. The QL Group was the first to publish detailed guidelines on development of questionnaire modules that have set the standard internationally and have been widely used by researchers and clinicians worldwide. The most notable achievement of the QL Group is the development and validation of the core EORTC HRQOL questionnaire, known as EORTC QLQ-C30. The EORTC QLQ-C30 was validated in multiple European countries and published in 1993. Evidence-based information on clinically meaningful differences in the scores of EORTC QLQ-C30 and recommendations for sample size calculations using the EORTC QLQ-C30 sub-scales are available. The EORTC-QLQ-C30 has been one of the most widely used cancer questionnaires in randomised trials in oncology, as demonstrated by systematic reviews. User agreements for the EORTC QLQ-C30 have been signed off in more than 9,000 Clinical Trials or academic studies worldwide.

In addition to the EORTC QLQ-C30, there is a portfolio of supplementary questionnaire modules; cancer site-specific or symptom/quality of life domain-specific, many of which are used in Clinical Trials. A truly unique feature of the EORTC questionnaires is that attention is paid to cultural and linguistic issues from the beginning of the developmental process. As the globalization of clinical trials continues to increase, the issues of



the quality of translations and cultural equivalence of any subjective measures are of paramount importance. To date, the EORTC QLQ-C30 has been translated and linguistically validated into more than 60 languages, with more than 20 additional local adaptations and further translations currently in progress.

The QL Group undertakes successful methodological research in a number of key areas, including *Cross-cultural differences between populations in HRQOL assessment, Computer-Adaptive Testing (CAT) Version of QLQ-C30, Electronic administration of EORTC QLQ-C30*.

Examples of practice-changing EORTC trials that included HRQOL

HRQOL is an integral part of most EORTC Clinical Trials, and has been systematically implemented over the last 15 years. Over 130 EORTC Clinical Trials have a HRQOL element, typically as a secondary endpoint. However, given that most regulatory bodies such as EMA and FDA now accept HRQOL as a valid endpoint, and issue label claims based on the impact of treatment on patients, we believe the use of HRQOL in future

Continued on page 5.

Health-Related Quality of Life in EORTC, Continued from page 4.

EORTC studies will only continue to grow.

There are numerous trials we could mention, but we note just a few below and we refer readers to our future publication or to visit the recent online conference presentations of the EORTC (www.theinformed-scientist.org). In patients with glioblastoma, we studied the addition of concomitant and adjuvant temozolomide to the standard treatment with radiotherapy, and demonstrated that temozolomide significantly improved survival without a negative effect on HRQOL. This treatment is now the standard of care in newly diagnosed patients with glioblastoma.

Dose-intensive chemotherapy has generated much interest in the treatment of patients with locally advanced breast cancer, as it might offer a survival benefit. We compared the effects of such an approach with those of standard chemotherapy on HRQOL. Patients assigned to the intensified treatment had a significantly lower overall HRQOL score during the first 3 months, but scores returned to near baseline, with no difference between groups at 12 months and up to 2 years. This was the first RCT to show that dose-intensive treatment may lead to a temporary reduction of HRQOL, followed by recovery, thus enabling clinicians to give accurate information to their patients and informing further research on intensive treatment for patients with breast cancer.

These collaborative efforts have proved to be highly successful, demonstrating the importance of multidisciplinary international collabora-

tion. The EORTC, with its strong network of clinical and methodological groups and a keen interest in HRQOL, can provide important clinical and patient-reported outcomes results that are wide-reaching, and have an impact on patient care on an international scale. EORTC now collaborates with the EMA and is helping establish guidelines for new oncology compounds that need testing, either via EORTC or other commercial bodies, where QOL is an endpoint.

The QL Department, on behalf of the EORTC Clinical Groups, has shown that QOL is prognostic, using one of the largest data sets ever published. These results strongly indicate that, in some cancer populations, selected EORTC QLQ-C30 HRQOL scales provide valuable prognostic information when combined with socio-demographic and clinical data.

In summary

EORTC has over 50 years of experience in conducting international cancer Clinical Trials. The EORTC QL Group and QL Department have been international leaders in the development of patient-reported outcome measures in oncology and their implementation in oncology trials. While the EORTC has achieved a significant amount over the last 50 years, we expect that over the next 50 years QOL will only become more essential to patients and clinical trials within our network.

Acknowledgements

A more detailed review of all the topics discussed in this newsletter article will be published in the European Journal of Cancer in March 2012.



Faculty Positions in Outcome Science: Open Rank

The Department of Medical Social Sciences (www.mss.northwestern.edu) is seeking candidates for two faculty positions with emphasis on research methods or applications that advance outcomes research, comparative effectiveness research, or clinical trials. This can include research on study design, measurement, and analysis using psychometric, econometric, decision-analytic or other related approaches. Departmental research emphasizes pediatric and adult outcomes measurement science, item response theory, and applied clinical research. Candidates with expertise in Item Response Theory (IRT) including the development and application of item banks are of particular interest. The candidates will play a critical role in the outcomes science portfolio of the department and be encouraged to capitalize on the studies and datasets at MSS. Candidates should have an outstanding record of scholarly publication and evidence of collaborative and interdependent biomedical research, including a history of extramural funding or exceptional promise of such for junior applicants. Demonstrated commitment to teaching is desired. For fullest consideration please apply by June 1st 2012.

Please send a statement of interest, curriculum vitae, representative reprints and names of three references to Search Chair, Lauren Wakschlag, PhD, c/o of Robin Morrissey at mss@northwestern.edu. Reference search #P-116/117N-12.

Northwestern University is an Affirmative Action, Equal Opportunity Employer.

NEWS FROM THE CHALKBOARD

By: Sharon Chaplock, PhD, Director of Education, EDI

WHAT IT TAKES TO BE AN ISOQOL SUBJECT MATTER EXPERT

This is an exciting time to be an adult learner. Never before have there been so many alternatives to learn outside traditional post-secondary institutions. From professional development to building competencies within a given domain, adult learners today have a wide array of choices to suit their goals, learning styles and lifestyles. They may select from instructor-led online courses in real time, or self-paced courses offered asynchronously. Webinars offer engaging, live delivery of content, and podcasts provide recordings of highly focused interviews and lectures for listening anytime, anywhere. Smart phones have apps for feeds with the latest developments in most disciplines, not to mention web-enabled video delivery of content via YouTube and other venues.

But where does all the content come from? And how reliable is it?

Within specialized fields of study, members and volunteers in professional organizations have a tremendous opportunity to share their knowledge through these new learning tools by becoming subject matter experts (SMEs). Working with an instructional designer, SMEs contribute their knowledge and communicate what they know on a given topic to others in the profession. ISOQOL is one such organization poised to develop purposeful educational initiatives to further its stated mission: *To advance the scientific study of*

health-related quality of life and other patient-centered outcomes to identify effective interventions, enhance the quality of health care and promote the health of populations.

What does it take to become a Subject Matter Expert?

According to Comolli and Prestera (2007), subject matter experts share five qualities: interest, availability, expertise, experience and influence. Ask yourself these questions if you have an interest in volunteering to be a SME for ISOQOL:

Are you passionate about Quality of Life issues? Chances are that you do have a passion for the field if you are already a member of ISOQOL.

Do you have the time to attend highly focused meetings intended to develop a learning opportunity for colleagues who hope to elevate their level of expertise? As a busy professional, it's important to be realistic about the time you can set aside for a short-term but intense project that will call upon you to provide information and meet deadlines.

What are your areas of expertise?

This includes having the factual information as well as knowledge of the context where it is applied. Take some time to do an honest appraisal of areas where you shine.

What experience do you have in the topic? Often, SMEs are called upon not only for information, but for providing anecdotal stories and shedding light on the thought processes gained from working in the trenches.

Having current experience is vital to providing relevant, forward thinking contributions that will inform the instructional design process.

Finally, are you willing to collaborate with other SMEs in order to ensure the content is valid and/or accepted as a best practice? Being a team player committed to arriving at consensus for the sake of the truth is essential to the process of developing learning modules with an instructional designer for any medium.

What's in it for you?

The benefits of contributing to your organization as a SME are many. Subject matter experts report that they have grown personally and professionally from collaborative activities that are part of the instructional design process. Their network of colleagues expands and their knowledge of the topic deepens as they learn with and from each other. Subject matter experts differentiate themselves as experts and leaders in their field. They are influential in developing instruction and training that advances their profession. And they take pride in mentoring future generations as they "pay it forward." The rewards can be gratifying.

In the coming months, ISOQOL leadership will be considering a variety of learning opportunities to offer stakeholders. Look for opportunities to contribute and benefit as a subject matter expert when the call for volunteers comes in the near future.



CALENDAR OF EVENTS

JANUARY

- *January 23-24*
EMA - Committee for Herbal Medicinal Products (HMPC) – January Meeting
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2011/08/event_detail_000447.jsp&mid=WC0b01ac058004d5c3
- *Begins January 26*
Institute for Healthcare Improvement
A three-part web-based program Improving Employee Health, Costs and Care
http://www.ihl.org/offering/VirtualPrograms/Webinars/Web_Action/Employer/Pages/default.aspx

FEBRUARY

- *Application Deadline: February 1*
PhRMA Foundation of America Foundation 2012 Awards in HEALTH OUTCOMES
www.phrmafoundation.org
- *February 7- 9*
Summit for Clinical Operations Executives (SCOPE)
Hilton Miami Downtown
1601 Biscayne Blvd
Miami, FL 33132
T: +1 (305) 374-0000
<http://www.scopesummit.com/>
- *February 15-16*
Outsourcing in Clinical Trials West Coast
San Francisco Airport Marriott Waterfront
1800 Old Bayshore Highway
Burlingame, California 94010
<http://www.arena-international.com/poutwestcoast>

MARCH

- *March 5-7*
Partnerships in Clinical Trials
Orlando World Center Marriott Resort
8701 World Center Drive
Orlando, FL 32821
T: +1 (407) 239-4200
<http://www.iirusa.com/cropartners/welcome-to-CROs.xml>
- *March 8-11*
The 6th World Congress on Controversies in Neurology (CONy)
Vienna, Austria
<http://www.comtecmed.com/cony/2012/>
- *March 10-12*
BioPharma Asia Convention
Marina Bay Sands, Singapore
<http://www.terrapinn.com/exhibition/biopharma-asia/index.stm>
- *March 12-13*
CHI – Phase III Clinical Trials
Crowne Plaza, Philadelphia, PA
http://www.healthtech.com/phase_III_trials
- *March 12-17*
2012 ASCPT Annual Meeting
Gaylord National Hotel and Convention Center
National Harbor, MD
<http://www.ascpt.org/2012AnnualMeeting/tabid/8104/Default.aspx>
- *March 19-22*
First World Congress on Healthy Ageing
Kuala Lumpur, Malaysia
<http://www.healthyageing.org/>
- *March 22-23*
Fourth workshop on the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)
<http://www.ema.europa.eu/>
European Medicines Agency workshop on medicines for older people
<http://www.ema.europa.eu/>
- *March 26-28*
DIA 24th Annual EuroMeeting
Bella Center, Copenhagen, Denmark
<http://www.diahome.org/diahome/FlagshipMeetings/home.aspx?meetingid=25205>
- *March 27-28*
Outsourcing in Clinical Trials East Coast
Philadelphia, PA
<http://www.arena-international.com/octeast>

APRIL

- *April 17-19*
PROficiency™ 2012, the 5th annual conference on the collection of patient perspective in clinical research.
Naples Grande Beach Resort, Naples, Florida
<http://invivodata.com/proficiency-2012/>
- *April 11-14, 2012*
33rd Annual Meeting & Scientific Sessions of the Society of Behavioral Medicine
New Orleans, Louisiana
Hilton New Orleans Riverside
<http://www.sbm.org/meetings/2012>



Refer to the experts in ePRO translations.

Developing translation instruments for use on ePRO devices requires early collaboration among the sponsor, ePRO vendor, and language service provider. This important step can eliminate many technical problems and instrument administration issues. Partnering with Corporate Translations ensures a thorough review and proper linguistic validation of the adapted instrument for use on an ePRO device when required. That's why Corporate Translations is the preferred supplier of ISO 9001 translation and linguistic validation solutions to the world's leading life science companies.

www.corptransinc.com
1-855-727-6003

Linguistic Validation | Back Translation | Harmonization | Cognitive Debriefing | ePRO Consultation



QUALITY OF LIFE RESEARCH —

LIST OF WINNING ARTICLES AND HONORABLE MENTIONS FOR 2011

By: Ana Popielnicki on behalf of the journal co-editors, Carolyn Schwartz, ScD and Dennis Revicki, PhD

ISOQOL's research journal, [Quality of Life Research](#), continues to publish excellent, thought-provoking articles for the scientific community. Please join us in congratulating the authors of this past year's winning articles and nominees – details on the articles appear below:

1ST PLACE

Post, W.J., Buijs, C., Stolk, R.P., deVries, E.G.E., and le Cessie, S. **The analysis of longitudinal quality of life measures with informative drop-out: A pattern mixture approach.** QLR 2010; 137-148.

2ND PLACE

Choi, S. W., Reise, S. P., Pilkonis, P. A., Hays, R. D. & Cella, D. **Efficiency of static and computer adaptive short forms compared to full-length measures of depressive symptoms.** QLR 2010; 19 (1), 125-136.

3RD PLACE

Molzahn A. Skevington SM. Kalfoss M. Makaroff KS. **The importance of facets of quality of life to older adults: an international investigation.** QLR 2010; 19(2):293-8.

HONORABLE MENTION

Hayduk, L., Olson, K., Quan, H., Cree, M., Cui, Y. **Temporal changes in the causal foundations of palliative care symptoms.** QLR 2010; 19 (3): 299-306

Young, TA, Rowen, D., Norquist, J., Brazier, JE. **Developing preference-based health measures: using Rasch analysis to generate health state values.** QLR 2010; 19(6):907-917, DOI: 10.1007/s11136-010-9646-0

Sprangers, MAG, Sloan, JA, Barsevick, A., Chuahan, C., Dueck, AC, Raat, H., Shi, Q., Noorden, C, Cornelis, JF. **Scientific imperatives, clinical implications, and theoretical underpinnings for the investigation of the relationship between genetic variables and patient-reported quality-of-life outcomes.** QLR 2010; 19: 1395-1404

Kievit, W., Hendriks, J., Stalmeier, PFM, van de Laar, MAFJ, Van Riel, LCM, Adang, EM. **The relationship between change in subjective outcome and change in disease: a potential paradox.** QLR 2010; 19:985-994.

Herman KM, Hopman WM, Craig CL. **Are youth BMI and physical activity associated with better or worse than expected health-related quality of life in adulthood? The Physical Activity Longitudinal Study.** QLR 2010 Apr;19(3):339-49.

Bailey H, Kind P. **Preliminary findings of an investigation into the relationship between national culture and EQ-5D value sets.** QLR. 2010 Oct;19(8):1145-54.

Mulvaney-Day NE, Horvitz-Lennon M, Chen CN, Laderman M, Alegría M. **Valuing health in a racially and ethnically diverse community sample: an analysis using the valuation metrics of money and time.** QLR 2010 Dec;19(10):1529-40.

Lauzier, S., Maunsell, E., Drolet, M., Coyle, D. and Hébert-Croteau, N. **Validity of information obtained from a method for estimating cancer costs from the perspective of patients and caregivers.** QLR 2010; 19 (2): 177-189, DOI: 10.1007/s11136-009-9575-y

van Mastriigt GA. Joore MA. Nieman FH. Severens JL. Maessen JG. **Health-related quality of life after fast-track treatment results from a randomized controlled clinical equivalence trial.** QLR 2010; 19(5):631-42.



ISOQOL TO IDENTIFY STANDARDS FOR THE DESIGN AND SELECTION OF PRO MEASURES FOR USE IN PATIENT-CENTERED OUTCOMES RESEARCH

By: Bryce B. Reeve, PhD

Your expert help is needed to shape the field of patient-centered outcomes research (PCOR). Drs. Zeeshan Butt (Northwestern University) and Bryce Reeve (University of North Carolina) received a contract award from the Patient-Centered Outcomes Research Institute (PCORI; www.PCORI.org) to propose minimum standards for the development and use of tools to assess patient-reported outcomes.

The PCORI is an independent, non-profit research organization created by the US Patient Protection and Affordable Care Act of 2010. The mission of PCORI is to help people make informed health care decisions – and improve health care delivery and

outcomes – by producing and promoting high-integrity, evidence-based information derived from research guided by patients, caregivers and the broader health care community.

Under the PCORI contract, Drs. Butt and Reeve will actively involve the ISOQOL members in two ways: The first will be to solicit your help to identify any published or unpublished standards or guidance document on the design and/or selection of PRO measures for use in PCOR (or related field). By the time you are reading this article, you will have already received an email from ISOQOL requesting such information. Drs. Butt and Reeve will then synthesize this information

with additional guidance they may find through a literature review to come up with an evidence-base for selection of the standards. Second, you will be asked to complete an online survey (early February) seeking your expert judgment on the recommended ISOQOL standards. These suggestions will inform the final selection of criteria. ISOQOL was selected for this critical work because of the expertise and global perspective of its members. Findings from this work will be shared with you through newsletters and the ISOQOL 2012 Annual Conference in Budapest.



Technical Language Service

www.tls-translations.com

YOUR CLINICAL & REGULATORY TRANSLATION EXPERTS

- ✓ Unparalleled Clinical & Regulatory Affairs Expertise
- ✓ Rigorous Linguistic Validation Process for PRO materials
- ✓ Developer Liaison/Copyright & Licensing Management
- ✓ In-Country Clinical Reviewers & Interview Teams
- ✓ Highly Trained Project Coordinators
- ✓ Confidentiality Guaranteed
- ✓ 24/7 Availability
- ✓ 150+ Languages
- ✓ Global Offices
- ✓ Quick Turnaround
- ✓ Best Industry Pricing
- ✓ FREE Quotes
- ✓ FREE Initial Consultation & Needs Assessment
- ✓ FREE Certification/Methodology Documentation



phone: 1-203-507-8774 (call 24/7) fax: 1-702-973-6009 email: lvsd@tls-translations.com

Technical Language Services, Inc. is an **ISO 9001-2008 certified** translations company.

IVAN BAROFSKY — AN ENRICHING LEARNING EXPERIENCE

By: Ana Popielnicki

This past summer, I had the privilege of meeting our very own Dr. Ivan Barofsky. In person! I mean, how many people can say that? (I know, I know, MANY of you already know him but this is me!). As all who know him will agree, anyone who finds him/herself even in the *general vicinity* of Ivan can't help but learn, be enriched, challenged, catch his contagious thirst for knowledge, and share his joy in new learning. I know I certainly have experienced all that.

In any case, as you know Ivan proclaims to be "retired". That, I can assure you, is not your usual retired lifestyle. It is just his view of doing MORE than he did while he was in practice, except now he's not getting paid. During his "retirement", Ivan has managed to finish and publish his latest book (see details on page 13 of this newsletter), present not one but TWO times during

the 2011 Conference in Denver (as a presenter in the oral session – "How Cognitive-Linguistic Factors Contribute to Judgments of Quality of Life" and as a panelist in the symposium "How Can Methodological Innovation Occur in Health-Related Quality of Life Research?"). And I'm only talking about the last 4 months of 2011.

But that's not all. I was also incredibly fortunate (by way of coincidentally living in the same area as Ivan) to participate in a 12-week course he recently coordinated at the Academy for Lifelong Learning (ALL), titled "Metaphors: Their Role in Literature, Science/Medicine & Politics". We met every Monday at Cape Cod Community College to, basically, have fun. An incredibly interesting group of students from various disciplines in life met and discussed Ivan's presentations. I

had the honor of contributing to one of the classes with a mini presentation of my own (translating metaphors), which Ivan graciously presented on my behalf when I couldn't attend due to some health issues. For anyone who is interested in learning more about the fascinating metaphors (or just simply participating in fun discussions with Ivan), rumor has it he may be persuaded to turn this class into a more structured course/workshop. I am changing my name and entering the witness protection program soon after this is published and Ivan sees I am promising stuff for him — although, knowing Ivan, he will most likely only laugh and just do it, with his usual energy and joy. And for that, we are all lucky.



SUBMISSION DEADLINES FOR THE 19TH ANNUAL CONFERENCE:

• MARCH 1

**Workshop Abstracts
Symposium Abstracts**

• MAY 1

Oral & Poster Presentation Abstracts

Workshop and Symposium Abstract Submission opens in late January. Oral & Poster Presentation Abstract Submission opens in Spring. Visit the [19th Annual Conference website](#) for more information.



ERRATUM IN 18TH ANNUAL CONFERENCE ABSTRACT SUPPLEMENT

Note from the Editor: The first author and presenter of the following abstract was not included in the 18th Annual Conference Abstract Supplement. Please see the correction below, and our sincerest apologies to Dr. Bjorner for the omission.

Evaluating the Impact of Method of Administration on Item Response: Results from the PROMIS Initiative (Abstract # 1019/240)

Jakob B. Bjorner, MD PhD, National Research Centre for the Working Environment, Copenhagen, Denmark; Barbara Gandek, Department of Quantitative Health Sciences, University of Massachusetts Medical School, Worcester, MA United States; Matthias Rose, Department of Psychosomatic Medicine, University Medical Center, Hamburg-Eppendorf, and Schön-Klinik Hamburg Eilbek, Germany; Arthur A. Stone, Department of Psychiatry, Stony Brook University, Stony Brook NY United States; Doerte U. Junghaenel, Department of Psychiatry, Stony Brook University, Stony Brook NY United States; John E. Ware, Department of Quantitative Health Sciences, University of Massachusetts Medical School, Worcester, MA United States.

PUBLICATIONS

MEASUREMENT IN MEDICINE A PRACTICAL GUIDE

Henrica C. W. de Vet, Caroline B. Terwee, Lidwine B. Mokkink,
Dirk L. Knol

Practical Guides to Biostatistics and Epidemiology

EXCLUSIVE PROMOTION CODE: A2ISOQOL

This down-to-earth book provides practical advice, underpinned by theoretical principles, on developing and evaluating measurement instruments in all fields of medicine. It equips you to choose the most appropriate instrument for specific purposes. The book covers measurement theories, methods and criteria for evaluating and selecting instruments. It provides methods to assess measurement properties, such as reliability, validity and responsiveness, and interpret the results. Worked examples and end-of-chapter assignments use real data and well-known instruments to build your skills at implementation and interpretation through hands-on analysis of real-life cases. All data and solutions are available online. This is a perfect course book for students and a perfect companion for professionals/researchers in the medical and health sciences who care about the quality and meaning of the measurements they perform.

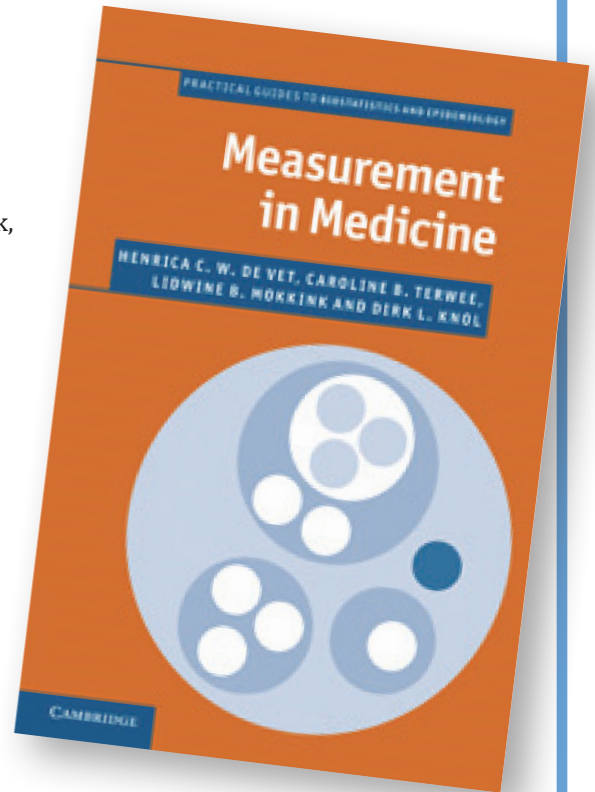


Table of Contents:

1. Introduction; 2. Concepts, theories and models, and types of measurements; 3. The development of a measurement instrument; 4. Field testing – item reduction and data structure; 5. Reliability; 6. Validity; 7. Responsiveness; 8. Interpretation; 9. Systematic reviews of measurement properties; Index.

~~\$99.00~~: Hardback: 978-0-521-11820-0: 348 pp.

Exclusive ISOQOL Member Price: **\$74.25**

~~\$45.00~~: Paperback: 978-0-521-13385-2

Exclusive ISOQOL Member Price: **\$33.75**

EXCLUSIVE PROMOTION CODE: A2ISOQOL

www.cambridge.org/us/9780521133852

800.872.7423

PUBLICATIONS

QUALITY: ITS DEFINITION AND MEASUREMENT AS APPLIED TO THE MEDICALLY ILL

By: Ivan Barofsky, PhD

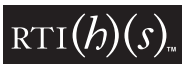
Springer, Oct 1, 2011, 514 pages



Quality of life (QoL) is frequently discussed among health care professionals and often invoked as a goal for improvement, but somehow rarely defined, even as it is measured. It is understood that some medical patients have a better QoL than others, but should it be assessed against an ideal state of well-being, or is it too personal and subjective to gauge? Can a better understanding of the

concept help health care systems deliver services more effectively? Is QoL worth measuring at all? Probing sophisticated concepts in psychology, philosophy, neurocognition, and linguistics, Quality of Life breaks down the cognitive components that comprise the judgment of quality, including description, evaluation, and valuations, and applies them to issues specific to individuals with chronic medical illness. In this context, QoL assessment becomes essential to ethical practice, a critical step toward improving the relationship between

providers and clients. The author considers linear, non-linear, and complexity-based models in analyzing key methodology and content issues in health-related QoL assessment. Quality of Life is certain to stimulate debate in the research and scientific communities. This forward-looking volume takes great strides toward promoting a common language in the discussion of QoL issues, and a greater appreciation of the ongoing moral issues involved in health care.



RTI HEALTH SOLUTIONS®



Value: Define. Measure. Communicate.



We provide expertise in patient-reported outcomes to define, measure and communicate your products' value.

Let us help you:

- Create a PRO strategy that meets your clinical development and post-marketing objectives.
- Develop and validate PRO instruments to support product approval, label claims, reimbursement decisions, and publication strategies.
- Support regulatory submissions in the US and Europe.

Contact Sheri Fehnel, PhD
VP, Patient-Reported Outcomes
sfehnel@rti.org

www.rtihs.org

LEADING RESEARCH...
MEASURES THAT COUNT

Research Triangle Park • Ann Arbor • Barcelona • Lund • Manchester • Sheffield • Waltham

ISOQOL GLOBAL NEWS: NEW CHAPTER STRUCTURE

TRANSFORMATION OF ISOQOL CHAPTERS INTO “AFFILIATED ORGANIZATIONS” AND “SECTIONS”

By: Henrica C.W. de Vet, PhD, Board member and Liaison for Affiliate organizations and Sections of ISOQOL

Editor's Note: Those of you who attended our annual business lunch meeting at the 2011 Conference in Denver, Colorado, will recall that Henrica presented an outline of the changes to our Chapters' structure. Please see below a summary of that presentation for your reference, and information for those who could not attend.

ISOQOL has established national and regional chapters with the goal to foster the field of health-related quality of life (HRQOL) research in countries and regions beyond ISOQOL's traditional membership base in North America and Western Europe. The development and growth of such chapters will not only increase ISOQOL's membership and lead to a more truly international network of HRQOL research and researchers, but also promote understanding and use of HRQOL measures in a wider and more culturally and geographically diverse range of countries and regions. This in turn will promote more cultural and geographical balance in the field of HRQOL research.

By now, ISOQOL has an Asian-Chinese Chapter, an Ibero-American Chapter, a Russian Chapter, a Dutch

Chapter, and Turkey is knocking at the door. Because of financial and legal issues regarding the Turkish organization, EDI has reviewed the organization of the Chapters and has decided to change the Chapter structure into “Affiliates” and “Sections”. The word “chapter” will no longer be used to define a relationship between an organization and ISOQOL; instead, ISOQOL will establish “Affiliate organizations” and “Sections” as defined below.

Affiliate: An existing, established organization within a country or region that wishes to be formally linked to ISOQOL. Affiliates are not linked to ISOQOL through financial obligations and not all members but some (the number to be decided) of an Affiliate are required to be members of ISOQOL. The application process to become an Affiliate is through formal request by the organization to the ISOQOL Board of Directors. Any activities which will require the use of ISOQOL's logo, website or membership list will require Board approval. Reports to the Board of Directors are not generally required, unless a specific co-sponsored program is taking place.

Section: All ISOQOL members residing within a specific country or region which will formally be recognized by ISOQOL as a distinct group with distinct needs. The process by which a Section is established by ISOQOL is through a formal request to the Board from at least five members within a country or ten members within a region outlining the need to be recognized as a Section. All members of a Section must be ISOQOL members. Sections are required to provide a written report to the Board at each Board meeting.

During this year a transformation shall take place to change the organizational structure of Chapters in a way that is legally acceptable for ISOQOL and that works well in the different countries.

The guidelines for national and regional Chapters will be adapted to give guidance to the current Affiliations and Sections, but also to stimulate more countries or regions to get a closer relationship with ISOQOL.

For further questions please email me: hcw.devnet@vumc.nl



PhRMA FOUNDATION AWARDS

The PhRMA Foundation is accepting applications for its 2012 Health Outcomes Award Program. All applicants must be U.S. citizens or permanent residents. Pre and Post Doctoral Fellowships, Sabbatical Fellowships and Research Starter Grants are available. Applications must be received at the PhRMA Foundation by February 1, 2012. For instructions on how to apply for the grant and where to send an application, please visit: <http://www.phrmafoundation.org>



What's the right blend of ePRO to satisfy your study?



Telephone

Handheld

Digital Pen

Web

Now you can choose which flavor works best for you, your patients and your sites.

With ERT ePRO Solutions you can choose between all proven modalities of technology to ensure that the ideal device is matched to every protocol for every patient population across all phases of clinical research. The right modality for the right trial.



info@ert.com
+1 866 538 2808
www.ert.com

Ironwood Pharmaceuticals (NASDAQ: IRWD) is an entrepreneurial pharmaceutical company dedicated to the art and science of great drugmaking. Linaclotide, Ironwood's GC-C agonist, is an investigational drug for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation. Ironwood also has a growing pipeline of additional drug candidates in earlier stages of development. Ironwood is located in Cambridge, Mass.



Senior Research Associate, PRO Development

Position Description:

To support the development of Patient-Reported Outcome (PRO) strategies during clinical development. The inclusion of PRO measures in trials is critical for creating robust and differentiated product profiles and for providing information important for therapeutic decision-making to patients, physicians and payers.

Requirements:

- BA/BS required, Master's degree preferred;
- Experience in epidemiology, public health, health services research, clinical research, outcomes research, PRO development, or related discipline preferred;
- Three years of pharmaceutical industry experience;
- Well-developed multi-tasking skills, works very well under pressure, suited to a fast-paced environment, flexible;
- Familiarity and experience with the development and implementation of research strategies.

To apply, send CV and cover letter with a subject of "Job Code MBSAP" to careers@ironwoodpharma.com.

THE ISOQOL NOMINATING COMMITTEE, CHAIRED BY PAST PRESIDENT CAROL MOINPOUR, PHD, IS ACCEPTING NOMINATIONS FOR THE FOLLOWING ISOQOL LEADERSHIP POSITIONS:

Member, Board of Directors 2012-2015 (Three open positions, three-year term)

President-elect 2012-2013

The position of President-elect commits to serving as President from 2013-2015 and Past President 2015-2016.

Self-nominations are accepted and encouraged. The ISOQOL Nominating Committee is committed to encouraging a strong diversity on the Board of Directors regarding geographic representation as well as representation from all aspects of health-related quality of life research.

An e-mail with full position descriptions will be e-mailed to all members in January. If you are interested in learning more about being nominated for a position, please contact Becky Brandt, ISOQOL Executive Director at rbrandt@isoqol.org.



International Society for Quality of Life Research

BUDAPEST



19th ANNUAL CONFERENCE

October 24-27, 2012

*The Journey of Quality of Life Research:
A Path Towards Personalized Medicine*

<http://www.isoqol.org/2012conference/>

Abstract Submission Deadlines

March 1, 2012

Workshop Submissions

Symposium Abstracts

May 1, 2012

Oral & Poster

Presentation Abstracts

